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# "Squaring-up the Conflict Between Pharmaceutical Patents and the Right to Access to Medicines"

A dissertation submitted

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for

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Supervised by

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*Acknowledgment*

This dissertation has enriched and challenged my life during the past four years. I first learned about the issue of patent rights and access to medicines in 2015 when I was doing my master's degree in International Intellectual Property Law at Brunel University in London. I am indebted to Dr. Alison Slade, the former IP Law lecturer at Brunel University and currently at Leicester University, for clarifying the concepts of patent rights and the peculiarities of pharmaceutical patents.

When I embarked on my doctoral research, I realized the tension between the whole regime embodying patent rights, WTO law, and general international law, including human rights. Prof. Benedict Abrahamson Chigara, my Ph.D. supervisor, is the one who recommended directing the scope of research to tackle not only patent law and human rights but also the nature and structure of public international law. I would avail this opportunity to extend my sincere gratitude to him for his continuous support and advice. This work could not have been completed without his invaluable insights and comments. During the writing of this dissertation, he instructed me to develop and strengthen my arguments with reasons. He gave me generous encouragement, a swift response to any inquiry, and recommended rich and informative books and articles to read and analyse. This has been crucial in keeping motivated and deepening my perspectives on this research.

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Dedication: I dedicate this humble work to my Dad

*Abstract*

*The pharmaceutical patent system seeks to protect the private rights of patentees while at the same time ensure the public right to access to essential medicines. It has been argued that the TRIPS agreement unfairly tilts the balance against the public interest in favour of patentees' rights. Advocates of the patent system insist that without it, there would be no incentives for future innovation and the pharmaceutical industry would not be able to recoup its investments in Research and Development. Meanwhile, human rights scholars assert that states are obliged to ensure the availability and accessibility to medicines as an indispensable component of the right to health as guaranteed, for example, by the International Covenant on Economic, Social and Cultural rights. While the TRIPS agreement provided several flexibilities to permit states to protect public health, in practice, it makes that task onerous. To remedy the deficiencies in the pharmaceutical patent system in TRIPS, the WTO issued three decisions on TRIPS and Public health. The first (Doha Declaration) represents a forward step towards a fair balance between patents and the right to health. However, the other two decisions (30 August 2003 and 6 December 2005) appear to have negated the fundamentals of the Doha Declaration due to failure to resolve the outstanding issue of generic medicines. Consequently, pharmaceutical patents appear to be in conflict with the human right to health. The conflict echoes that deeply rooted in the underlying principles and goals of the WTO system versus the human rights regime. This dissertation attempts to find a more realistic way forward to guarantee patentees' interests without inhibiting states, through intellectual property claims, from fulfilling their public health responsibilities in their territories. The dissertation distinguishes between the obligations under both the WTO and human rights systems. It deconstructs the normative and de facto hierarchy of both systems and explains the conflict of norms in public international law. The dissertation also scrutinizes the role of human rights law in WTO disputes settlement to explore whether and to what extent the human right to health is accommodated within the ambit of the patents system in the TRIPS agreement. It concludes that this role is limited to aiding the interpretation process of the WTO agreements rather than being part of the applicable law. The actual and rhetorical practice of the WTO adjudicating bodies emphasize that they favoured WTO law, allowing it to prevail over human rights law. The dissertation recommends several solutions to allow the patent system in TRIPS to take into account human right to health in case of conflict.*

List of Acronyms

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|---|---|
| 30 August 2003 Decision | WTO General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health |
| ARV | Antiretroviral Medicines |
| CESCR | UN Committee on Economic, Social and Cultural Rights |
| CPRs | Civil and Political Rights |
| Doha Declaration | Doha Ministerial Declaration on TRIPS and Public Health in 2001 |
| DSB | WTO Dispute Settlement Body |
| DSU | WTO Dispute Settlement Understanding |
| EPC | European Patent Convention |
| ESCRs | Economic, Social and Cultural Rights |
| FTAs | Free Trade Agreements |
| GATT | General Agreement on Tariffs and Trade |
| ICCPR | International Covenant on Civil and Political Rights |
| ICESCR | International Covenant on Economic, Social and Cultural Rights |
| ICJ | International Court of Justice |
| ILC | International Law Commission |
| IPRs | Intellectual Property Rights |
| Paris Convention | Paris Convention for the Protection of Industrial Property |
| R&D | Research and Development |
| SPC | Supplementary Protection Certificate |
| TRIPS | Agreement on Trade-Related Aspects of Intellectual Property Rights |
| UDHR | Universal Declaration of Human Rights |

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|---|---|
| UNCLOS | United Nations Convention on the Law of the Sea |
| VCLT | Vienna Convention on the Law of Treaties |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| WTO | World Trade Organization |

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*Abstract*

List of Acronyms

## Chapter 1: Introduction

### 1.1 Background

The lack of accessibility to essential medicines is a global issue. Nearly 2 billion people worldwide have no access to affordable medicines which causes prolonged illness, suffering, and deaths.[1] One of the UN Sustainable Development Goals is to "ensure access to safe, effective, quality, and affordable essential medicines and vaccines for all."[2] Accessibility to medicines in health systems includes the availability, affordability, and quality acceptability of medicines. Although access to medicines is an indispensable component of the human right to health and states are obliged, accordingly, to guarantee the accessibility to medicines to all people within their jurisdiction,[3] many people in developing countries are deprived of essential medicines due to their high prices.[4]

The main impediment to the right to access to medicines is patent law. Although patent law generally has been used from a long time ago, the advent of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter referred as TRIPS) provoked a lot of controversy due to the new challenges it constitutes to the realization of the right to health.[5] The TRIPS obliged WTO member states to incorporate provisions in their national legislations that grant patent protection for any invention, *inter alia*, pharmaceuticals, for a limited period of 20 years, as a minimum standard, commencing from the date of filing the patent application.[6] Unlike copyrights which is not a true monopoly right, the TRIPS confers to the patentees a

[1] Sachiko Ozawa et al, 'Access to Medicines Through Health Systems in Low- and Middle-Income Countries' (2019) 34 issue supp_3 Health Policy and System Research Journal iii1, iii2

[2] 'Sustainable Development Goals: Goal 3. Target 3.8 (WHO, 2016) < https://apps.who.int/iris/handle/10665/208286 > accessed 11 December 2020

[3] Human Rights Council, 'Report of the Special Rapporteur Anand Groover on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights Including the Right to Development' (31 March 2009) UN Doc A/HRC/11/12, paras 10, 11. **See also**, Veronika J. Wirtz et al, 'Access to medications for Cardiovascular Diseases in Low- and Middle-Income Countries' (2016) 133(21) Circulation 2076, 2077-2081. **See also**, Paul Hunt and Rajat Khosla, 'The human right to medicines' (2008) 5(8) Sur International Journal of Human Rights 99, 100 <https://sur.conectas.org/wp-content/uploads/2017/11/sur8-eng-full.pdf > accessed 16 April 2019

[4] Sachiko Ozawa et al, 'Access to Medicines Through Health Systems in Low- and Middle-Income Countries' (2019) 34 issue supp_3 Health Policy and System Research Journal iii1, iii3

[5] Saeed Ahmadiani and Shekoufeh Nikfar, 'Challenges of Access to Medicine and the Responsibility of Pharmaceutical Companies: A Legal Perspective' (2016) 24(13) Daru Journal of pharmaceutical Sciences < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855755/> accessed 22 March 2021

[6] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 33

monopoly right to exclude others from making, using, offering for sale, selling, or importing the patented invention without their consent for the duration of the patent term.[7]

Pharmaceutical companies seek to obtain robust patent protection for their inventions in order to obtain market exclusivity. Such exclusivity allows them to set differential pricing for their invented medicines in order to gain more revenues. As their profits increase, so does the unaffordability of medicines for many people in developing countries.[8] As such, an intersection exists between two interests; the public interest seeking accessibility to medicines and the private interest striving for robust monopoly rights over pharmaceuticals.[9] Similarly, a possible conflict could be recognized between states' obligations under the TRIPS and their obligations according to the human right to health.

Developing countries and human rights activists asserted that pharmaceutical patents under the TRIPS agreement are used to restrict competition and set the prices of essential medicines higher than they would be if competitive generic products were available.[10] During the patent term, they do not have the right to produce generic alternatives of patented drugs. Therefore, patients are expected to afford the high prices of patented medicines or rely on the public health insurance systems.[11] Given the higher demand for medicines in developing countries and their low economic ability, providing patented medicines constitutes a big financial load for many developing countries. Their weak health insurance systems cannot afford to provide patented medicines to all people; thus, an increase in mortality rates occurs due to low accessibility to medicines.[12] Developing countries argued that the human right to health would entail flexible options within the patent system in TRIPS to ensure better accessibility to medicines. Their

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[7] Stavroula Karapapa and Luke McDonagh, *Intellectual Property Law* (Oxford University Press 2019) 16-18. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 28(1)

[8] Olga Gurgula & Wen Hwa Lee, 'COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?' (23 January 2021) Forthcoming in the Journal of generic Medicines 3 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3771935> accessed 23 March 2021

[9] Olga Gurgula, 'Monopoly v. Openness; Two Sides of IP Coin in the Pharmaceutical Industry' (2017) 20 World Intellectual property Journal 206, 214

[10] Carlos M. Correa, 'Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective' (June 2016) UNDP Working Paper <https://www.researchgate.net/publication/304396604_Carlos_Correa_Guidelines_for_Pharmaceutical_Patent_Examination_Examining_Pharmaceutical_Patents_from_a_Public_Health_Perspective_UNDP_New_York_2016 > accessed 13 March 2021

[11] Saeed Ahmadiani and Shekoufeh Nikfar, 'Challenges of Access to Medicine and the Responsibility of Pharmaceutical Companies: A Legal Perspective' (2016) 24(13) Daru Journal of pharmaceutical Sciences < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855755/> accessed 22 March 2021. **See also**, Sarah Joseph, *Blame it on the WTO* (Oxford university Press UK 2013) 214

[12] Eddy van Doorslaer et al, 'Catastrophic Payments for Health Care in Asia' (2007) 16 Health Economics 1159

claim was based on the existence of a legal right to ensure such accessibility by virtue of the human rights law. Indeed, as Sarah Joseph argued, the TRIPS agreement represents an actual turning point affecting the national patent legislations in developing countries.[13]

On the other hand, patents proponents and developed states supported by pharmaceutical companies contend that pharmaceutical patents are necessary to enable the industry to recoup its huge investments on research and development (hereinafter referred as R&D) and prevent free- riding. Since they are not charity organizations, the pharmaceutical companies are in dire need of the patent monopoly rights to incentivize future innovation and creativity.[14]

Before the TRIPS adoption,[15] developing states had a certain margin of appreciation in adjusting their national intellectual property laws to their socio-economic needs. They were able to avoid paying the high prices of patented medicines set by pharmaceutical companies and instead they were capable of buying the generic equivalents at lower prices.[16] Other developing countries with pharmaceutical manufacturing capacities, such as India, South Africa, and Brazil, enjoyed latitude in producing cheap generic alternatives to original medicines to safeguard the needs of their people and to export low-priced medicines to other countries. As such, they refused to adopt any measures that would curtail their generics industry.[17] These countries conceived

[13] Sarah Joseph, *Blame it on the WTO* (Oxford university Press UK 2013) 214

[14] Olga Gurgula & Wen Hwa Lee, 'COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?' (23 January 2021) Forthcoming in the Journal of generic Medicines 2,3 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3771935> accessed 23 March 2021. **See also**, Olga Gurgula, 'Monopoly v. Openness; Two Sides of IP Coin in the Pharmaceutical Industry' (2017) 20 World Intellectual property Journal 206, 207. **See also**, Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 28. **See also**, Peter S. Menell et al, *Intellectual Property in the New Technological Age: 2019 Volume I: Perspectives, Trade Secrets & Patents* (Clause 8 Publishing 2019) 16 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3415161&download=yes> accessed 12 January 2019. **See also**, Erik Hovenkamp, 'Challenges Restraints and the Scope of the Patent' (2016) 4(3) CPI Antitrust Chronicle Journal 4-6 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2866630> accessed 12 January 2019

[15] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS)

[16] Valbona Muzaka, *The Politics of Intellectual Property Rights and Access to Medicines* (Palgrave Macmillan UK 2011) 60. **See also**, Olga Gurgula, 'The 'Obvious to Try' Method of Addressing Strategic Patenting: How Developing Countries Can Utilise Patent Law to Facilitate Access to Medicines' (April 2019) South Centre Policy Brief No 59, 1 < https://www.southcentre.int/wp-content/uploads/2019/04/PB59_The-obvious-to-try-method-of-addressing-strategic-patenting_EN.pdf > accessed 29 January 2021

[17] Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (Routledge London and New York 2002) 10. **See also**, Olga Gurgula & Wen Hwa Lee, 'COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?' (23 January 2021) Forthcoming in the Journal of generic Medicines 3, 4 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3771935> accessed 23 March 2021

patents and intellectual property rights (hereinafter referred as IPRs) in general as "part of the common heritage belonging to all human beings."[18]

The tension between pharmaceutical patents and accessibility to medicines escalated after the expiration of the transitional period granted to developing countries on 1 January 2005. During this period, developing countries were granted an exception from their obligations under the TRIPS.[19] Since then, all WTO member states, except the least-developed countries, are obliged to adopt the TRIPS minimum standards of patent protection.[20] The countries with pharmaceutical manufacturing capacities are no longer authorized to produce generic equivalents. India, for example, as a thriving generic medicine manufacturer and exporter, after issuing its Patent Act amendments in 2005, was obliged to stop manufacturing generic versions of patented drugs, even if its pharmaceutical companies were granted compulsory licences from other countries.[21]

It is worthwhile to illustrate some events that triggered a heated debate around the issue at the international arena. Those events provide a practical view to the tension between both rights and an introduction that facilitates understanding of the legal arguments made in the dissertation.

In the 1980s, the tension between pharmaceutical patenting and accessibility to medicines started to receive global attention. Burroughs Welcome, a British pharmaceutical company, discovered the first treatment to HIV/AIDS called Azidothymidine (AZT). It patented the medicine and set a high price for its commercial usage, at more than $10,000 per patient per year, to recoup the investments spent on R&D. This high price, which was beyond the reach of many people suffering from HIV/AIDS, induced NGOs and human rights activists to express their concerns regarding the inaccessibility to the only available life-saving therapy for that virus. With the reluctance of governments to afford the high costs of AZT to their patient population, activists called for reduction of the drug price to save the lives of infected people. However, Burroughs Welcome refused due to the huge expenditure on R&D, marketing, and

[18] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 14-16

[19] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 65

[20] Olufunmilayo Arewa, 'TRIPS and Traditional Knowledge: Local Communities, Local Knowledge and Global Intellectual Property Frameworks' (2006) 10(2) Marquette Intellectual Property Law Review 154, 156

[21] Frederick M. Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) 99 The American Journal of International Law 317, 320-322. **See also**, Indian Patents (Amendment) Act No 15 of 2005, sec 3(d)

the need to guarantee revenues.[22] The AZT case was followed by subsequent release of other patented medicines with high prices rendering them inaccessible. Examples include Glivec for Cancer produced by Novartis,[23] Tamiflu treating Bird Flu produced by Gilead,[24] and Cipro produced by Bayer treating a deadly poison called Anthrax.[25] These cases caused fierce debate regarding the patenting practices pursued by the global pharmaceutical industry and its effect on the accessibility to life-saving medicines in the developing world.

The Ebola crisis in 2014 also demonstrates that the pharmaceutical patent system in TRIPS does not serve its social function. Pharmaceutical companies have largely neglected to perform sufficient experimental treatments because Ebola mainly threatens developing countries. The WHO's assistant director-general, Dr. Marie-Paul Kieny, emphasized that the lack of an approved Ebola drug is a "market failure because the disease typically strikes poor people in poor countries where there is no market."[26]

The most recent debate about the topic is embodied in the COVID-19 case. On 11 March 2020, the World Health Organization (hereinafter referred as WHO) declared the COVID-19 a global pandemic.[27] The World Trade Organization (hereinafter referred as WTO) cautioned that "the pandemic represents an unprecedented disruption to the global economy and world trade, as production and consumption are scaled back across the globe."[28] Responding to such global emergency, India and South Africa, co-sponsored by several developing countries members in the WTO, requested that the TRIPS Council recommends to the WTO General Council a waiver

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[22] Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 263-264. **See also**, Ethan B. Kapstein and Joshua W. Busby, *AIDS Drugs for All: Social Movements and Market Transformations* (Cambridge University Press USA 2013) 39-40 < http://sites.utexas.edu/busby/files/2013/02/PrefaceChapter1.pdf> accessed 2 February 2021. **See also**, Vivek K. Sharma et al, 'An Engrossing History of Azidothymidine' (2015) 15(2) Immunology, Endocrine & Metabolic Agents in Medicinal Chemistry Journal < https://www.academia.edu/16198897/engrossing_history_of_azidothymidine > accessed 27 February 2021

[23] Ravinder Gabble and Jillian Clare Kohler, 'To Patent or Not to Patent? The Case of Novartis' Cancer Drug Glivec in India' (2014) 10(3) Globalization and Health Journal < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3884017/> accessed 12 December 2020

[24] Yogendra Kumar Gupta et al, 'The Tamiflu Fiasco and Lessons Learnt' (2015) 47(1) Indian Journal of Pharmacology 11 < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4375804/ > accessed 12 December 2020

[25] Christopher K. Eppich, 'Patenting Dilemma: Drugs for Profit Versus Drugs for Health' (2002) 43(1) Santa Clara Law Review 289

[26] 'Would a Prize Help Speed Development of Ebola Treatments?' (CPR News, 21 August 2014) < https://www.cpr.org/2014/08/21/would-a-prize-help-speed-development-of-ebola-treatments/ > accessed 19 September 2020

[27] 'WHO Declares COVID-19 Outbreak a Pandemic' (Pharmaceutical Technology, 12 March 2020) < https://www.pharmaceutical-technology.com/news/who-declares-covid-19-pandemic/?utm_source=Army%20Technology&utm_medium=website&utm_campaign=Must%20Read&utm_content=Image> accessed 9 February 2021

[28] 'COVID-19 and World Trade' (WTO) < https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm > accessed 10 February 2021

from the implementation, application, and enforcement of pharmaceutical patents obligations in the TRIPS agreement "in relation to the prevention, containment, and treatment of COVID-19."[29] The waiver would be temporary, i.e., enforceable for a specific number of years till the global widespread of the COVID-19 vaccination.[30] It would prevent WTO member states from challenging any measure, taken in conformity with the provisions of the waiver, in front of the WTO dispute settlement system.[31]

The waiver request indicated that the effective response to the COVID-19 pandemic requires that the WTO member states should co-operate to ensure the rapid availability and accessibility to medicines, including vaccines, in sufficient quantities and at affordable prices to meet the global demand. It warned against the effect of patent rights in hindering the accessibility to affordable medicines for the prevention and treatment of patients in dire need. Further, the waiver request referred to the legal difficulties facing developing countries when utilizing the TRIPS flexibilities to ensure better accessibility to essential medicines. For example, the requirements under article 31 of the TRIPS agreement to issue compulsory licences with its cumbersome and lengthy process for the import and export of pharmaceuticals.[32]

Since October 2020, WTO member states exchanged views and sought clarifications and information on the waiver request. However, they could not reach consensus on whether it is appropriate to waive the pharmaceutical patents obligations in TRIPS responding to a global health crisis or otherwise.[33]

At the formal TRIPS Council meeting on 10 March 2021, South Africa noted that after convening various meetings, the WTO member states are still reluctant to move to a text-based discussion regarding the waiver request. South Africa exhorted WTO members to pass the waiver as soon as possible to save the lives of people. Developed countries confirmed on several

[29] WTO TRIPS Council, Communication from India and South Africa for Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 (2 October 2020) WTO Doc IP/C/W/669. **See also**, 'Members Discuss TRIPS Waiver Request, Exchange Views on IP Role Amid a Pandemic' (WTO, 23 February 2021) < https://www.wto.org/english/news_e/news21_e/trip_23feb21_e.htm > accessed 17 March 2021

[30] WTO TRIPS Council, Communication from India and South Africa for Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 (2 October 2020) WTO Doc IP/C/W/669, para 13

[31] Ibid, annex para 5

[32] WTO TRIPS Council, Communication from India and South Africa for Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 (2 October 2020) WTO Doc IP/C/W/669

[33] 'Members Discuss TRIPS Waiver Request, Exchange Views on IP Role Amid a Pandemic' (WTO, 23 February 2021) < https://www.wto.org/english/news_e/news21_e/trip_23feb21_e.htm > accessed 17 March 2021

occasions that if patents become a barrier to access to medicines and vaccines, the TRIPS provides for several flexibilities, including compulsory licences, to safeguard public health. However, South Africa reminded the TRIPS Council of the realpolitik world of sanctions in addition to other trade pressure imposed when developing countries utilized the TRIPS flexibilities to ensure better accessibility to medicines. Pharmaceutical corporations are also still exploiting patent monopolies to decide on critical elements, such as controlling the scale of pharmaceutical production, creating price differentials, and setting higher prices for medicines. For example, while South Africa and Uganda have paid $5.25 and $8.50 respectively for one shot of COVID-19 vaccine, the European Commission paid only $3.50 per shot. This renders vaccines, as essential medicines, inaccessible and unaffordable to many developing countries. Pharmaceutical companies explained such price differential on the grounds that developed countries have invested in R&D, while developing ones have a minimal contribution. Consequently, the TRIPS Council postponed discussions to a meeting scheduled for 8-9 June 2021.[34]

At the TRIPS Council meeting on 8-9 June 2021, the delegations of the WTO member states agreed to move to a text-based process that addresses the proposals of states aiming to provide global accessibility to COVID-19 vaccines. Two proposals tabled by states were discussed.[35]

The first is a revised decision text of the waiver request from all pharmaceutical patents obligations in TRIPS as illustrated above. The revised decision, which was proposed by the African countries and other developing ones, stated that the waiver shall be in force for at least three years starting from the date of adopting the waiver. The WTO General Council shall review the waiver annually and shall decide, after the end of the third year, whether the existence of the exceptional circumstances justifying the waiver are still existing or otherwise. In case "such circumstances cease to exist, the General Council shall determine the date of termination of the waiver."[36] As mentioned above, the waiver prevents WTO member states from

[34] '10 March 2021: South Africa Raises the Banner for the TRIPS Waiver at the WTO' (Knowledge Ecology International, 11 March 2021) < https://www.keionline.org/35578 > accessed 3 April 2021. **See also**, 'Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role for Small Business' (WTO, 11 March 2021) < https://www.wto.org/english/news_e/news21_e/trip_11mar21_e.htm > accessed 3 April 2021

[35] 'Members Approach Text-Based Discussions for an Urgent IP Response to COVID-19' (WTO, 9 June 2021) < https://www.wto.org/english/news_e/news21_e/trip_09jun21_e.htm> accessed 6 September 2021

[36] Ibid. **See also**, WTO TRIPS Council, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text (25 May 2021) WTO Doc IP/C/W/669/Rev.1, annex paras 2, 5

challenging any measure, taken by a WTO member in conformity with the waiver, before the WTO dispute settlement system.[37]

The second proposal is a communication from the European Union on urgent trade policy responses to the COVID-19 crisis.[38] The communication underlines that the EU supports a "multilateral and comprehensive response to the COVID-19 pandemic" to ensure rapid and equal accessibility to vaccines worldwide. It underscores that the trading system can contribute to expand "the production of and equitable access to COVID-19 vaccines and therapeutics swiftly."[39] The EU drafted the communication in the form of a draft declaration and requested that the TRIPS Council recommend to the WTO General Council adopting it. The draft declaration calls for a global trade initiative for equal accessibility to COVID-19 vaccines that encompasses limiting export restrictions and facilitating the use of the compulsory licences flexibility in the TRIPS.[40] It stipulates that the COVID-19 pandemic should be considered a situation of national emergency that entails waiving several requirements for granting compulsory licences, stipulated in article 31 of the TRIPS agreement, such as, for example, the requirement to negotiate with the patentee before granting the licence.[41] While recognizing that the IPRs should not stand in the way of ensuring equal accessibility to vaccines, the EU members emphasized the importance of IPRs for incentivising investment in innovation.[42]

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[37] WTO TRIPS Council, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text (25 May 2021) WTO Doc IP/C/W/669/Rev.1, annex para 6

[38] 'Members Approach Text-Based Discussions for an Urgent IP Response to COVID-19' (WTO, 9 June 2021) < https://www.wto.org/english/news_e/news21_e/trip_09jun21_e.htm> accessed 6 September 2021. **See also**, WTO TRIPS Council, Urgent Trade Policy Responses to the COVID-19 Crises: Intellectual Property: Communication from the European Union to the Council for TRIPS (4 June 2021) WTO Doc IP/C/W/680

[39] WTO TRIPS Council, Urgent Trade Policy Responses to the COVID-19 Crises: Intellectual Property: Communication from the European Union to the Council for TRIPS (4 June 2021) WTO Doc IP/C/W/680, paras 2, 3

[40] Ibid, para 4. **See also**, WTO TRIPS Council, Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic: Communication from the European Union to the Council for TRIPS (18 June 2021) WTO Doc IP/C/W/681. **See also**, 'TRIPS Council Agrees to Continue Discussions on IP Response to COVID-19' (WTO, 20 July 2021) < https://www.wto.org/english/news_e/news21_e/trip_20jul21_e.htm > accessed 8 September 2021

[41] WTO TRIPS Council, Urgent Trade Policy Responses to the COVID-19 Crises: Intellectual Property: Communication from the European Union to the Council for TRIPS (4 June 2021) WTO Doc IP/C/W/680, para 9. **See also**, WTO TRIPS Council, Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic: Communication from the European Union to the Council for TRIPS (18 June 2021) WTO Doc IP/C/W/681

[42] Members Approach Text-Based Discussions for an Urgent IP Response to COVID-19' (WTO, 9 June 2021) < https://www.wto.org/english/news_e/news21_e/trip_09jun21_e.htm> accessed 6 September 2021. **See also**, WTO TRIPS Council, Urgent Trade Policy Responses to the COVID-19 Crises: Intellectual Property: Communication from the European Union to the Council for TRIPS (4 June 2021) WTO Doc IP/C/W/680, para 6. **See also**, WTO TRIPS Council, Draft General Council Declaration on the TRIPS Agreement and Public

The previous two text-based proposals discussed in the TRIPS Council reflect the divergent positions of the developing and developed countries in WTO regarding the most appropriate and effective way to address the inequitable accessibility to COVID-19 vaccines. It indicates the reluctance of the developed countries to adopt a full waiver of pharmaceutical patents obligations in the TRIPS agreement. Unable to settle on a way to waive pharmaceutical patent obligations in response for the COVID-19 pandemic, the chair of the TRIPS Council urged the WTO members to continue discussions aiming to agree on a pragmatic response to the COVID-19 by adopting any of the two text-based proposals and reporting it to the WTO General Council as stipulated in article IX(3) of the WTO agreement. The chair expressed his intention to invite the states' delegations for open-ended informal meeting to continue deliberations on this issue until the next formal meeting of the TRIPS Council scheduled for 13-14 October 2021.[43]

In relation to COVID-19 pandemic, the case of Remdesivir antiviral medication, developed by the biopharmaceutical company "Gilead Sciences,"[44] best sums up how patents can block accessibility to medicines in developing countries. The primary patent on the base compound of Remdesivir was granted to Gilead in more than 70 developing countries, thus potentially blocking access to cheaper generic alternatives. Human rights proponents called for non-enforcement of Gilead's patent, but such request went unheeded. Alternatively, Gilead chose few generic manufacturers and granted them a licence to supply specific countries with the medicine. Other generic manufacturers in countries, where Remdesivir was patented, were excluded from producing it.[45] According to the TRIPS, the patented medicine cannot be produced without an authorization from the patentee or upon the expiry of the patent term.[46] As such, many developing countries were denied accessing a more affordable generic alternative of Remdesivir medicine. Remdesivir was later declared ineffective for treatment of COVID-19

Health in the Circumstances of a Pandemic: Communication from the European Union to the Council for TRIPS (18 June 2021) WTO Doc IP/C/W/681

[43] 'Members Approach Text-Based Discussions for an Urgent IP Response to COVID-19' (WTO, 9 June 2021) < https://www.wto.org/english/news_e/news21_e/trip_09jun21_e.htm> accessed 6 September 2021. **See also**, TRIPS Council Agrees to Continue Discussions on IP Response to COVID-19' (WTO, 20 July 2021) < https://www.wto.org/english/news_e/news21_e/trip_20jul21_e.htm > accessed 8 September 2021

[44] 'Development of Remdesivir' (Gilead, 2020) < https://www.gilead.com/-/media/gilead-corporate/files/pdfs/covid-19/gilead_rdv-development-fact-sheet-2020.pdf> accessed 28 February 2021

[45] WTO TRIPS Council, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of COVID-19 – Responses to Questions (15 January 2021) WTO Doc IP/C/W/672, para 38

[46] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) arts 28, 33

by the WHO.[47] This case strikes a lucid example of the deeply flawed patent system under the TRIPS agreement.

The WHO called for taking actions to realize equitable global accessibility to COVID-19 medicines through "pooling of knowledge, intellectual property, and data."[48] Other initiatives for voluntary sharing of knowledge related to life-saving medicines, such as the Open COVID Pledge, *inter alia,* were launched to increase the production of affordable medicines and vaccines.[49] However, without the effective engagement of pharmaceutical companies as principle key players in such initiatives, there is little chance for their success. Big pharmaceutical companies are still patenting the results of their R&D, which allows them to control the quantity, distribution, and prices of COVID-19 medicines.

Gurgula and Wen Hwa Lee argued that the pharmaceutical patent system in the TRIPS agreement contains fundamental flaws that constitute significant barriers to the affordability and accessibility to medicines in COVID-19 pandemic.[50] The existing patent practices by pharmaceutical companies slowed down the reaction speed for the current pandemic, thus intensifying the traditional tension between pharmaceutical patents and the human right to health especially in developing countries.[51] The monopoly rights granted to pharmaceutical companies in producing COVID-19 vaccines allow them to set high prices that suit only the wealthier developed countries. Such a situation occurred before during the 2009 N1H1 Influenza pandemic, where almost all vaccines manufactured were sold to developed countries due to their high prices, leaving very few to developing ones.[52]

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[47] 'Solidarity Therapeutics Trial Produces Conclusive Evidence on the Effectiveness of Repurposed Drugs for COVID-19 in Record Time' (WHO, 15 October 2020) < https://www.who.int/news/item/15-10-2020-solidarity-therapeutics-trial-produces-conclusive-evidence-on-the-effectiveness-of-repurposed-drugs-for-covid-19-in-record-time> accessed 14 February 2021

[48] 'Solidarity Call to Action: Making the Response to COVID-19 a Public Common Good' (WHO, 1 June 2020) < https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action > accessed 25 February 2021

[49] 'Make the Pledge to Share Your Intellectual Property in the Fight Against COVID' (Open COVID Pledge, 2020) < https://opencovidpledge.org/ > accessed 9 March 2021. **See also**, Olga Gurgula & Wen Hwa Lee, 'COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?' (23 January 2021) Forthcoming in the Journal of generic Medicines 2,5 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3771935> accessed 23 March 2021

[50] Olga Gurgula & Wen Hwa Lee, 'COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?' (23 January 2021) Forthcoming in the Journal of generic Medicines 2 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3771935> accessed 23 March 2021

[51] Ibid

[52] Ibid

### 1.2 The Issue

Over the years, impediments to trade have diminished considerably.[53] State sovereignty has also been diluted due to the recent proliferation of economic blocs and multinational treaties in various aspects.[54] This proliferation reflects the recent transformation of general international law from a law of co-existence that protected reciprocal/bilateral relations between states to a law of cooperation that achieve common goals, including trade liberalization and other international communal interests. Newly developed areas, *inter alia*, IPRs, have emerged with an impact on the traditional setting of international law. With the expansion of international norms in diversified subject matters, a fragmentation of international law occurred leading to potential conflicts between international law norms.[55] A lucid example of the fragmentation phenomenon is the case of pharmaceutical patents in the TRIPS agreement and its impact on the right to health.

The expansion of IPRs and human rights led to blurring of the demarcation between both regimes. It created dense policy spaces in which the previously unrelated norms in IPRs and human rights systems increasingly overlapped in inconsistent and incoherent ways.[56] In the last few years, it is said that the "two systems that were once strangers are now becoming increasingly intimate bedfellows."[57]

Incorporating IPRs within the ambit of the WTO, since TRIPS is one of the WTO covered agreements, brought those rights to a global level and coined them with international trade. Unlike the General Agreement on Tariffs and Trade (hereinafter referred as GATT) where IPRs were framed as barriers to trade,[58] the IPRs under the TRIPS are conceptualized as a tradable

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[53] Patrick Love and Ralph Lattimore, *International trade: Free, Fair and Open?* (OECD publications Paris 2009) 54- 67 < https://www.oecd-ilibrary.org/trade/international-trade_9789264060265-en> accessed 13 June 2021

[54] Hans Mahncke, 'Sovereignty and Developing Countries: Current Status and Future Prospects at the WTO' (2009) 22(2) Leiden Journal of International Law 395

[55] Zain Jaffery, 'The Exceptions to Patent Rights under the WTO-TRIPs Agreement: Is the Right to Health Denied?' (LL.M thesis, University of Nottingham 2008) 4 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2213216> accessed 18 September 2020. **See also**, Santiago Villalpando, 'The Legal Dimension of the International Community: How Community Interests are Protected in International Law' (2010) 21(2) The European Journal of International Law 387, 388-389.

[56] Laurence R. Helfer, 'Toward a Human Rights Framework for Intellectual Property' (2007) 40 University of California Davis Law Review 971, 980-982

[57] Laurence R. Helfer, 'Human Rights and Intellectual Property: Conflict or Coexistence?' (2003) 5(1) Minnesota Journal of Law, Science and Technology 47, 47-48.

[58] General Agreement on Tariffs and Trade (adopted 30 October 1947, entered into force 1 January 1948) 55 UNTS 194 (GATT 1947) art XX(d). The GATT 1947 exempted measures "necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including … the protection of patents, trademarks, and copyrights."

commodity worth protection to enhance global trade. Like any form of trade which is successful when the owner's right to property is protected, the IPRs were enforced on the international agenda under the rhetoric of property rights.[59] Accordingly, the justification of IPRs had changed from natural rights to economic incentives. The latter is used to argue that protecting IPRs induce investment in R&D, spur innovation-based industrial development, and promote the transfer of technology, thereby contributing to the promotion of global trade in general.[60]

The main thrust behind the TRIPS agreement was provided by industrial lobbies in the US, particularly the big pharmaceutical and software industry. They wanted to dominate the field of international trade and the only way to do that was by aggressively protecting their technology. Before TRIPS, many countries recognized different kinds of IPRs protection in their domestic legislation, but they were not effective enough in a globalized economy. Developed countries sought harmonization of IPRs on each and every level of protection; so, they put pressure to include IPRs protection in the WTO negotiations.[61]

The long and arduous negotiations of the TRIPS provisions and the pressure that was put on developing countries during the period of negotiations resulted in drafting its provisions in an ambiguous way. Instead of achieving the required level of harmonization, it provided certain minimum standards for IPRs protection. As a result of such controversial nature, the agreement contains numerous gaps and ambiguities which leave more room for manoeuvre via interpretation.[62] Such interpretation more often achieves the standards and norms of developed countries and allows trade values to prevail over human rights norms. It did not take into consideration the accessibility of medicines as a public health concern. Therefore, as Frederick Abbott argued, the TRIPS agreement "represents a flawed bargain in the sense that great economic pressure was brought to bear on developing countries to establish private stakeholder interests without adequate evaluation of public interest consequences from a developmental

[59] Rochelle Dreyfuss and Suzy Frankel, 'From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property' (2015) 36(4) Michigan Journal of International Law 557, 559
[60] Daniel J. Gervais, 'TRIPS and Development' (28 August 2013) Vanderbilt Public law Research paper No 13-46, 95-97 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2313836 > accessed 20 September 2020
[61] Peter Drahos, 'Four Lessons for Developing Countries from Trade Negotiations over Access to Medicines' (2007) 28(1) Liverpool Law Review 11, 15-17
[62] Ibid. **See also**, Carlos M. Correa, 'The TRIPS Agreement: How Much Room for Maneuver?' (2001) 2(1) Journal of Human Development 79, 92, 103

perspective."[63] This has raised debates regarding whether the pharmaceutical patent regime in TRIPS is in conflict with human right to health or otherwise.

The UN Sub-Commission on the Promotion and Protection of Human Rights recognized the existence of a tension between the IPRs system in TRIPS and human right to health. It stated that "the implementation of the TRIPS does not adequately reflect the fundamental nature and indivisibility of all human rights, including … the right to health."[64] Therefore, "the TRIPS agreement could affect the enjoyment of the right to health - in particular through its effect on access to pharmaceuticals."[65] Also, the UN High-Level Panel on Access to Medicines issued a report in 2016 titled "Promoting Innovation and Access to Health Technologies." The report aims to "review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."[66]

Moreover, the Millennium Development Goals Gap Task Force flagged the effect of the current international patent regime on the prices of medicines in developing countries. In one of its reports, the Task Force stated that the pharmaceutical patent system in TRIPS foreseeably aggravates the health problems in developing countries due to inflating the prices of medicines rendering them inaccessible and unavailable to many people. It noted that the cost of many essential medicines, particularly those for chronic diseases, remains prohibitive in many developing countries.[67]

Benedict Chigara asserted the existence of a tension between the WTO system and the human rights regime. Chigara argued that the WTO system is premised on the theory of absolute and comparative advantage, where its primary concern is to maximize the international wealth by liberalizing trade rather than to seek an equitable distribution of resources or wealth.

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[63] Frederick M. Abbott, 'TRIPS and Human Rights: Preliminary Reflections' in Frederick M. Abbott et al (eds), *International Trade and Human Rights: Foundations and Conceptual Issues* (Michigan University Press 2006) 145, 165

[64] UN Sub-Commission on the Promotion and Protection of Human Rights, 'Resolution 2000/7 on Intellectual Property Rights and Human Rights' (17 August 2000) UN Doc E/CN.4/Sub.2/RES/2000/7, para 2

[65] UN Sub-Commission on the Promotion and Protection of Human Rights, 'Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights' (27 June 2001) UN Doc E/CN.4/Sub.2/2001/13, para 2

[66] UN Secretary-General's High-Level Panel on Access to Medicines, 'Report on Promoting Innovation and Access to Health Technologies' (September 2016) 7 < http://www.unsgaccessmeds.org/final-report> accessed 12 December 2019

[67] UN Millennium Development Goal Gap Task Force, *Millennium Development Goal 8: The Global Partnership for Development: Making Rhetoric a Reality* (UN Publication 2012) 63-64, 67-68 < https://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2012/mdg8report2012_engw.pdf> accessed 17 January 2021

Consequently, an economic inequality between states is created due to globalization supported by the WTO robust adjudicative system and enforcement mechanism. The system places WTO concepts at a higher level than the human rights concepts, where it favours economic and trade policies allowing it to prevail over human rights.[68]

The TRIPS agreement contains several flexibilities that limit the exercise of patent rights with the proviso that certain conditions are fulfilled.[69] Such flexibilities could be utilized by developing economies to balance the pharmaceutical patent rights with the protection of public health, thus safeguarding better accessibility to patented medicines. However, practically, they proved to be onerous, thus making developing countries reluctant to use them. Furthermore, in trying to remedy the deficiencies of the TRIPS agreement in the area of access to medicines, the WTO adopted the Doha Ministerial Declaration on TRIPS and Public Health in 2001 (hereinafter referred as Doha Declaration);[70] then the WTO General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (hereinafter referred as the 30 August 2003 Decision);[71] finally, the WTO General Council Decision on 6 December 2005 to amend the TRIPS agreement.[72] Nevertheless, whether such decisions mitigate the effect of patenting medicines on public health is a subject of continuous debate.

### 1.3 Research problem

The intersection between the TRIPS provisions related to patents and the human right to health embodies a tension between WTO law and human rights law. The TRIPS agreement forms an integral part of the WTO law. The WTO law is a whole unit, where each part is consistent with the other.[73] Examining how the WTO law interacts with other international law norms, *inter alia*, human rights norms, is also an examination of whether or not the TRIPS agreement

[68] Benedict Chigara, 'Social Justice: The Link Between Trade Liberalisation and Sub-Saharan Africa's Potential to Achieve the United Nations Millennium Development Goals by 2015' (2008) 26(1) Netherlands Quarterly of Human Rights 9, 10-14

[69] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) arts 6, footnote 6 of arts 28, 30, 31

[70] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration)

[71] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision)

[72] Amendment of the TRIPS Agreement (8 December 2005) WT/L/641 (Decision of 6 December 2005)

[73] Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement) art II(2)

accommodates human right to health within its ambit. Moreover, according to the WTO Dispute Settlement Understanding (hereinafter referred as WTO DSU), any dispute arising from the WTO covered agreements is subject to the WTO dispute settlement system.[74] Therefore, the disputes arising from the implementation of the TRIPS agreement are subject to the WTO dispute settlement system. This system armed TRIPS with teeth to defend IPRs at a global level. In case of non-compliance with TRIPS obligations, the WTO adjudicating bodies (WTO panels and Appellate Body) will interpret the TRIPS provisions and issue binding decisions. Those decisions allow the successful party in WTO disputes, upon authorization by the WTO Dispute Settlement Body (hereinafter referred as WTO DSB), to impose trade sanctions on the losing party in case of non-compliance.[75]

This dissertation seeks to investigate whether, how, and to what extent the human right to health, as a part of the general international law, is accommodated within the ambit of the pharmaceutical patent system in the TRIPS agreement.

## 1.4 Aims and Objectives

### 1.4.1 Aims

The dissertation aims to reconcile the right to access to medicines as an indispensable component of the human right to health and the pharmaceutical patents rights in the TRIPS agreement. Since the protection of public health is one of the TRIPS principles, as stipulated in article 8, it is inevitable to strike a balance between the patent holders' right (economic objectives) and the public right to access to essential medicines (social/moral objectives). Moreover, the dissertation aims to allow human right to health to prevail over pharmaceutical patents in WTO disputes. In such disputes, the WTO dispute settlement mechanism should take into consideration the states' obligations under international law to respect, protect and fulfil the human right to health. This provides WTO member states, especially developing countries, more freedom to use the TRIPS flexibilities to promote public health.

Despite the large volume of literature on the impact of pharmaceutical patents on the right to access to medicines in developing countries since the advent of the TRIPS Agreement, the issue

[74] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 1(1)
[75] Ibid, arts 3, 22

has mainly been studied from the paradigm of the arguments and justifications from the pharmaceutical industry and IPRs proponents on one side and those of human rights proponents on the other. Additionally, the literature focused mainly on whether the TRIPS flexibilities and the WTO successive decisions can provide an adequate balance between the TRIPS regime providing for pharmaceuticals protection and the human rights regime obliging states to safeguard affordability and accessibility to medicines. Furthermore, the literature addressed the tension between both rights, viewing it as a tension between treaty norms, i.e., between the pharmaceutical patents' provisions in TRIPS and the right to access to essential medicines as a component of the right to health stipulated in the International Covenant on Economic, Social and Cultural Rights (hereinafter referred as ICESCR).

The dissertation also aims to make contribution to the contemporary literature with particular emphasis on the relation between the WTO law and human rights law. It examines the extent to which the patent protection in the TRIPS agreement is consistent with the right to health, specifically the right to access to medicines, by soberly analysing the role of human rights law in WTO disputes settlement. It considers the fragmentation and institutionalization of international law which created a *de facto* hierarchy entirely different from the normative hierarchy of international law. The dissertation aims to dilute the effect of the *de facto* hierarchy of the WTO law in the implementation level in order to advance the coherence and unity of international law norms. One of the methods to achieve such aim is to interpret the TRIPS agreement with reference to the wider corpus of international law which includes human rights law.

Furthermore, the dissertation aims to utilize various concepts to prevent conflicts between the right to health and pharmaceutical patents. These concepts include; conflict of norms in public international law, the presumption against conflicts known as "the principle of systemic integration" embodied in the rules of interpretation in the Vienna Convention on the Law of Treaties (hereinafter referred as VCLT), the secondary rule of recognition theory, and the WTO jurisprudence.

Finally, although the dissertation focuses on the right to access to essential medicines as a component of the right to health in the ICESCR, it also invokes the right to access to life-saving medicines as an element of the right to life stipulated in the International Covenant on Civil and Political Rights (hereinafter referred as ICCPR) and the right to access to medicines in the context of pandemics, like HIV/AIDS, Malaria and Tuberculosis, which is considered

customary international law. In other words, the dissertation aims to introduce to the contemporary literature the tension between pharmaceutical patents in the TRIPS Agreement and accessibility to medicines in the ICCPR and customary international law.

### 1.4.2 Objectives

To achieve the aforementioned aims, the dissertation will, therefore, provide answers to the following questions:

a) How, and to what extent, can the TRIPS flexibilities and the successive WTO decisions mitigate the impact of the TRIPS agreement on public health? Are they capable of achieving the required balance between the private interests in the protection of pharmaceuticals and the public interests in accessibility to medicines?

b) Whether the right to access to medicines conflicts or coexists with pharmaceutical patents in the TRIPS Agreement? In the first case, what is the type of such conflict and how could it be resolved?

c) How, and to what extent, can the WTO dispute settlement system take into account human rights law, *inter alia*, the human right to health?

d) Whether, and to what extent, the WTO law is linked to the wider corpus of general international law? Does the nature of the WTO law further fragmentation or enhances integration of international law norms?

## 1.5 Methodology

The main sources of international law are examined in this dissertation to give a clear understanding of the international patent system and the human right to health, to reach evidence-based outcomes, and to answer the research question.

The dissertation applies the doctrinal analysis methodology, where textual, comparative and critical analysis methods are implemented to study the WTO system and the international law in general, the pharmaceutical patenting system in TRIPS, and the human rights law, *inter alia*, the right to access to medicines. The dissertation also examined different philosophical justifications for IPRs and human rights and resorted to concepts and theories written by prominent international law authors to integrate and build on them to arrive at the findings.

Additionally, it examined a diverse amount of case law from the WTO, the ICJ, and national courts' rulings either supporting patents and WTO law in general or taking the side of international human rights law. This dissertation is multi-faceted in that whilst it contains mainly legal arguments, it also includes historical and political aspects, international economic concepts and studies, social science, and scientific strategies and instruments used in the pharmaceutical field for patenting medicines, like the "Bolar exemption," the "Evergreening Strategy," and the Supplementary Protection Certificate (hereinafter referred as SPC); with genuine analyses conducted and conclusions reached. It also integrates a number of laws, namely, patent law, human rights law, international trade law, WTO law, and public international law.

The dissertation examined different perspectives and approaches on the topic and reviewed and analysed a wide spectrum of primary and secondary sources. The primary sources include treaty legislation, national legislation, international resolutions and declarations, International Law Commission (hereinafter referred as ILC) reports, UN and other governmental organizations reports, and decisions of international and national courts. The secondary sources include non-governmental reports, books, contributions to edited books, journal articles, working and research papers, websites, and general expert academic commentary in the field.

### 1.6 Scope of the Research

The dissertation focuses on the examination of the right to access to medicines as an element of the right to health in the ICESCR. However, it also examines the right to access to medicines in the context of the right to life in the ICCPR and as customary international law. It will not refer to other aspects of the right to health, such as access to healthcare facilities and basic health services. It will also not examine other human rights related to the protection of IPRs, like the right to property and the right to fruits of creation. Only the patent rights in section 5 of the TRIPS Agreement will be considered, specifically the predicament between pharmaceutical patents and accessibility to medicines. The dissertation will also analyse the Doha Declaration, the 30 August 2003 Decision, and the WTO General Council Decision on 6 December 2005 to amend the TRIPS agreement. However, the relation between patents and competition law is out of the scope of the research.

Another limitation is that the dissertation does not focus on the bilateral and free trade agreements (hereinafter referred as FTAs) in patent protection which are referred to as TRIPS-

Plus Agreements. In a very concise manner, chapter 2 of the dissertation critiques them for impeding the freedom of developing countries to fully utilize the TRIPS flexibilities.

Although there are other factors which contribute to hindering the accessibility to medicines in developing countries, the dissertation examines only the impact of pharmaceutical patents in TRIPS on the affordability and accessibility to medicines in those countries.

Finally, the dissertation uses the phrase developing countries to refer to both developing and least-developed countries in contrast to developed ones, except in specific reference to least-developed countries in the provisions of the TRIPS Agreement, the Doha Declaration, and the 30 August 2003 Decision. Also, when the dissertation uses the word "medicines" only, it refers to "essential medicines."

### 1.7 Contribution to Knowledge

By analysing the TRIPS provisions related to patents and the human right to health obligations in the ICESCR, the dissertation will contribute to a clear understanding of the requirements of both rights and delineate the obligations of states at the implementation level.

The dissertation provides a defence of the right to access to medicines and calls for renewed focus on its content and applicability when it comes into conflict with the pharmaceutical patents in the TRIPS agreement. Contrary to the arguments stating that the right to health, as a positive right, is not worth protection similar to negative rights in the ICCPR, the dissertation argues that the right to health is binding on all states parties to the ICESCR. They cannot escape from their obligations to respect, protect, and fulfil such right on any grounds including financial constraints. Thus, the dissertation argues that the WTO system should allow its member states to apply and interpret the TRIPS provisions in a manner consistent with their obligations under the right to health by making full use of the TRIPS flexibilities.

Furthermore, the dissertation introduces the notions of the right to access to life-saving medicines as a *jus cogens* norm and the right to access to medicines in the context of pandemics as customary international law. In the first, the dissertation argues that since the right to life is considered a *jus cogens* norm in public international law, then the right to access to life-saving medicines, as one of its components, should reach the same status. Contrary to the principle of *pacta tertiis nec nocent nec prosunt*, the protection of life-saving medicines, as a *jus cogens* norm, is binding on all states whether parties to the ICCPR or not. In the second, the dissertation

builds on the existing state practice and *opinio juris* supporting the protection of the right to access to medicines in the context of pandemics to argue that such right is a customary international law binding on all states. Therefore, any interpretation to patents provisions has to take into consideration both forms of the right to medicines, otherwise it would be considered violating a *jus cogens* norm or running contrary to customary international law.

After evaluating the patent system and its different justifications, the dissertation found that it turned to be a monopolized system due to the change in its nature; - from a legal tool to achieve social objectives to a tool that protects only economic incentives. As such, the dissertation justifies patent protection by combining moral rights with economic incentive perspectives in order to provide a room for invoking human rights into the patent system. Relying on the economic incentives only may have a significant impact on the pharmaceutical sector because it impedes the sharing of scientific progress. It is crucial to invoke moral rights (which are considered universal values) beside economic incentives in drafting patent laws and policy in the field of medicines.

The TRIPS agreement, the Doha Declaration, and the 30 August 2003 Decision tried to strike a balance between granting patent rights and the protection of public health. However, the dissertation proves that they failed to allow health concerns to prevail over TRIPS obligations.

Jennifer Anna Sellin and others justify pharmaceutical patents in developing countries as the rights of authors to benefit from the protection of the moral and material interests resulting from their scientific productions as stated in article 15(1)(c) of the ICESCR.[76] However, the dissertation found that the article is not meant to justify pharmaceutical patents interference with the right to access to medicines.

In line with Petersmann's argument that the law of specialized organizations should be interpreted in conformity with human rights law,[77] the dissertation argues that the WTO adjudicating bodies should apply not only the norms of their legal systems, but also other international law rules including human rights norms.

[76] Jennifer Anna Sellin, 'Does One Size Fit All' Patents, the Right to Health and Access to Medicines' (2015) 62 Netherlands International Law Review 445, 462

[77] Ernst-Ulrich Petersmann, 'Time for a United Nations 'Global Compact' for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration' (2002) 13(3) European Journal of International Law 621, 625

The dissertation explored the normative hierarchy of both human rights and WTO systems and found that the institutionalization process created a *de facto* hierarchy independent and completely different from the normative hierarchy of international law. The former is responsible for degrading the human rights regime in relation to the WTO system. Unlike the human rights system, the WTO system is endowed with a robust adjudication and enforcement mechanism. It seems natural to invalidate the utilitarian and instrumental WTO norms whenever they conflict with human rights norms based on morality and superiority of human rights. However, the current international law cannot accommodate such claim according to the normative hierarchy in international law which clashes with the factual hierarchy resulting from institutionalization. Thus, states shall comply with their obligations under the WTO system and relax their obligations under the human rights system.

Contrary to Wilfred Junks, Wolfram Karl, Hans Kelsin, and Gabrielle Marceau who adopted the strict/narrow definition of conflict of norms in international law,[78] the dissertation adopted the broad/wide definition of conflict following Erich Vrans and Joost Pauwelyn.[79] The strict definition does not realize the existence of any conflict between the patent system in TRIPS and the human right to health in ICESCR since their obligations are not mutually exclusive. In such case, the TRIPS obligations shall prevail over the flexibilities that grant states the right to restrict patents for public health consideration. However, the dissertation argues that the strict definition of conflict runs counter to the object and purpose of the WTO agreements. All WTO norms should be given their full meaning. The obligations to liberalize trade should be equal to the rights to restrict trade to protect public health. The dissertation shows that there is a potential conflict existing between both regimes according to the wide definition of conflict since the commands in both regimes are merely different rather than mutually exclusive. This approach allows balancing between both rights rather than applying the patent right and excluding the TRIPS flexibilities.

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[78] Hans Kelsen, *General Theory of Norms* (Clarendon Press UK 1991) chapter 1. **See also**, Clarence Wilfred Jenks, 'The Conflict of Law-Making Treaties' (1953) 30 British Yearbook of International Law 401, 426-427. **See also**, Wolfram Karl, 'Conflicts Between Treaties' in Rudolf Bernhardt (ed), *Encyclopedia of Public International Law*, Vol 7 (North Holland, 1984) 467, 468; cited in Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 167. **See also**, Gabrielle Marceau, 'Conflicts of Norms and Conflicts of Jurisdictions: The Relationship Between the WTO Agreement and MEAs and Other Treaties' (2001) 35(6) Journal of World Trade 1081, 1082-1083, 1086

[79] Erich Vranes, 'The Definition of 'Norm Conflict' in International Law and Legal Theory' (2006) 17(2) The European Journal of International Law 395, 418. **See also**, Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 170-188

Moreover, the dissertation shows that the conflict-resolution-techniques, *lex posterior derogat legi priori*, *lex specialis derogat legi generali*, and *lex superior derogate legi inferiori* do not provide a suitable solution to the conflict between the right to access to medicines in the ICESCR and the patent protection to medicines in the TRIPS agreement.

The dissertation criticized Joost Pauwelyn's argument trying to enlarge the scope of jurisdiction of the WTO adjudicating bodies to include non-WTO claims.[80] Such argument is untenable since the WTO panels and Appellate Body have limited jurisdiction *ratione materiae*, thus they do not have jurisdiction over human rights violation complaints. Due to the continuous debate about the applicable law in WTO disputes between restricting the applicable law to WTO law,[81] endorsing full applicability of non-WTO law,[82] or allowing partial application of non-WTO law in WTO disputes settlement,[83] the dissertation conducted an in-depth analysis to the WTO DSU to conclude that human rights law is not part of the applicable law in WTO dispute settlement system. Human rights cannot be raised as a defence against claims of WTO law violation. They can only be invoked when interpreting WTO provisions or when it is referred to in procedural matters. However, the usage of non-WTO law, *inter alia*, human rights law, in interpretation does not mean that it is part of the applicable law in WTO disputes, rather, it is used only to clarify the meaning of the WTO provisions.

Finally, the dissertation used Herbert Hart's theory of the secondary rule of recognition[84] to construct a new definition for WTO law which is the actual and rhetorical practice of the WTO adjudicating bodies when they use international law in interpreting WTO provisions. Their practice represents their internal point of view towards WTO law. As such, the dissertation explored the practice of the WTO adjudicating bodies when they use the VCLT rules of interpretation, namely articles 31 and 32, in WTO disputes. It found that the WTO adjudicating bodies are primarily advancing trade liberalization allowing it to prevail over human rights law;

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[80] Joost Pauwelyn, 'The Role of Public international Law in the WTO: How Far Can We GO?' (2001) 95(3) The American Journal of International law 535, 554. **See also**, Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 444

[81] Gabrielle Marceua, 'WTO Dispute Settlement and Human Rights' (2002) 13(4) European Journal of International Law 753, 773-777. **See also**, Anja Lindroos and Michael Mehling, 'Dispelling the Chimera of Self-Contained Regimes International Law and the WTO' (2006) 16(5) The European Journal of International Law 857, 862. **See also**, Joel P. Trachtman, 'The Domain of WTO Dispute Resolution' (1999) 40(2) Harvard International Law Journal 333, 342-343

[82] Joost Pauwelyn, 'The Role of Public international Law in the WTO: How Far Can We GO?' (2001) 95(3) The American Journal of International law 535, 562, 566, 577

[83] Lorand Alexander Bartels, 'Applicable Law in WTO Dispute Settlement Proceedings' (2001) 35(3) Journal of World Trade 499, 506

[84] H. L. A. Hart, *The Concept of Law* (3rd edn, Oxford University Press 2012) 79-123

this represents their internal point of view regarding WTO law. The dissertation thus shows the reluctance of the WTO Appellate Body to adopt a revolutionary/dynamic interpretation, provided by article 31(3) of the VCLT. The Appellate Body gave more value to textual and contextual interpretation as an indication of the common intention of the WTO member states.

On the contrary, in line with Benedict Chigara, the intention of treaty parties would be best represented by adopting an evolutionary/dynamic interpretation, rather than sticking to the actual wording of the treaty. The evolutionary interpretation allows invoking the state practice, subsequent to the adoption of a treaty, in the interpretation process. The state practice reflects the intention of treaty parties regarding its implementation which could change from time to time responding to the variables in international relations and the fast-moving pace of international law.[85] By adopting the evolutionary/dynamic interpretation, the dissertation develops an understanding of interpretive techniques to be used within the WTO disputes settlement. This could open a room for taking into consideration, when interpreting the TRIPS provisions, the practice of the states when utilizing the TRIPS flexibilities to provide better accessibility to medicines. Refraining from doing this, as Holger Hestermeyer wrote, indicates the limited role of the WTO adjudicating bodies in interpretation to the "deal inherent in the treaty"[86] which they were set up to enforce.

### 1.8 Structure of the Research

The dissertation comprises of an introductory chapter, four main chapters, and a concluding chapter. Chapter two provides a thorough background on the patent system, particularly pharmaceutical patents, showing its subject matter, peculiarities, and the requirements to grant a patent right to an invention. It demonstrates the historical development of the patent system from the territorial period reaching to the global period. It explores and analyses the philosophical justifications for IPRs to locate the justification that allows invoking human rights considerations in the pharmaceutical patent system. The chapter then conducts an in-depth analysis of the TRIPS flexibilities to explore their effect on the accessibility to medicines in developing countries. It also explores the efforts exerted by the WTO to mitigate the impact of

[85] Benedict Chigara, 'Treaty-Text Loyalists' Burden with Subsequent State Practice' (2021) 68(1) Netherlands International Law Review 61

[86] Holger Hestermeyer, 'International Human Rights Law and Dispute Settlement in the World Trade Organization' in Martin Scheinin (ed), *Human Rights Norms in 'Other' International Courts* (Cambridge University Press UK 2019) 199, 225

the TRIPS agreement on public health, specifically, the Doha Declaration, the 30 August 2003 and 6 December 2005 Decisions, culminating in amending the TRIPS on 23 January 2017. The chapter concludes that the patent monopoly system is often restricting the accessibility to medicine in developing countries, i.e., interfering with the right to access to essential medicines.

Chapter three addresses the human rights framework for access to medicines as an indispensable component of the right to health. The chapter begins by shedding light on the international human rights framework in general, showing its prominent instruments and the categories of human rights. Then, it addresses the right to health showing the international instruments and regional charters recognizing it and obliging states to protect it. This is followed by exploring the justiciability of the human right to health and demonstrating the legal characters bound by it. The chapter further demonstrates the right to access to medicines showing its elements, the international instruments that recognize it and the national court rulings which address it as a legally binding norm. The chapter then explores the nature of the right to access to medicines in public international law, namely treaties and customary international law. Eventually, the chapter illustrates the challenges facing developing countries in their pursuit to improve access to medicines for their citizens.

Chapter four explores the interference between the pharmaceutical patent system in TRIPS and accessibility to medicines. It seeks an answer to whether both rights conflict or coexist; and in the first case, the nature of conflict. First, the chapter scrutinizes the different justifications for the interference between both rights. It finds that the patent system in TRIPS is unjustifiably interfering with the right to access to medicines, thus a conflict is recognized between both regimes. Such conflict signifies a larger conflict between the WTO system and the human rights system. To identify the type of conflict, the chapter explicates the structure and the development of international law norms since the problem of regime conflict is rooted in such development. It shows the development of international law from a law of co-existence without any normative hierarchy to a law of co-operation and community interests. To illustrate the development in the international law structure, the chapter analyses the UN obligations, the *erga omnes* obligations, and the *jus cogens* norms. Further, the chapter analyses the fragmentation phenomenon, which occurred due to the institutionalization of the international legal system, and its consequences on establishing a *de facto* hierarchy beside and entirely independent from the normative hierarchy. After exploring the nature of WTO and human rights obligations and the effect of the normative hierarchy and the *de facto* hierarchy on the WTO and human rights regimes, the

chapter finds that the *de facto* hierarchy created by the WTO robust adjudication and enforcement mechanism is responsible for placing the human right regime at a lower level than the WTO system. Such downgrade is not recognized under the normative hierarchy which generally places human rights norms at a higher position. The chapter applies the concept of conflict of norms in international law with its broad definition to rest on a potential and systemic conflict between human right to health in the ICESCR and the pharmaceutical patents in TRIPS. The chapter concludes by suggesting that the conflict between both regimes turned to be an objective question which aims to explore possible methods, if any, that could be utilized to overcome the factual hierarchy of the WTO system by applying human rights law in the WTO system.

Chapter five re-examines the role of human rights law in the WTO disputes settlement system to find suitable methods for implementing the right to access to medicines within the TRIPS agreement. It conducts an in-depth analysis of different views to find an answer to whether and to what extent the WTO normative framework allows human right to health to prevail over pharmaceutical patents in TRIPS in different situations of conflicts? First, it examines whether the conflict resolution techniques could resolve the conflict between human right to health and pharmaceutical patents in the TRIPS agreement. Then, it analyses the argument viewing the WTO law as a self-contained regime or a closed-legal circuit outside the wider corpus of public international law, which applies only its own rules. Further, it scrutinizes the approach trying to resolve the conflict by considering the DSU normative framework. The chapter then uses Hart's theory of the secondary rule of recognition to construct a new definition for the WTO law which is the actual and rhetorical practice of the WTO adjudicating bodies when they use international law in interpreting WTO provisions. Accordingly, the chapter explicates the VCLT rules of interpretation, namely articles 31 and 32, to explore whether the WTO adjudicating bodies in their interpretation had applied the principle of systemic integration, thus advancing the coherence and unity of international law, or otherwise. The chapter then analyses the WTO cases that refer to the tension between pharmaceutical patents in TRIPS and the right to access to medicines to explore the reality of the use of the latter in the interpretation process of TRIPS disputes. The chapter concludes with a critical note regarding the role of human rights law in WTO disputes settlement system.

Chapter six highlights findings and conclusions from previous chapters. It suggests several recommendations to resolve the conflict between pharmaceutical patents and accessibility to

medicines. Among such recommendations is integration of human rights law into the WTO DSU by amending the provisions of the latter to include explicit reference to other international law agreements as an applicable law in the WTO system.

## Chapter 2: Pharmaceutical Patents

### 2.1 Introduction

A patent is a monopoly right over the commercial exploitation of an invention in any field of technology. It is granted for a limited period usually 20 years starting from the date of filing the patent application. In return for the disclosure of the invention, the state grants the inventor an exclusive right to exploit the patented product, if it meets specific requirements, and to control the way of its exploitation till the patent term expires. The monopoly right of the patentee gives him the right to exclude others from using the patented product without his authorization.[1]

The patent system is frequently justified as a substantial system necessary to promote technological innovation. It is strongly correlated with the transfer and dissemination of knowledge in technology which effectively boosts economic growth.[2] Supporters of the patent system argue that patents enable industry to recoup its investment in R&D which incentivizes inventors for future innovation and creativity and creates competition for the benefit of the society in whole. However, patents can also be used to restrain competition and set the prices of inventions higher than they should be when competitive products are available.[3]

Before adopting the TRIPS Agreement, many states had chosen not to patent medicines. They feared its influence on the accessibility to medicines, especially the essential ones, and consequently its effect on public health. Developing countries disallowed pharmaceutical patents fearing that the monopoly rights granted to patentees would render the prices of medicines unaffordable for a large sector of their population. Other developing countries with

[1] Lionel Bently and Brad Sherman, *Intellectual property law* (4th edn, Oxford University Press 2014) 375. **See also**, Tanya Aplin and Jennifer Davis, *Intellectual property Law: Text, Cases and Materials* (2nd edn, Oxford University Press 2013) 534. **See also**, Peter Drahos, 'Intellectual Property and Human Rights' (1999) 3 Intellectual Property Quarterly 349, 350

[2] David Kline, 'Do Patents Really Promote Innovation?' (The Michelson Institute for Intellectual Property, 24 April 2017) < https://michelsonip.com/patents-really-promote-innovation/> accessed 12 January 2019. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 7

[3] Adam Thierer and Clyde Wayne Crews (eds), *Copy Fights: The future of Intellectual property in the Information Age* (Cato Institute Washington 2002) 101. **See also**, Peter S. Menell et al, *Intellectual Property in the New Technological Age: 2019 Volume I: Perspectives, Trade Secrets & Patents* (Clause 8 Publishing 2019) 16 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3415161&download=yes> accessed 12 January 2019. **See also**, Erik Hovenkamp, 'Challenges Restraints and the Scope of the Patent' (2016) 4(3) CPI Antitrust Chronicle Journal 4-6 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2866630> accessed 12 January 2019

pharmaceutical industrial capacities, like India, opposed the system because it would oblige their pharmaceutical industry to stop producing cheap generic alternatives.[4]

Starting from the second half of the twentieth century, most developed countries began to incorporate patent systems in their national legislations. They sought to bring patent rights within a broader framework that could provide a minimum standard for patent protection with a robust enforcement mechanism. This was achieved after the adoption of the TRIPS agreement in 1994, as part of the WTO agreement, which obliged all member states to implement in their national patent laws, the TRIPS standards for patent protection including pharmaceutical patents.[5]

In the pharmaceutical field, a conflict started to appear between patenting pharmaceutical products and the right to access medicines after the TRIPS adoption. Such conflict escalated after the expiration of the transitional period granted by the TRIPS to developing and least-developed countries to delay fulfilling their TRIPS obligations. Starting from 1 January 2005, all WTO members, except the least-developed countries, are obliged to adopt the TRIPS minimum standards of patent protection.[6] They are obliged to adopt patent legislations that provide for the grant of pharmaceutical patents, whether products or processes, for a limited term, commonly twenty years starting from the date of filing the patent application, provided that such inventions meet the criteria of patentability stipulated in the TRIPS, namely novelty, inventive step, and capability of industrial application.[7]

Patents prevent competitors from producing generics until the expiration of the patent term of the original brand-name patented medicine. As such, developing countries with manufacturing capacities became unable to produce generic versions of patented drugs which are usually sold at a lower price than the original patented ones. Due to the monopoly rights granted to patent holders, they usually set high prices for the patented medicines, thus affecting the accessibility to medicines for many people in developing countries. Unlike developed countries, consumers

[4] Jean O. Lanjouw and Iain M. Cockburn, 'New Pills for Poor People? Empirical Evidence after GATT' (2001) 29(2) World Development Journal 265, 265-266, 288. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) xxxiv (Introduction)
[5] Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (Routledge London and New York 2002) 10
[6] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 65
[7] Ibid, arts 27, 33. **See also**, European Patent Convention (adopted 5 October 1973, entered into force 7 October 1977, revised by the Act revising article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000) art 52(1)

in developing countries do not benefit from comprehensive health insurance systems. They rely mostly on cheap generics instead of the expensive patented medicines.[8] With the state obligation to safeguard accessibility to medicines to people as an essential component of the right to health,[9] pharmaceutical patents in TRIPS appear to interfere with the right to access to medicines.

This chapter will provide a thorough background on the patent system, particularly pharmaceutical patents. It will analyse the intersection between the patent system since its inception, and public health, specifically, accessibility to medicines. This demonstration is indispensable because it builds up the base for analysing the interference between the right to access to medicines in the human rights law and the patent system in the WTO law.

The chapter will first present an overview of the international patent system showing its subject matter and the requirements to grant a patent right to an invention. It will briefly explain the TRIPS flexibilities which limit the exercise of the patent right, provided that certain conditions are fulfilled. An in-depth analysis of these flexibilities will be conducted at the end of the chapter to explore their effect on the accessibility to medicines in developing countries.

The chapter will then demonstrate the historical development of the patent system from the territorial period, to the international one, reaching the global period and the post-TRIPS period. It will show that the patent system had been ineffective under the Paris Convention for the Protection of Industrial Property (hereinafter referred as Paris Convention)[10] due to the weak enforcement mechanism of the World Intellectual Property Organization (hereinafter referred as WIPO) which administers the Paris Convention. However, the TRIPS agreement imposed stringent patent protection standards obliging all WTO members to implement such standards in their legislations. This is due to the robust enforcement mechanism of the WTO. The chapter will demonstrate the efforts exerted to mitigate the impact of the TRIPS agreement on public

[8] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) xxxiv (Introduction). **See also**, Peter Drahos, 'Intellectual Property and Human Rights' (1999) 3 Intellectual Property Quarterly 349, 354, 362

[9] UN Human Rights Council, 'Access to Medicine in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (12 October 2009) UN Doc. A/HRC/RES/12/24, para 1. **See also**, UN Human Rights Council, 'Resolution 6/29: Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (14 December 2007) UN Doc A/HRC/RES/6/29, Para 4(i). **See also**, UN Commission on Human Rights, 'Resolution 2003/29: Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria' (22 April 2003) UN Doc E/CN.4/RES/2003/29, Paras 1, 4

[10] Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, entered into force 7 July 1884) 21 UST 1583, 828 UNTS 305 (Paris Convention)

health starting from the Doha Declaration;[11] then the 30 August 2003 Decision;[12] culminating in the WTO General Council Decision on 6 December 2005 to amend article 31 of the TRIPS agreement.[13] On 23 January 2017, the amendment was formally built into the TRIPS after accepting the amendment protocol by two-thirds of the WTO members.[14]

Afterwards, the chapter will explore and analyse the philosophical justifications for IPRs, namely, the natural rights and labour argument, the utilitarian argument, and the economic incentives argument. As a result of trade globalization, patents became tools to boost national development and incentivize further innovation. It will be argued that combining the moral rights arguments with the economic incentive arguments is crucial to invoke human rights considerations in the pharmaceutical patent system. This will be followed by demonstrating the peculiarity of pharmaceutical patents, namely; the regulatory data protection and the SPC, showing how pharmaceutical companies utilized both instruments to extend market exclusivity in medicines after the expiration of the patent term.

The chapter concludes that the patent monopoly system often restricts the accessibility to medicine in developing countries, thus interfering with the right to access to essential medicines.

### 2.2 Overview of the International Patent System

Patents are means of protection for inventions. They can be defined as "monopoly rights that are granted for a limited time, usually 20 years, in return for the disclosure of technical information or the commercial exploitation of inventions."[15] Another detailed definition for patents would be "exclusive rights awarded to inventors to prevent others from making, selling, distributing, importing or using their inventions without licence or authorization."[16]

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[11] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration)
[12] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision)
[13] Amendment of the TRIPS Agreement (8 December 2005) WT/L/641 (Decision of 6 December 2005)
[14] WTO, 'Intellectual Property: TRIPS and Public Health: Amendment of the TRIPS Agreement' < https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 24 May 2020. **See also**, TRIPS Agreement (as amended on 23 January 2017) < https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm#:~:text=(as%20amended%20on%2023%20January,force%20on%2023%20January%202017> accessed 24 May 2020
[15] Lionel Bently and Brad Sherman, *Intellectual property law* (4th edn, Oxford University Press 2014) 375. **See also**, Tanya Aplin and Jennifer Davis, *Intellectual property Law: Text, Cases and Materials* (2nd edn, Oxford University Press 2013) 534
[16] Commission on Intellectual Property Rights, Innovation and Public Health, *Public health, Innovation and Intellectual Property Rights* (WHO Geneva 2006) 194 <

Patents encompass any invention, whether product or process, in all technology fields, *inter alia*, chemical, pharmaceutical, mechanical, biotechnology and Information technology. The absence of an exhaustive list of subject matters eligible for patent protection suits the open character of technological advancement. However, the discoveries that already exist in nature, like ideas and materials found in nature, are not patentable subject matters. So, substances found in nature having certain medicinal properties cannot be patented.[17]

Unlike copyright protection which is granted automatically as soon as the work is created, i.e. the copyright protection does not depend on registration,[18] a patent is granted when the invention satisfies specific requirements of registration.[19] To be eligible for patenting, the invention has to comply with 3 universally accepted requirements, namely; novelty, involving an inventive step, and capability of industrial application.[20] To ensure that such requirements are met, the invention has to be disclosed to the patent office in the state by presenting an application for granting the patent. The application consists of a clear detailed description of the invention (Specification), the claims of the technology that had been invented which will be the subject of the monopoly right, and the drawings of the invention.[21]

Once the requirements are met, the proprietor of the invention is granted an exclusive right (patent right) from the state to exploit and control the use of the invention, for a certain period, in a way which prevents others from using the protected invention without authorization. The proprietor of the patent can also make decisions about when and under which conditions the patent can be assigned, licensed, transferred or mortgaged to a third party.[22] Thus, the patent right acts as a reward granted by the state to the inventor for his contribution to industry or technology. Should the inventor decide to disclose and publicize the invention to the society,

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http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> accessed 12 February 2019

[17] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed Books 2000) 52

[18] Stavroula Karapapa and Luke McDonagh, *Intellectual Property Law* (Oxford university press 2019) 15

[19] Lionel Bently and Brad Sherman, *Intellectual property law* (4th edn, Oxford University Press 2014) 375

[20] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 27(1). **See also**, Tanya Aplin and Jennifer Davis, *Intellectual property Law: Text, Cases and Materials* (2nd edn, Oxford University Press 2013) 534

[21] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford university press 2008) 19

[22] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 28(1). **See also**, Lionel Bently and Brad Sherman, *Intellectual property law* (4th edn, Oxford University Press 2014) 592

the state grants him a monopoly right that prevents others from utilizing the invention without his consent.[23]

Patent rights are primarily granted to inventors or joint inventors. However, this does not necessarily mean that they will always be the owners of the patent rights. Where the inventors are employees in corporations or enterprises, they usually sign an employment agreement that includes assigning their patent rights in the inventions they created to their employers. Even without written agreements, professional researchers may be employed specifically to create inventions and transfer their patent rights in them to the corporations they are working for. This situation has expanded with the growth of what is called "big-science."[24] The European patent Convention (hereinafter referred as EPC) stated that the assignment of a patent right "shall be made in writing and shall require the signature of the parties to the contract."[25] National laws also affirmed the assignment of patent rights. The US Patent Code stipulated that the applications for patents "shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States."[26] Further, the UK Patents Act 1977 provides that an invention belongs to the employer in two situations. First; when the invention was made in the course of the employee's normal duties or specifically assigned duties. Second; when the nature and responsibilities of the employee's duties show that "he had a special obligation to further the interests of the employer's undertaking."[27] Thus, for example, if the employee occupies a managerial level, any invention that he produces belongs to his employer.

The most comprehensive multilateral agreement on IPRs protection recognized worldwide is the TRIPS agreement. According to the TRIPS, patents are granted only for a limited period of

[23] Silvia Salazar, 'Intellectual Property and the Right to Health'(WIPO Discussion on Intellectual property and Human Rights WIPO-UNHCHR/IP/PNL/98/INF/1 REV, Geneva, 9 November 1998) < http://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_3.pdf > accessed 12 February 2019

[24] Lionel Bently and Brad Sherman, *Intellectual property law* (4th edn, Oxford University Press 2014) 592, 601, 602. **See also**, Richard Stim, 'Who owns Patent Rights: Employer or Inventor?', *NOLO Legal Encyclopedia* < https://www.nolo.com/legal-encyclopedia/who-owns-patent-rights-employer-inventor.html> accessed 18 September 2021. **See also**, Fred Carbone, 'Employee Inventors and Patent Ownership: Whose Rights are they Anyway' (2021) 13(4) Landslide Magazine - American Bar Association Publications < https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2020-21/march-april/employee-inventors-patent-ownership-whose-rights-are-they-anyway/> accessed 18 September 2021

[25] European Patent Convention (adopted 5 October 1973, entered into force 7 October 1977, revised by the Act revising article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000) art 72

[26] Patent Act of 1952, 35 US Code, ch 950, 66 stat 797 (19 July 1952) sec 261

[27] UK Patents Act 1977 (as amended) sec 39(1)

20 years, as a minimum standard, commencing from the date of filing the patent application.[28] Such period is not long enough in comparison to the period granted for copyrights protection, yet patent rights are more extensive than copyrights because the right granted to the patentee covers almost all the commercial uses of the patented invention. After the period expires, the patented invention falls into the public domain where it can be commercially exploited without the consent of the patentee.

Like all other kinds of rights which can be transferred by the usual means specified in civil law, the patent right granted to the inventor entitles him to assign, license, mortgage or transfer the patented invention to a third party.[29] Silvia Salazar contends that the only requirement imposed on transferring the patent right is publicity, to safeguard the legal rights of third parties,[30] yet article 28(2) of the TRIPS does not contain such requirement. The TRIPS agreement distinguished between patenting a product or a process in regard to the exclusive rights conferred to the patent owner. Patenting a product entitles the patentee to prevent others from making, using, selling, offering for sale or importing the patented product without his consent.[31] Meanwhile, patenting a process entitles the patentee to prevent others, who did not get his consent, from using the patented process in addition to preventing them from using, offering for sale, selling or importing the patented process to directly obtain a product.[32]

Noticeably, where the subject matter of a patent is a product, the patent right does not grant the patentee a positive right to market or use that product, but rather it confers to the patentee negative rights which is the right to exclude others from making, using, selling, etc., that product without his consent. The negative rights to exclude others allow him to fully exploit the value of the patented product. However, patent rights are not meant to give patentees control over products once they have placed them on market.[33] The patent right is exhausted after placing the product in the market, i.e., the patented product can be subject to any of the previous practices without the permission of the patentee. This is called the doctrine of exhaustion of

[28] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 33
[29] Ibid, art 28 (2)
[30] Silvia Salazar, 'Intellectual Property and the Right to Health'(WIPO Discussion on Intellectual property and Human Rights WIPO-UNHCHR/IP/PNL/98/INF/1 REV, Geneva, 9 November 1998) 7 < http://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_3.pdf > accessed 12 February 2019
[31] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 28(1)(a)
[32] Ibid, art 28(1)(b)
[33] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 68

patent rights or the first sale of the product.[34] The dissertation shall demonstrate later in this section the doctrine of exhaustion when addressing the parallel importation flexibility due to the impact relation between them.

The TRIPS agreement obliged all WTO members to incorporate provisions in their national legislations that grant patent protection for any invention without discrimination "as to the place of invention, the field of technology and whether products are imported or locally produced."[35] As such, the national legislation of each state is necessary for implementing the TRIPS minimum standards. It cannot discriminate against the field of technology, thus it cannot exclude pharmaceuticals from patentability.

Further, the TRIPS permitted specific exclusions from patentability of inventions as stipulated in article 27(2). It provided that "members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre* public or morality, including to protect human, animal or plant life or health."[36] For example, the US excluded from patentability any invention related to special nuclear materials or atomic energy.[37] It also denied a patent on a new type of water pipes invented to enhance the pleasure of opium smoking.[38] However, article 27(2) has two limitations on excluding an invention from patentability. First; the focus of the exception is on the potential harm occurring to the *ordre public* or morality from the "commercial exploitation" of the invention within the territory of the concerned state not from the invention *per se*.[39] The commercial exploitation of the invention is the marketing of the invention for profit.[40] Therefore, to exclude an invention from patentability, the marketing of the invention, rather than the invention *per se*, must pose a

[34] Marco M. Slotboom, 'The Exhaustion of Intellectual Property Rights: Different Approaches in EC and WTO' (2003) 6(3) World Intellectual Property Journal 421, 422
[35] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 27(1)
[36] Ibid, art 27(2)
[37] 42 US Code § 2181 (a) (2012) Inventions Relating to Atomic Weapons and Filing of Reports
[38] Alan O. Sykes, 'TRIPs, Pharmaceuticals, Developing Countries, and the Doha Solution' (2002) 3(1) Chicago Journal of international Law 47, 52
[39] Daniel J. Gervais, *The TRIPS Agreement: Drafting History and Analysis* (2nd edn, Sweet & Maxwell UK 2003) 261. **See also**, Eric M. Solovy and Pavan S. Krishnamurthy, 'TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines' (2017) 50(1) George Washington International Law Review 69, 108-109. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 27(2)
[40] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 56

risk to the *ordre public* or morality in the concerned state.[41] Second; the exclusion of the invention from patentability must not be made merely because its commercial exploitation is prohibited by domestic law.[42]

Such exclusion from patentability seems consistent with the principles of the TRIPS which allowed WTO members to adopt measures necessary to protect public health and to promote public interest in socio-economic areas. The exclusion from patentability stipulated in article 27(2) of the TRIPS may allow states to consider the impacts of an invention on human life or health as a ground for denying patentability. In this regard, states may adopt measures that balance between the patentees' interests and the public interest, provided that such measures are consistent with the TRIPS provisions.[43] The exclusion from patentability also appear to echo the exceptions stipulated in article XX of the GATT. This article allowed states to adopt or enforce several measures, including those necessary to protect public morals and human life or health, with the proviso that such measures are not applied arbitrarily, or unjustifiably discriminate between countries having the same conditions, or constitute a sort of restriction to international trade.[44]

Few scholars expressed the view that article 27(2) permits states to exclude certain pharmaceutical inventions from patentability if there is a legitimate health reason to prevent their commercial exploitation within that state.[45] Since the article explicitly states that the *ordre public* includes the protection of human health, any interpretation to the *ordre public* according to this article has to realize the right to health consideration.[46] Accordingly, the protection of human health can be a ground for the exclusion of certain medicines from patentability when

[41] Eric M. Solovy and Pavan S. Krishnamurthy, 'TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines' (2017) 50(1) George Washington International Law Review 69, 108-109

[42] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 171. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 27(2)

[43] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 8. **See also**, Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 115

[44] General Agreement on Tariffs and Trade, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187, 33 ILM 1153 (GATT 1994) art 20

[45] Wesley A. Cann Jr., 'On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply under a Theory of Progressive Global Constitutionalism' (2004) 25(3) Pennsylvania Journal of International Law 755, 811. **See also**, Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 176

[46] Ibid

the public health issue threatens security, such as causing or exacerbating riots or other civil disobedience.[47] Cann argued that a state experiencing a high incidence of HIV/AIDS epidemic could utilize article 27(2) to exclude certain medicines from patentability on the grounds that this epidemic constitutes a threat to the security of all states and destroys their social, economic, and political structures.[48]

Such arguments are erroneous for several reasons. First: They misread article 27(2) of the TRIPS Agreement. The article is not meant to create a general public health exception from patentability for pharmaceutical inventions.[49] Rather, the exclusion is targeted towards dangerous or repugnant inventions that their commercial exploitation may be detrimental/harmful to *ordre public*, including human life and health, and not medicines.[50] While the protection of human health is explicitly included in the concept of *ordre public* as provided by article 27(2), its provision restricts the exclusion from patentability to the commercial exploitation of the invention, when it is necessary to protect the *ordre public* , not to the invention *per se* as illustrated above. In other words, article 27(2) requires the denial of patentability to be linked to a denial of the commercial exploitation of the invention.[51] In the context of pharmaceutical patents and access to medicines, the risk to human life or health stems from the unaffordable prices of medicines arising from the patenting process itself, not from the marketing of medicines for profit.[52] Consequently, article 27(2) does not provide a way to exclude pharmaceutical inventions from patentability for public health purposes.

Second: The application of article 27(2) of the TRIPS agreement creates significant burdens on states when using the exception. A necessity test has to be performed each time the exclusion is invoked to determine whether the prevention of the commercial exploitation is necessary to protect *ordre public* or not. This involves a process of weighing and balancing of several factors.

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[47] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 176

[48] Wesley A. Cann Jr., 'On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply under a Theory of Progressive Global Constitutionalism' (2004) 25(3) Pennsylvania Journal of International Law 755, 812, 827

[49] Alan O. Sykes, 'TRIPs, Pharmaceuticals, Developing Countries, and the Doha Solution' (2002) 3(1) Chicago Journal of international Law 47, 51. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 57

[50] Alan O. Sykes, 'TRIPs, Pharmaceuticals, Developing Countries, and the Doha Solution' (2002) 3(1) Chicago Journal of international Law 47, 51-52. **See also**, Caroline Henckels, 'The Ostensible 'Flexibilities' in TRIPS: Can Essential Pharmaceuticals be Excluded from Patentability in Public Health Crises?" (2006) 32(2) Monash University Law Review 335, 355

[51] Caroline Henckels, 'The Ostensible 'Flexibilities' in TRIPS: Can Essential Pharmaceuticals be Excluded from Patentability in Public Health Crises?" (2006) 32(2) Monash University Law Review 335, 347

[52] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 115

If there is an alternative measure that could be taken to protect the *ordre public*, then the exclusion from patentability is deemed not necessary.[53] This means that a state has to show that there was no other measure it could reasonably take to protect its *ordre public* before resorting to the exclusion from patentability provided in article 27(2).[54] The WTO Appellate Body emphasized this understanding in *Korea - Various Measures on Beef* case. It stated that a necessary measure could be understood on one hand as indispensable and on the other as "making contribution to." It viewed that the necessary measure is "located significantly closer to the pole of 'indispensable' than to the opposite pole of simply 'making a contribution to.' "[55] It indicated that the determination of whether a measure is necessary or otherwise, "involves in every case a process of weighing and balancing a series of factors."[56] While it is evident that the protection of human health is an important objective, it is apparent that excluding medicines from patentability is "antithetical to intellectual property protection and liberalised trade in patented products, particularly where other options, for example compulsory licensing, could be seen to be reasonably available to achieve the goal of access to essential pharmaceuticals and still compensate the right holder."[57] Thus, the necessity threshold would not be met if article 27(2) is utilized to exclude pharmaceuticals from patentability.

Third: The impermissibility of excluding pharmaceutical inventions from patentability is reinforced by the obligation of non-discrimination stipulated in article 27(1) of the TRIPS. The article states that patents must be allowed to all inventions without discrimination as to the field of technology. Therefore, excluding pharmaceutical inventions from patentability would be incompatible with article 27(1) since it constitutes impermissible discrimination as to the field of technology.

Returning to the three patentability requirements demonstrated above, the novelty requirement constitutes a substantial part in the patent system. To be patented, the invention has to be "new" or "novel" before the date of filling the patent application, i.e., it is not part of a prior art or has not been previously disclosed to the public, by any form either in writing or orally, before the

[53] Eric M. Solovy and Pavan S. Krishnamurthy, 'TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines' (2017) 50(1) George Washington International Law Review 69, 109-110
[54] Caroline Henckels, 'The Ostensible 'Flexibilities' in TRIPS: Can Essential Pharmaceuticals be Excluded from Patentability in Public Health Crises?" (2006) 32(2) Monash University Law Review 335, 348-349
[55] WTO Appellate Body Report, *Korea – Measures Affecting Import of Fresh Chilled and Frozen Beef* (adopted 10 January 2001) WTO Doc WT/DS161/AB/R, WT/DS169/AB/R, para 161
[56] Ibid, para 164
[57] Caroline Henckels, 'The Ostensible 'Flexibilities' in TRIPS: Can Essential Pharmaceuticals be Excluded from Patentability in Public Health Crises?" (2006) 32(2) Monash University Law Review 335, 349

filing date.[58] Since the nature of the invention is novel, it follows that the discovery of things that already exist in nature, for example, new minerals or plants, is not considered an invention.[59] Hence, and as McCarthy stated in the Intellectual Property Encyclopedia, "novelty is opposite to anticipation." The disclosure of the invention in the prior art rebuts the claim of an applicant that his invention is novel.[60]

Various jurisdictions employ different types of novelty, including absolute novelty, under which the invention must be new anywhere in the world to be patented; and relative novelty, which is restricted to a specific country.[61] This classification is crucial in pharmaceutical patent protection in relation to access to medicine. Countries that apply relative novelty will not be able to restrict patenting medicines that already exist in the public domain because inventions while have been disclosed outside of the country, nevertheless, are considered unknown inside this country. Therefore, practically, even when an invention is not in fact new or novel globally, it will be considered novel within a particular jurisdiction, i.e., meeting the novelty requirement, and accorded a patent right.[62] Neither the TRIPS agreement nor the Paris Convention provides a definition of the term "novelty." Therefore, the definition differs among states allowing them to set the novelty criteria they choose within their own jurisdiction.[63] For example, the US applies relative novelty, where novelty is not defeated by disclosures outside the US unless the disclosures are made in a written form.[64] This permits the patenting of traditional knowledge (knowledge of indigenous communities) that has been used for a long time but not published in a written form outside the US.[65] On the contrary, the EPC and the European countries including, UK, France and Germany, adopted the absolute novelty criteria. The EPC stipulates that the prior art is considered to include everything made publicly available anywhere in the world by

[58] Carlos M. Correa (ed), *A Guide to Pharmaceutical patents* (South Centre Geneva 2012) 1-2 < https://www.southcentre.int/wp-content/uploads/2016/05/Bk_2012_A-Guide-to-Pharmaceutical-Patents_EN.pdf> accessed 19 September 2021
[59] ICTSD - UNCTAD, *Resource Book on TRIPS and Development* (Cambridge University Press New York 2005) 359 < https://unctad.org/en/PublicationsLibrary/ictsd2005d1_en.pdf> accessed 20 February 2019
[60] J. Thomas McCarthy et al, *McCarthy Desk Encyclopedia of Intellectual Property* (3rd edn, Washington DC 2004) 406
[61] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed Books 2000) 2-3
[62] Ibid, 3, 27, 28. **See also**, Carlos M. Correa (ed), *A Guide to Pharmaceutical patents* (South Centre Geneva 2012) 3 < https://www.southcentre.int/wp-content/uploads/2016/05/Bk_2012_A-Guide-to-Pharmaceutical-Patents_EN.pdf> accessed 19 September 2021
[63] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 161
[64] Patent Act of 1952, 35 US Code, ch 950, 66 stat 797 (19 July 1952) sec 102(a)
[65] Carlos M. Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) 41

means of a written or oral description before the date of filing of the European patent application.[66]

In traditional medicines, for example, pharmaceutical companies produce commercial drugs from the components of medicinal plants and patent them in another country arguing that they are novel, thus depriving people from future access to traditional medicines.[67] Such narrative of bio piracy and misuse of the patent system is shown in the "Turmeric Tree" case. The US granted a patent for the use of such tree in healing wounds, despite its prior usage in India in traditional medicines. It was only due to the robust challenge of the Council of Scientific and Industrial Research in India, that the patent was revoked on grounds of lacking novelty.[68] Another example is the famous "Neem Tree" case, traditionally used in medicines among other applications. Although the European patent office revoked a "Neem tree" related patent due to bio piracy, other pharmaceutical inventions related to the tree were patented in the US.[69]

Once the novelty criterion is fulfilled, another requirement should be fulfilled which is the inventive step. According to footnote 5 of the TRIPS agreement, the term "inventive step" means "non-obvious."[70] So, the invention has to not only be new but also "non-obvious," i.e., the invention has to "go beyond the normal progress of technology." It should add significant improvement to the prior art which is not expected to a person skilled in the art.[71]

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[66] European Patent Convention (adopted 5 October 1973, entered into force 7 October 1977, revised by the Act revising article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000) art 54(2). **See also**, Jeffrey M. Kaden, 'Patent Protection and the Novelty Requirement' (Gottlieb, Rackman & Reisman Professional Corporation, September 2016) < https://grr.com/publications/patent-protection-novelty-requirement/> accessed 21 September 2021. **See also,** Kevin J. Zilka and Dominic M. Kotab, 'Patent Novelty Requirements of the World and Strategic Foreign Patent Procurement Practices' (Silicon Valley IP Group, 2003) < http://www.zilkakotab.com/pdf/publication1.pdf> accessed 21 September 2021

[67] Norman R. Farnsworth, 'Screening Plants for New Medicines' in E.O.Wilson and Frances M.Peter (eds), *Biodiversity* (National Academy Press Washington DC 1988) 83, 95

[68] J. Janewa OseiTutu, 'Traditional Knowledge: Is Perpetual Protection a Good Idea?' (2010) 50(4) Intellectual Property Law Review 697, 712. **See also**, David Downes, 'How Intellectual Property could be a Tool to Protect Traditional Knowledge' (2000) 25(2) Colombia Journal of Environmental Law 253, 277

[69] David Downes, 'How Intellectual Property could be a Tool to Protect Traditional Knowledge' (2000) 25(2) Colombia Journal of Environmental Law 253, 280. **See also**, Olufunmilayo Arewa, 'TRIPS and Traditional Knowledge: Local Communities, Local Knowledge and Global Intellectual Property Frameworks' (2006) 10 (2) Marquette Intellectual Property Law Review 154, 170-171

[70] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 27(1) footnote 5

[71] European Patent office, *Guidelines for Examination in the European Patent Office* (European patent Office Germany 2021) Part C - Chapter VII, para 4 < https://www.epo.org/law-practice/legal-texts/guidelines.html> accessed 15 April 2021. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 66

The TRIPS leaves significant freedom for WTO member states to determine the degree of strictness to be applied in judging the inventive step. Adopting a high standard of inventive step rewards only substantive departures from the prior art, while adopting a low standard facilitates the grant of patent rights to a broad range of incremental developments.[72] The manner in which the inventive step criteria is applied in each state has a noticeable effect on the pharmaceutical industry. The high inventive step threshold creates a stringent pharmaceutical patent system that prevents the proliferation of patents on incremental modified versions of drugs.[73] This high threshold creates broad patents by making it difficult for anyone, including the primary inventor, to make only minor or insignificant modifications to an existing medicine and apply for a patent right. Thus, the primary inventor will have an effective defence against insignificant improvements, made by competitors, to the patented medicine.[74] On the other hand, the low inventive step threshold results in granting too many secondary patents on minor modifications of existing medicines, such as new forms and uses of known active ingredients, thus permitting the registration of a large number of pharmaceutical patents on minor modifications.[75]

To prevent secondary patenting, a practice commonly known as "evergreening" or strategic patenting, some jurisdictions apply the stringent inventive step criteria. Pharmaceutical companies often resort to "evergreening" to extend the patent protection and market exclusivity of existing medicines by patenting multiple aspects of their successful medicines, including formulations, uses, dosages, and forms.[76] Therefore, as affirmed by the European Commission,

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[72] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 107-108. **See also**, Carlos Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press 2007) 276-277

[73] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 108

[74] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed Books 2000) 45-46. **See also**, Commission on Intellectual Property Rights, Innovation and Public Health, *Public health, Innovation and Intellectual Property Rights* (WHO Geneva 2006) 193 < http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> accessed 12 February 2019. **See also**, Carlos M. Correa (ed), *A Guide to Pharmaceutical patents* (South Centre Geneva 2012) 45-46 < https://www.southcentre.int/wp-content/uploads/2016/05/Bk_2012_A-Guide-to-Pharmaceutical-Patents_EN.pdf> accessed 19 September 2021

[75] Andrieansjah, 'The Impact of COVID-19 on Intellectual Property Legal System Related to Public Health in Connection with TRIPS Flexibilities in Indonesia' (2020) 13(2) Indonesian Law Journal 165, 181

[76] Ibid, 180, 182, 183. **See also**, Olga Gurgula, 'The 'Obvious to Try' Method of Addressing Strategic Patenting: How Developing Countries Can Utilise Patent Law to Facilitate Access to Medicines' (April 2019) South Centre Policy Brief No 59, 1-2 <https://www.southcentre.int/wp-content/uploads/2019/04/PB59_The-obvious-to-try-method-of-addressing-strategic-patenting_EN.pdf> accessed 29 January 2021. **See also**, Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?' (2020) 51 International Review of Intellectual Property and Competition Law 1062, 1067-1068. **See also**, Carlos M. Correa (ed), *A Guide to Pharmaceutical patents* (South Centre Geneva 2012) xiv < https://www.southcentre.int/wp-content/uploads/2016/05/Bk_2012_A-Guide-to-Pharmaceutical-Patents_EN.pdf> accessed 19 September 2021

they "extend the breadth and duration of the [originators'] patent protection"[77] and "delay or block the market entry of generic medicines."[78] Obviously, impeding the entry of generic competition after the expiration of the primary patent affects the accessibility to cheaper generic medicines and allow "originators to maintain artificially high drug prices."[79] The US low threshold of inventive step, for example, has been criticized frequently because it allows for a large number of patents on minor developments, often aggressively used to artificially extend the duration of patent protection in order to impede legitimate competition.[80] Supporting the stringent inventive step, the World Bank suggested that states should set high standards for the inventive step "to prevent routine discoveries from being patented."[81] Further, the Commission on Intellectual Property Rights demonstrated that most developing countries, especially those without research capabilities, should strictly exclude new uses of known products from patentability.[82]

Recently, the pharmaceutical companies have been taking undue advantage of patent laws and associated regulatory processes by frequently using strategic patenting to file secondary patents, specifically over lucrative drugs. They usually file disguised patent rights on drugs shortly before their patent term expire in order to extend the patent protection beyond the basic patent term and thus prolong their market exclusivity.[83] Asserting such practices, the European Commission flagged up the issue of the increasing number of secondary patents concerning "formulations, processes and non-formulation products …, such as salts, polymorphic forms,

[77] European Commission, 'Pharmaceutical Sector Inquiry: Final Report' (8 July 2009) 201 < https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> accessed 23 September 2021

[78] European Commission, 'Executive Summary of the Pharmaceutical Sector Inquiry Report' (8 July 2009) 10 < https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf> accessed 23 September 2021. **See also**, Olga Gurgula, 'The 'Obvious to Try' Method of Addressing Strategic Patenting: How Developing Countries Can Utilise Patent Law to Facilitate Access to Medicines' (April 2019) South Centre Policy Brief No 59, 1 <https://www.southcentre.int/wp-content/uploads/2019/04/PB59_The-obvious-to-try-method-of-addressing-strategic-patenting_EN.pdf> accessed 29 January 2021

[79] Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?' (2020) 51 International Review of Intellectual Property and Competition Law 1062, 1064

[80] ICTSD - UNCTAD, *Resource Book on TRIPS and Development* (Cambridge University Press New York 2005) 360 < https://unctad.org/en/PublicationsLibrary/ictsd2005d1_en.pdf> accessed 20 February 2019

[81] World Bank, *Global Economic Prospects and the Developing countries* (Washington D.C. 2001) 143 < https://documents1.worldbank.org/curated/en/285571468337817024/310436360_20050012014722/additional/multi0page.pdf > accessed 22 September 2021

[82] Commission on Intellectual Property Rights, 'Report of the Commission on Integrating Intellectual Property Rights and Development Policy' (Commission on Intellectual Property Rights, September 2002) 50 < http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 1 May 2019

[83] Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?' (2020) 51 International Review of Intellectual Property and Competition Law 1062, 1068-1069

particles, solvates and hydrates."[84] The Commission stated that the increase of secondary patents will negatively affect the generics industry and provide little or no therapeutic benefit to patients compared to the original medicine.[85] As Olga Gurgula argued, the strategic patenting practice will reduce the incentives for future innovation since the pharmaceutical companies focus on securing the most efficient and longest possible protection for their products rather than engaging in genuine innovation. This contradicts the rationale of the patent system.[86]

Therefore, it is advisable for developing countries with pharmaceutical manufacturing capacities to apply a high threshold of inventive step in order to avoid granting patents to incremental improvements on existing medicines. A high inventive threshold would preclude the pharmaceutical industry in developing countries, as elaborated above, from resorting to certain mechanisms to file secondary patents on existing medicines, thus extending patents protection and unduly blocking generic medicines competition.[87] Although the high inventive step may also prevent the protection of locally developed medicines having minor innovations, they could be protected by a *sui generis* protection that provide compensatory rewards without monopoly rights rather than diluting the high inventive step threshold.[88]

A prominent example of how a high inventive step threshold was used to prevent incremental changes in medicines, i.e., the new form of a known compound, is the Novartis case and the challenge of section 3(d) that was introduced in April 2005 into the Indian Patent Act.[89] This section introduced pharmaceutical product patents in India for the first time. Before the enactment of this amendment, the protection was limited to methods or processes of manufacture.[90] The section explicitly states that inventions that are "mere discovery of a new

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[84] European Commission, 'Pharmaceutical Sector Inquiry: Final Report' (8 July 2009) 189 < https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> accessed 23 September 2021

[85] Ibid, 189, 352

[86] Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?' (2020) 51 International Review of Intellectual Property and Competition Law 1062, 1073-1075

[87] Olga Gurgula, 'The 'Obvious to Try' Method of Addressing Strategic Patenting: How Developing Countries Can Utilise Patent Law to Facilitate Access to Medicines' (April 2019) South Centre Policy Brief No 59 <https://www.southcentre.int/wp-content/uploads/2019/04/PB59_The-obvious-to-try-method-of-addressing-strategic-patenting_EN.pdf> accessed 29 January 2021

[88] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed Books 2000) 46- 47. **See also**, Carlos M. Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) 46-47

[89] *Novartis v Union of India*, High Court of Madras, (2007) 4 MLJ 1153. **See also**, Indian Patents (Amendment) Act No 15 of 2005, sec 3(d)

[90] 'The Patent Act, 1970' (Intellectual Property India) 9 < https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_113_1_The_Patents_Act_1970_-_Updated_till_23_June_2017.pdf > accessed 25 September 2021. **See also**, Aayush Sharma, 'Section 3(d) of Indian Patents Act 1970: Significance and Interpretation' (Lexology, 7 February 2014) <

form of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any property or new use for a known substance" are not patentable. An explanation is added in the amendment below section 3(d) explaining what should be considered to be "the same substance." These are "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, complexes, combinations and other derivatives of known substance, unless they differ significantly in properties with regard to efficacy."[91] The aim of introducing section 3(d) was to avoid the evergreening process in India, thus rejecting patents that claim a change in one of these compounds without proving an enhanced medical efficacy of the new form.[92]

Applying section 3(d), the Madras Patent Office in India in 2006 rejected a patent application filed by Novartis to obtain a patent on the beta crystalline form of "Glivec", a medicine used for treating Leukaemia, after gaining a patent on its free base compound. The first ground for rejection was that the application of Novartis did not meet the requirements of novelty and inventive step because the beta crystalline form was already included in Novartis' earlier US patent on the free base compound. Therefore, it falls within the prior art. The second ground for rejection was that the beta crystalline form did not demonstrate improved efficacy according to section 3(d) of the 2005 amendment.[93] Consequently, Novartis filed two legal challenges against the Indian government. The first is an appeal against the decision of the Madras Patent office. In the second, it challenged the validity of section 3(d) on the ground that the requirement of "enhanced efficacy" and granting patents only for new compounds is inconsistent with article 27 of the TRIPS and violates article 14 of the Indian Constitution providing for equality before law.[94]

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https://www.lexology.com/library/detail.aspx?g=3f92413f-107c-4886-aca7-24633a341e22> accessed 25 September 2021

[91] Indian Patents (Amendment) Act No 15 of 2005, sec 3(d)

[92] Clara Ducimetière, 'Second Medical Use Patents - Legal Treatment and Public Health Issues' (December 2019) South Centre Research paper No 101, 24-25 < https://www.southcentre.int/wp-content/uploads/2019/12/RP101_Second-Medical-Use-Patents-Legal-Treatment-and-Public-Health-Issues_EN.pdf > accessed 12 August 2020

[93] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 112-113. **See also**, Linda L. Lee, 'Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India**'** (2008) 23(1) Berkeley Technology Law Journal 281, 298-299. **See also**, Ravinder Gabble and Jillian Clare Kohler, 'To Patent or Not to Patent? The case of Novartis' Cancer Drug Glivec in India' (2014) 10(3) Globalization and Health Journal < https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-10-3#citeas > accessed 26 September 2021

[94] Ravinder Gabble and Jillian Clare Kohler, 'To Patent or Not to Patent? The case of Novartis' Cancer Drug Glivec in India' (2014) 10(3) Globalization and Health Journal < https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-10-3#citeas > accessed 26

On the validity of section 3(d), the Madras High Court held that it did not have jurisdiction to decide a case concerning the compliance of domestic legislation with an international treaty namely, article 27 of the TRIPS.[95] Regarding the unconstitutionality of section 3(d), the High Court held that the section did not violate article 14 of the Indian Constitution and was not vague, arbitrary, or conferring uncontrolled power to the Patent Controller.[96] The court observed that the meaning of the expression "efficacy" under section 3(d) is understood in the field of pharmacology as "the ability of a drug to produce the desired therapeutic effect."[97] The court noted that the Indian legislature did not arbitrarily enact section 3(d), but did so with the aim "to prevent evergreening; to provide easy access to the citizens of [India] to life saving drugs and to discharge their constitutional obligation of providing good health care to its citizens."[98] Following the understanding of the Madras High Court to the term "efficacy," the Intellectual Property Appellate Board in India in 2009 upheld the decision of the Patent Controller that the beta form of "Glivec" cannot be patented because it did not demonstrate an enhanced efficacy.[99] Later in 2013, the Supreme Court of India upheld the rejection of Novartis application stating that efficacy under section 3(d) is therapeutic efficacy and the Novartis patent claim for a modified version of Glivec "fails in both the tests of invention and patentability as provided under … section 3(d)."[100]

Another example of a high inventive step threshold is the Indonesian Patent Law system which does not grant patent rights to "new use of existing and/or known product; and/or new forms from existing compound which does not generate significantly enhanced efficacy and contains different relevant known chemical structures to compound."[101]

The last requirement for patentability is the capability of industrial application. According to footnote 5 of the TRIPS agreement, the term "capable of industrial application" means

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September 2021. **See also**, Linda L. Lee, 'Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India**'** (2008) 23(1) Berkeley Technology Law Journal 281, 299

[95] *Novartis v Union of India*, High Court of Madras, (2007) 4 MLJ 1153, paras 7-8

[96] Ibid, para 19

[97] Ibid, para 13

[98] Ibid, paras 12, 19

[99] Ravinder Gabble and Jillian Clare Kohler, 'To Patent or Not to Patent? The case of Novartis' Cancer Drug Glivec in India' (2014) 10(3) Globalization and Health Journal < https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-10-3#citeas > accessed 26 September 2021

[100] *Novartis Ag vs Union Of India & Ors*, Supreme Court of India, Civil Appeal Nos. 2706-2716 of 2013 (Arising Out of SLP(c) Nos 20539-20549 of 2009, paras 180, 195

[101] Law of the Republic of Indonesia No 13 of July 28, 2016 on Patents, art 4(f)

"useful."[102] The invention has to be useful in any field of industry and not only an abstract idea which cannot be applicable in industry.[103] The TRIPS did not determine a specific standard for industrial applicability leaving each state to opt for the level that best suits its needs. In the pharmaceutical field, if the policy objective in developing countries is to facilitate access to medicines, it may be advisable to set a high threshold for industrial application to eliminate patents with dubious or no utility that result in patent thickets, thus ensuring that only inventions with real industrial application could be patented.[104] Importantly, the lack of industrial application is only an issue for genetic sequences or newly identified chemical compounds. It does not constitute a problem for follow-on pharmaceutical inventions because these inventions, by nature, "involve a new form or mode of use of a pharmaceutically active chemical entity of known therapeutic potential."[105]

The threshold of usefulness differs from one legal system to another. The US patent law, for example, applies a low threshold, where certain improvements that do not lead to industrial application may be patented. The US law considers an invention to be useful if it operates to perform some function of benefit to humanity, i.e., has a practical and beneficial utility.[106] The low threshold of usefulness, as such, may encompass purely experimental inventions that cannot be used or made in an industry or that do not produce a technical effect, like patenting therapeutic and diagnostic methods having no industrial application.[107] The Australian Patent

[102] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 27(1) footnote 5

[103] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed Books 2000) 81

[104] Carlos M. Correa (ed), *A Guide to Pharmaceutical patents* (South Centre Geneva 2012) 108 < https://www.southcentre.int/wp-content/uploads/2016/05/Bk_2012_A-Guide-to-Pharmaceutical-Patents_EN.pdf> accessed 19 September 2021

[105] Christopher M. Holman, Timo Minssen, & Eric M. Solovy, 'Patentability Standards for Follow-On Pharmaceutical Innovation' (2018) 37(3) Biotechnology Law Report 131, 142

[106] Patent Act of 1952, 35 US Code, ch 950, 66 stat 797 (19 July 1952) sec 101. **See also**, Herbert F. Schwartz, *Patent Law and Practice* (3rd edn, Federal Judicial Centre Washington DC 2001) 64. **See also**, 'Patentability Requirements' (Justia, June 2019) < https://www.justia.com/intellectual-property/patents/patentability-requirements/> accessed 12 November 2020. **See also**, ICTSD - UNCTAD, *Resource Book on TRIPS and Development* (Cambridge University Press New York 2005) 361 < https://unctad.org/en/PublicationsLibrary/ictsd2005d1_en.pdf> accessed 20 February 2019

[107] Priyanka Rastogi, 'Worldwide: Worldwide Legal Status Of Medical Method Patents: An Overview' (Mondaq, 6 May 2014) < https://www.mondaq.com/india/patent/311404/world-wide-legal-status-of-medical-method-patents-an-overview> accessed 26 September 2021. **See also**, Carlos M. Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) 48

Law also allows granting patent rights to methods of medical treatment, particularly those methods requiring the administration of therapeutic drugs.[108]

On the contrary, other countries apply a high threshold requiring an industrial applicability for an invention to be patented.[109] Thus, mere methods of therapeutic treatment are not granted patent rights due to lacking industrial applicability. For example, Japan excludes from patentability "inventions of methods of surgery, therapy or diagnosis of human" because they are industrially inapplicable inventions.[110] Noticeably, the EPC contains a similar provision which excludes therapeutic and diagnostic methods from patentability. However, unlike the Japanese patent law which state that these methods of treatment or diagnosis shall not be granted patent rights since they are not capable of industrial application, the EPC regards them as exceptions to patentability, i.e., they are not patentable subject matter.[111]

The EPC considers an invention to be susceptible of industrial application "if it can be made or used in any kind of industry, including agriculture."[112] Therefore, the convention has a low threshold of industrial applicability; it poses no significant barrier to patent rights.[113]

An additional element in patent application assessment is the disclosure of the invention. The TRIPS requires that the patentee should "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."[114] In other words, the patent application should contain adequate information about the claimed invention to allow

[108] Australian Law Reform Commission, *Genes and Ingenuity Report: Gene Patenting and Human Health* Methods of medical Treatment' (SOS Printing Group Australia 2004) 174-175 paras 7.28-7.31 < https://www.alrc.gov.au/publication/genes-and-ingenuity-gene-patenting-and-human-health-alrc-report-99/ > accessed 27 September 2021

[109] Carlos M. Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) 48

[110] Japan Patent Office, 'Examination Guidelines for Patent and Utility Model in Japan' (10 March 2020) part 3 ch 1 para 3.1(i) < https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/index.html > accessed 27 September 2021

[111] European Patent Convention (adopted 5 October 1973, entered into force 7 October 1977, revised by the Act revising article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000) art 53(c). **See also**, Australian Law Reform Commission, *Genes and Ingenuity Report: Gene Patenting and Human Health* Methods of medical Treatment' (SOS Printing Group Australia 2004) 177 para 7.38 < https://www.alrc.gov.au/publication/genes-and-ingenuity-gene-patenting-and-human-health-alrc-report-99/ > accessed 27 September 2021

[112] European Patent Convention (adopted 5 October 1973, entered into force 7 October 1977, revised by the Act revising article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000) art 57

[113] Christopher M. Holman, Timo Minssen, & Eric M. Solovy, 'Patentability Standards for Follow-On Pharmaceutical Innovation' (2018) 37(3) Biotechnology Law Report 131, 142

[114] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 29(1)

a person skilled in the art to make or practice it.[115] The disclosure requirement is considered to be one of the fundamental principles and justifications for the patent system since it achieves the social purpose of patents for the welfare of people.[116] It aims to ensure that an "actual technical contribution to the art" is made. Thus, a certain period of protection is awarded by the state to the patentee in exchange for the disclosure of such technical information. The lack of sufficient disclosure results in revocation of the patent or refusal of the patent application.[117] For the generic drug industry, disclosure is very important because it ensures that all the necessary information needed to produce generic medicines, under compulsory licence or after the expiration of the patent term, are available and exposed.[118]

The patentability requirements address the circumstances under which the application for a patent protection could be rejected in the first place. The TRIPS provides ex-ante flexibilities to states in this regard since it does not provide a fixed definition to the patentability criteria as illustrated above. Therefore, states are free to choose how to set those criteria and interpret them within their own jurisdictions. The TRIPS agreement also contains ex-post flexibilities that provide exceptions and limitations on the exercise of the patent right after granting it. They allow WTO member states to use specific measures that limit the exclusive rights of patent holders in order to balance patent protection with other public interests including accessibility to medicines. The ex-post flexibilities that are relevant to the scope of this dissertation are: the limited exceptions provided under article 30, the compulsory licensing stipulated in article 31, the parallel importation flexibility in article 6, and the patent revocation provided by article 32. The latter is relatively not recognized as a TRIPS flexibility in comparison to the first three, yet several scholars consider it one of the TRIPS flexibilities.[119] The dissertation shall explain

[115] Carlos M. Correa, 'Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective' (June 2016) UNDP Working Paper, 17 < https://www.researchgate.net/publication/304396604_Carlos_Correa_Guidelines_for_Pharmaceutical_Patent_Examination_Examining_Pharmaceutical_Patents_from_a_Public_Health_Perspective_UNDP_New_York_2016 > accessed 12 July 2019

[116] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 67

[117] Carlos M. Correa, 'Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective' (June 2016) UNDP Working Paper, 17-18 < https://www.researchgate.net/publication/304396604_Carlos_Correa_Guidelines_for_Pharmaceutical_Patent_Examination_Examining_Pharmaceutical_Patents_from_a_Public_Health_Perspective_UNDP_New_York_2016 > accessed 12 July 2019.

[118] Carlos M. Correa, 'Guidelines for the examination of pharmaceutical patents: Developing a Public Health Perspective' (January 2007) WHO- ICTSD- UNCTAD Working Paper, 4 < https://www.researchgate.net/publication/23777563_Guidelines_for_the_Examination_of_Pharmaceutical_Patents_Developing_a_Public_Health_Perspective > accessed 16 February 2019

[119] Hans Morten Haugen, 'Why are Intellectual Property Rights Hardly Visible in the United Nations Sustainable Development Goals?' in Ole-Andreas Rognstad and Inger B. Orstavik (eds), *Intellectual Property*

concisely within this section the first three flexibilities as they shall be thoroughly analysed at the end of this chapter.

Regarding the first flexibility, the TRIPS agreement allowed WTO members to provide exceptions to the exclusive rights conferred by a patent which can be applied "without the authorization of the right holder." Such exceptions should be limited, not unreasonably conflict with the normal exploitation of the patented invention, and not unreasonably prejudice the legitimate interests of the patent holders, taking into account the legitimate interests of third parties.[120] However, neither the agreement nor any official interpretation had defined what exactly those limited exceptions are. The difference between this flexibility, stated in article 30, and excluding inventions from patentability stipulated in article 27(2) of the TRIPS is that the first does not allow states to reject the patentability of a specific drug, rather, it gives them the right to regulate its usage only.

The second flexibility, compulsory licensing, refers to the licenses granted by national authorities permitting third parties authorized by the government or governmental entities to produce patented products or use the patented processes to manufacture products without the authorization of the patent holders. It represents an acknowledgment from the states that, in some situations, the public interests in having immediate accessibility to technical knowledge should take precedence over patent holders' rights. Each license is issued to an identified patent or several patents that relate to the same product, and is granted to an identified party. It serves several goals, including guaranteeing the availability of an adequate supply from the patented invention in the domestic market, encouraging competition by creating domestic competitors, and a tool to place the invention in the market if the patentee refuses to work the patent.[121] The

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*and Sustainable Markets* (Edward Elgar UK 2021) 12, 27. **See also**, Brook K. Baker, 'A Full Description of WTO TRIPS Flexibilities Available to ARIPO Member States and a Critique of ARIPO's Comparative Study Analyzing and Making Recommendations Concerning Those Flexibilities' (Boston University Global Development Policy Center, 5 March 2019) 5-6 < https://www.bu.edu/gdp/2019/03/05/a-full-description-of-wto-trips-flexibilities-available-to-aripo-member-states-and-a-critique-of-aripos-comparative-study-analyzing-and-making-recommendations-concerning-those-flexibilities/ > accessed 28 September 2021. **See also**, Yogesh Pai, 'The Growing Irrelevance of a TRIPS Challenge to India's Patent Law' in Wong-mog Choi (ed), *International Economic Law: The Asia-Pacific Perspectives* (Cambridge Scholars Publishing 2015) 286, 314. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 229, 230

[120] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 30

[121] ICTSD – UNCTAD, *Resource Book on TRIPS and Development* (Cambridge University Press New York 2005) 461-462 < https://unctad.org/en/PublicationsLibrary/ictsd2005d1_en.pdf> accessed 20 February 2019. **See also**, WTO, 'TRIPS and Pharmaceutical Patents' (September 2006) WTO Fact Sheet, 4 < https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf > accessed 13 October 2019.

TRIPS agreement provided several conditions for compulsory licensing to protect the legitimate interest of the patent holder.[122]

The third flexibility is parallel importation which refers to the practice of importing into a country a patented product, that is also patented within the territory of that country, without the authorization of the patentee after the product has been placed in a foreign market by the patentee or under his consent.[123] Parallel importation is closely related to the doctrine of exhaustion of patent rights which exists in most intellectual property legislations. According to the doctrine of exhaustion, the patentee exhausts his right to prevent the buyer of a patented product from selling or offering for sale the product once it is placed on the market by the patentee or under his consent. Thus, patentees are precluded from manipulating the exclusive rights granted to them to prevent exporting the patented inventions to another country. The notion behind the doctrine of exhaustion is to maintain a balance between the patentees' rights (remuneration for innovation) and the public interests (free trade of innovative products).[124]

Within patent laws, there are three types of exhaustion. The first is national exhaustion, where the patent holder cannot restrict the marketing of the patented product that has been placed on the national market by him or under his consent. However, the patentee can preclude parallel imports of his invention from foreign countries. The second type is the regional exhaustion, where the patent holder cannot restrict the marketing of the patented product that has been placed anywhere in a certain region, for example Custom Unions like the EC market, by him or under his consent. However, he can preclude parallel importation of his invention from countries outside that region. The last type is international exhaustion, where the patent holder cannot restrict the marketing of the patented invention that has been placed on any market in the world by him or under his consent.[125]

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**See also**, Christopher May, 'Why IPRs are a Global Political Issue' (2003) 25(1) European Intellectual Property Review 1, 4-5

[122] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 31. **See also,** TRIPS Agreement (as amended on 23 January 2017) < https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm#:~:text=(as%20amended%20on%2023%20January,force%20on%2023%20January%202017> accessed 24 May 2020

[123] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 116

[124] Adam Mcbeth, *International Economic Actors and Human Rights* (Routledge Oxford 2009) 140. **See also**, Marco M. Slotboom, 'The Exhaustion of Intellectual Property Rights: Different Approaches in EC and WTO' (2003) 6(3) World Intellectual Property Journal 421, 422

[125] Marco M. Slotboom, 'The Exhaustion of Intellectual Property Rights: Different Approaches in EC and WTO' (2003) 6(3) World Intellectual Property Journal 421, 422-423. **See also**, Mark Halle, 'The Exhaustion of Intellectual Property Rights: Should Countries Favour Consumers or Private Interests?' (The International

Whereas there is broad consensus on national exhaustion, the international exhaustion is considered one of the controversial issues in intellectual property law. The TRIPS agreement gave member states the freedom to choose the system of exhaustion of IP rights they prefer, whether national, regional, or international exhaustion. A country recognizing the doctrine of international exhaustion shall allow parallel importation because the patentee's right is exhausted once the product is first sold or marketed in any country.[126] It should be noted that the parallel importation flexibility is considered one of the measures that countries could resort to in order to safeguard public health needs. This flexibility allows consumers to buy medicines imported from foreign markets at lower prices rather than buying the local ones charged by the patent owners.[127]

The TRIPS agreement provided for patents revocation which represents, as Holger Hestermeyer argues, one of the TRIPS flexibilities of a harsher measure than compulsory licensing.[128] It is an inherent flexibility in the TRIPS since the agreement does not mention any grounds available for revocation nor does it define its concept.[129] The Agreement only requires the availability of a judicial review of any decision to revoke a patent.[130] Therefore, the TRIPS gives flexibility to each member state to determine the grounds of revocation or forfeiture of patents according to its national law.[131] Accordingly, most national patent legislations provide for such revocation or forfeiture of a patent according to a judicial review relying on the reasons for revocation or forfeiture of patents stipulated in the Paris Convention which is incorporated in the TRIPS.[132] This includes when the maintenance fees are not paid in due time,[133] or when the grant of

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Institute for Sustainable Development, June 2007) < https://www.iisd.org/system/files/publications/com_exhaustion.pdf?q=sites/default/files/publications/com_exhaustion.pdf > accessed 20 January 2021

[126] UNCTAD - ICTSD, *Resource Book on TRIPS and Development* (Cambridge University Press New York 2005) 92-94 < https://unctad.org/en/PublicationsLibrary/ictsd2005d1_en.pdf> accessed 20 February 2019. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 6

[127] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 116

[128] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 229, 230, 253

[129] Yogesh Pai, 'The Growing Irrelevance of a TRIPS Challenge to India's Patent Law' in Wong-mog Choi (ed), *International Economic Law: The Asia-Pacific Perspectives* (Cambridge Scholars Publishing 2015) 286, 314

[130] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 32

[131] ICTSD - UNCTAD, *Resource Book on TRIPS and Development* (Cambridge University Press New York 2005) 422-423 <https://unctad.org/en/PublicationsLibrary/ictsd2005d1_en.pdf > accessed 20 February 2019

[132] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 2

[133] Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, entered into force 7 July 1884) 21 UST 1583, 828 UNTS 305 (Paris Convention) art 5 bis

compulsory licences is not sufficient to prevent the abuses resulting from the exercise of the exclusive rights conferred by the patent, for example, failure to work the patent.[134] According to the EPC, for example, a patent right may be revoked for several reasons, *inter alia*, the subject matter is not patentable because it did not meet the patentability requirements stipulated in articles 52 to 57 of the EPC, the specification of the patent did not disclose the invention clearly enough to allow a person skilled in the art to perform it, the subject matter of the patent extends beyond the subject matter in the application, or the patent was granted to a person who was not entitled to that patent.[135]

With the silence of the TRIPS provisions regarding the grounds for revocation of patents, WTO member states did not agree on limits for the revocation requirements. India, for instance, has advanced the view that the revocation provision in the TRIPS gives member states latitude to revoke patents on any ground, including when the patent is being used in a manner prejudicial to the public interest.[136] Adversely, the US wanted to allow revocation only when the invention was not patentable, i.e., when it should never has been granted in the first place for failing to meet the requirements of patentability (novelty, usefulness, and obviousness).[137] The revocation flexibility, thus, could be used to prevent the abuse of patent rights in pharmaceuticals. It is also argued that it could be used to lower the prices of medicines by allowing competition, thus enhancing accessibility to medicines.[138]

Due to the growing concerns about the effects of pharmaceutical patents on restricting access to medicines, the WTO Ministerial Conference adopted the Doha Declaration.[139] The declaration recognized the rights of WTO member states to fully utilize the TRIPS flexibilities to protect public health. It affirmed that the TRIPS agreement should be interpreted and implemented in a manner supportive of WTO members' right to protect public health, particularly, promoting

[134] Ibid, art 5(a)(3)
[135] European Patent Convention (adopted 5 October 1973, entered into force 7 October 1977, revised by the Act revising article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000) arts 52-57, 138
[136] WTO Committee on Trade and Environment, 'Cluster on Market Access. Item 8: The Relationship of the TRIPS Agreement to the Development, Access and Transfer of Environmentally-Sound Technologies and Products (EST&PS). Input From India' (29 September 1997) WTO Doc WT/CTE/W/66, para 15
[137] WTO TRPS Council, 'Remarks on Revocation of patents and the TRIPS Agreement by the United States of America' (6 August 1996) WTO Doc IP/C/W/32. **See also**, Negotiating Group on TRIPS, Including Trade in Counterfeit Goods, 'Draft Agreement on TRIPS: Communication from the United States' (11 May 1990) MTN.GNG/NG11/W/70, arts 23, 24(2)
[138] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 253-254
[139] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration)

access to medicines for all people.[140] This interpretation would be of significant importance to developing countries in their continuous pursuit to improve the level of accessibility and availability of medicines. The dissertation shall critically analyse the content of the Doha Declaration later in this chapter.

### 2.3 The Historical Development of the Patent System

Patent rights have always been misinterpreted as being timeless natural rights to property in ideas or the only method for a society to encourage innovation and invention. The history of patents shows the development of patent protection from just a domestic system to an international system. During such development, the concepts justifying granting patent rights changed from the natural rights and labour argument to the utilitarian and economic arguments as a result of trade globalisation. It also helps in understanding the nature and characteristics of the current patent system and illustrates that many of the current controversies in patent international framework are not in fact new. This part attempts to provide a comprehensive view of the history of patents by reference to four historical periods, as classified by Peter Drahos; the territorial period, the international period, the global period and the post-TRIPS period.[141]

Notably, the early history of patents is restricted to the development of patents in Europe because not all societies knew the notion of IPRs as a method of encouraging innovation. China, for example, is known as "a society that achieved spectacular outcomes in science and innovation," yet China did not rely on IPRs or any customary equivalent.[142]

#### 2.3.1 The Territorial Period

Patent history reaches back to more than 500 years when patents were granted to induce the industrial advancement of the state. Although the natural right theory justifying the ownership of the one's invention had influenced patent law development, legislators had always tried to justify patent laws as a means of inducing new knowledge to the society. The first patent Act in the world is traced back to the Venice Statute in 1474 protecting new and indigenous devices

[140] Ibid, Para 4
[141] Peter Drahos, 'Intellectual Property and Human Rights' (1999) 3 Intellectual Property Quarterly 349, 350-354
[142] Peter Drahos, *A Philosophy of Intellectual Property* (Australian National University E-Text 2016) 17-18 < https://press-files.anu.edu.au/downloads/press/n1902/pdf/book.pdf > accessed 20 April 2019

not known in Venice. The reason for protection, as stated in its preamble, was inducing people to invent devices that could be used and operated for the common good. It obliged the government not to allow its usage to anyone except the patentee who was given a period of 10 years precluding anyone in the territory from making a similar device without his consent.[143]

Such statute sets forth the principles of novelty and being capable of industrial application for granting a patent. Moreover, it appeared to be the earliest known version of granting a patent by registration as it spurred inventors to give a notice to the office of General Welfare Board to use and operate the invented device. Also, it provided for a limited monopoly right for 10 years before transferring the invention to the public domain. Furthermore, the state was given a compulsory licence to use and operate the invention, albeit "no one but the author shall operate it."[144]

Starting from the Seventeenth century, the Venetians model of patent law and practices began to spread in various states in Europe. At this time, intellectual property protection was merely a territorial concept and the trade was only restricted to the territory of each country. As such, patent protection was based on national protection, where each state differed in the nature and stringency of this protection.[145]

The English patent system at this time envisaged patents as devices "to encourage the transfer of valuable trades and technologies to England."[146] So, patent rights were not only granted to those who invented something new but also to those who had brought new technologies from another country. In case a patentee sought a monopoly right to an invention, he had to implement without delay the invention and "ensure its continuance by communicating the necessary skills to native workmen."[147]

However, the practice of giving monopoly rights was inconsistent with the designed purpose. Patents were granted to wrong people who were neither specialists nor inventors but favourites of the crown. Furthermore, patentees were given the same authority as the crown to search and seize goods that infringes a patent right, in addition to levy fines and penalties on the infringers.

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[143] Edward C. Walterscheid, 'Early Evolution of the United States Patent Law: Antecedents' Pt 1 (1994) 76(9) Journal of the Patent and Trademark office Society 697, 708-709
[144] Ibid, 709-710
[145] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 64-65
[146] Peter Drahos, *A Philosophy of Intellectual Property* (Australian National University E-Text 2016) 42 <https://press-files.anu.edu.au/downloads/press/n1902/pdf/book.pdf > accessed 20 April 2019
[147] Christine MacLeod, *Inventing the Industrial Revolution: The English patent System 1660-1800* (Oxford university press 1988) 12

All of such practices led to the amendment of the patent Act to introduce judicial review to allow the courts to give their opinion on the validity of granting monopolies.[148]

A remarkable case about patent rights, that was filed in 1602 after the introduction of the judicial review of monopoly rights, is *Darcy v Allein*, also known as the *Case of Monopolies*.[149] In that case, Queen Elizabeth granted the plaintiff a licence for the sole making, importing and selling of all playing cards in England. She sought to regulate the activity of card-playing, which caused problems among her subjects, by having one person controlling the trade. Although the defendant knew about such licence, he made and sold his own playing cards, thus violating the patent right granted to the plaintiff. The latter brought an action for damages and the Queen's Bench found that the defendant was not guilty. The court invalidated the Queen's grant of monopoly for several reasons. Firstly, such monopoly rights prevent others who may be skilled in a trade from practicing their trade, thus violating common law which gives primacy to the freedom of trade. Secondly, the monopoly rights granted to the plaintiff for the public good had been abused to achieve private gains only, thus raising the prices of goods which could undermine public welfare. Finally, monopolizing a field of trade does not prejudice tradesman in such field only but also all people willing to use the product. The monopolist will raise the price of the product without having any incentive to maintain the quality of the products sold.[150] This case is considered the first court judgment that shows that patent rights are inherently harmful to public welfare. If patent rights are misused, they violate law.

In 1624, the English parliament passed the Statute of Monopolies which is considered the legal foundation of the British Patent system and reflects the prevailing view of the common law system. It granted patents for a period of 14 years or under to inventors of new manufactures within the territory.[151] The statute of Monopolies imposed a general prohibition on the grant of patents in which the patent shall not be contrary to the law or " mischievous to the state by raising the prices of commodities at home, or hurt of trade or generally inconvenient."[152] The

[148] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 7
[149] *Darcy v Allein* (1602) 74 ER 1131
[150] Ibid. **See also**, Sidney T. Miller, 'The Case of Monopolies-Some of its Results and Suggestions' (1907) 6(1) Michigan Law Review 1, 4-7. **See also**, Edward Coke, *The Selected Writings and Speeches of Sir Edward Coke*, Vol 1 (Steve Sheppard edn, Liberty Fund Indianapolis 2003) < https://oll.libertyfund.org/titles/coke-selected-writings-of-sir-edward-coke-vol-i--5#lf0462-01_head_109> accessed 2 May 2019
[151] Statute of Monopolies 1623, 21 Jac 1, ch 3, Sec VI. **See also**, Edward C. Walterscheid, 'Early Evolution of the United States Patent Law: Antecedents' Pt 2 (1994) 76(11) Journal of the Patent and Trademark Office Society 849, 849-850
[152] Statute of Monopolies 1623, 21 Jac 1, ch 3, Sec VI

Statute of Monopolies was commonly accepted to set the legal foundations for patents, yet the latter remained to be envisaged as " a creature of prerogative-based privilege" until the late 18th century.[153]

In the second half of the 18th century, it became a common practice for the patent owner to be required to provide a written description of the invention. This was due to the insistence of UK courts to do so. A landmark case showing this insistence is the *Liardet v Johnson* case, where Liardet brought an action for infringement against Johnson due to imitating a newly invented stucco used in covering the buildings facades. The court voided Liardet's patent stating that the specification of the invention had to be written in details to instruct others on how to make the invention.[154] The case is considered a shift from practising the invention to the disclosure of the invention. This led to a change in the concept of novelty which became dependent on whether the trader knew of the invention via publication or not.

The Industrial revolution in Europe and John Lock philosophical theory arguing that every person has a natural right to the fruits of his labour seems to be the *raison d'etre* for the French Patent Act which emerged in 1791.[155] The French revolution abrogated the privileges granted by the old regime and established a modern IP system based on the idea of the natural rights of authors and inventors. Section 1 of the French Patent Act stipulated that all the new discoveries are the property of the author. To assure the inventor the temporary enjoyment of his invention or discovery, the French Patent Act provided that discoveries or new inventions in any kind of industry were deemed to be the property of its inventor. It granted patent rights for periods of either 5, 10 or 15 years depending on the patentee choice. However, during the revolution there was a debate regarding the tension between private interests in ideas and public enlightenment. Some argued that "ideas were social rather than individual in origin and that the progress of enlightenment depends on public access rather than private claims to ideas." A contrasting argument clarified that the "sanctity of individual creativity should be protected as a natural right."[156]

[153] Brad Sherman and Lionel Bently, *The Making of Modern Intellectual Property Law: The British Experience 1760-1911* (Cambridge University Press 2002) 134
[154] *Liardet v Johnson* (1778) 62 ER 1000
[155] Edward C. Walterscheid, 'Early Evolution of the United States Patent Law: Antecedents' Pt 4 (1996) 78(2) Journal of the Patent and Trademark Office Society 77, 104
[156] Ibid. **See also**, Carla Hesse, 'Enlightenment Epistemology and the Laws of Authorship in Revolutionary France, 1777-1793' (1990) 30 Representations 109, 109-137

The French Patent Act seems to be incoherent with the natural rights argument. It recognized intellectual property as a natural right, yet, contrary to natural rights which have no expiry date, the Act stated a limited period of protection after which the invention or the work belongs to the public domain. Such limited period of protection was justified as a "mechanism for promoting and ensuring public enlightenment by encouraging and recompensing intellectual activity."[157] Thus, it may be inferred that the French revolution did not confine the justification for granting intellectual property on natural rights perspectives only.[158]

The US Constitution was first adopted in 1787 and included a provision for intellectual property protection. It granted the Congress the power to " promote the progress of science and useful Arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[159] The emphasis on "useful arts" underscores that the American legislators embraced the utilitarian/economic theory in justifying IPRs.[160] Implementing the constitutional provision, the Congress issued the first US Patent Act in 1790 which allowed the patentee an exclusive right to use the patent for a period of 14 years. Also, the patentee was required to submit a written specification of the invention to three officials and get the consent of at least two of them to obtain the patent. Thus, the grant of the patent right under such Patent Act was a discretionary affair. Further, the US Patent Act abolished patents for imported knowledge and required that patents be granted only for new matters not known or used before in the US, provided that they are sufficiently useful and important.[161]

Such examination process was criticized due to the long-time taken to assess the importance and usefulness of the product to be granted a patent.[162] Consequently, the 1790 US Patent Act was repealed and replaced by the Patent Act of 1793 to expedite the process of granting patent rights.[163] The Act includes a definition for the subject of patent which has not changed to date. It granted patents for "any new and useful composition of matter" encompassing pharmaceutical

[157] Carla Hesse, 'Enlightenment Epistemology and the Laws of Authorship in Revolutionary France, 1777-1793' (1990) 30 Representations 109, 128
[158] Peter Drahos, 'Intellectual Property and Human Rights' (1999) 3 Intellectual Property Quarterly 349, 350
[159] US Constitution, art 1 sec 8, cl 8
[160] Susan K. Sell, *Private Power, Private Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press 2003) 60-74
[161] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 24. **See also**, Patent Act of 1790, Ch 7, 1 Stat 109 (10 April 1790) sec 1
[162] Pasquale Joseph Fedrico, "Operation of the Patent Act of 1970" (2003) 33(85) Journal of the Patent and Trademark Office Society 33, 45
[163] Patent Act of 1793, Ch 11, 1 Stat 318 (21 February 1793)

substances.[164] The US Patent Act 1793 was interpreted by the US Supreme Court to grant the inventor the right to patent, although it did not explicitly state such right.[165]

The British, French and US patent laws served as examples to most European countries, (except Switzerland) and Japan to introduce Patent Acts into their legislations during the 19th century.[166]

Due to the industrial revolution in Europe, in the 19th century, patents became an important element of technological change. The arguments relying on natural property rights in ideas to justify granting patent protection have been replaced by the utilitarian arguments or economic incentive arguments. Accordingly, patent rights are justified either as ideas beneficial for the society and people or as means for encouraging inventors and inducing innovation by monopoly rewards which eventually benefit the public.[167] The dissertation shall scrutinize in this chapter such theories under the section titled "The Philosophical Justification for Patent Protection" to explore the most prevailing arguments used to justify the current patent system.

The enactment of the 1852 patent law amendment in UK was a step towards addressing the utilitarian or economic incentive views for granting patent rights. The new amendments established an effective system of patent registration which simplified granting patents. Patents were not perceived as products of royal grants as before, but rather, as legal instruments to protect the creative work of inventors from being freely copied and economically used without investing any time or money or exerting any effort in R&D. Rewarding the inventors by granting them patent rights encourage them to produce and disseminate more innovations for the welfare and happiness of people.[168]

Nevertheless, the new amendments of the UK patent law were not left uncontested at that time. Opponents argued that patents hinder free trade in goods, *inter alia*, technology, and are not an effective incentive to innovation. They also contended that obtaining licences to use the patented

[164] Ibid, sec 1
[165] *Grant v Raymond*, 31 US 218 (1832), 241
[166] Bronwyn H. Hall, 'Patents' in Steven N. Durlauf and Lawrence E. Blume (eds), *The New Palgrave Dictionary of Economics* (2nd edn, Palgrave Macmillan UK 2008) 2 < https://eml.berkeley.edu/~bhhall/papers/BHH06_Patents_Palgrave.pdf > accessed 4 April 2019
[167] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 9
[168] Brad Sherman and Lionel Bently, The *Making of Modern Intellectual Property Law: The British Experience 1760-1911* (Cambridge University Press 2002) 134. **See also**, H. I. Dutton, *The Patent System and Inventive Activity During the Industrial Revolution 1750-1852* (Manchester University Press 1984) 24-27

products or to manufacture them was so expensive that they imposed hardship on domestic manufacturers.[169]

The British Patent Act 1852 was amended in 1883 (Patents, Design and Trademarks Act) after the emergence of protectionism policy in which tariffs and taxes are imposed on imported goods. The 1883 reform reduced the cost of issuing a patent licence in response to the controversy about its expensive price. This resulted in greater access to the patent system. By virtue of the Patents and Designs Act of 1907, amending the 1883 Act, patent examiners had the privilege to exclude frivolous patents and to refuse others lacking novelty.[170]

The language of the 18th century British Patent Acts was very broad to encompass any new manufactures including "substances like medicines formed by chemicals and other processes."[171] Conversely, the French Patent Act 1844 excluded pharmaceuticals of all kinds and declared null and void any patent obtained on medicines. This was due to the fear from any appropriation from the inventors on essential medicines necessary to public health.[172] It was until 1959 when France issued a decree imposing special patents on pharmaceutical products and allowing for compulsory licences. A compulsory licence was granted if the production of medicines were insufficient in quality or quantity, or if their prices rose in an abnormal way.[173]

Similarly, many developed countries did not include pharmaceuticals in patent system till the second half of the 20th century when they were exposed to domestic and foreign pressure. Examples are Germany in 1968, Switzerland in 1977, Japan in 1976 and Italy and Spain in 1978 and 1992 respectively. To safeguard public health after patenting medicines, some developed countries, like Canada and UK, granted compulsory licences, though they abolished such practices after the adoption of the TRIPS agreement in 1994.[174]

Patent systems in North America and Europe in the 20th century have seen noticeable variations in some key areas. In the interpretation of novelty for instance, some countries, like France and Italy, considered that the prior knowledge, publication or usage of the invention revokes the novelty requirement needed to register the patent regardless of its origin. Meanwhile, in many

[169] H. I. Dutton, *The Patent System and Inventive Activity During the Industrial Revolution 1750-1852* (Manchester University Press 1984) 24-27
[170] Christine MacLeod et al, 'Evaluating Inventive Activity: The Cost of Nineteenth-Century UK Patents and the Fallibility of Renewal Data' (2003) 3 Economic History Review 537, 540-544
[171] *Boulton and Watt v Bull* (1795) 2 H. Bl. 463, 126 ER 651
[172] French Patent Act 1844, art 30(2)
[173] Ordonnance No 59-250 on 4 February 1959
[174] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 29

other countries, foreign use or prior knowledge could be patented if they are not published. Another example is the difference in patent terms of protection. They varied from 17 years in the US and Canada starting from the date of grant of the patent right to 14 years in the UK. A third example is the local working of the patented product or process, i.e., the usage of the patented product or process or the manufacture of patented product in the country that grants the patent. Many countries required that the patentee should locally work the patent, otherwise they would revoke the patent or even issue a compulsory licence to other manufacturers. Other countries, like the US, do not require working the patent domestically. Before concluding the TRIPS agreement, many European countries utilized the local working of the patent to exclude medicines from patentability on the grounds of public interests.[175]

On the other hand, most developing countries led by India and Brazil, the prominent suppliers of generic medicines to developing countries, were resisting the inclusion of pharmaceuticals in their patent systems. They were concerned that patents would impede the accessibility to affordable medicines and negatively affect their public health system. Developing countries enjoying pharmaceutical manufacturing capacities feared that patents would hinder the transfer of technology needed for their pharmaceutical industry.[176] At the end, they were obliged to amend their legislations to provide patent protection to medicines after adopting the TRIPS Agreement.

From the previous demonstration of the international patent system, it is obvious that justifying IPRs according to the utilitarian or economic incentive notions which accompanied the industrial revolution had stimulated the universal recognition of the value of inventions and the exclusive rights of inventors to their work. States had to enact specific laws for patent protection in order to design public policies to encourage technological advancement and promote their economic development. Developed countries recognized patents as a tool to encourage inventors to produce more innovation for the general welfare of people. Meanwhile, developing countries were reluctant to apply such rights due to fear of their implications on their pharmaceutical sector.

Nevertheless, the previous patent legislations were limited to national borders rendering international compliance neither regulated nor required. Further, the fears of monopoly and the

[175] Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (Ashgate Publishing 2003) 49-51

[176] M. Monirul Azam, 'The Experiences of TRIPS-Compliant Patent Law Reforms in Brazil, India, and South Africa and Lessons for Bangladesh' (2014) 7(2) Akron Intellectual Property Journal 61, 62-63

concerns about patent rights hindering free trade still exist, leading to the exclusion of pharmaceuticals from patentability in many countries, especially the developing ones. The dissertation shall show later in this chapter that such findings are consistent with the arguments against allowing property rights for intangible objects.

### 2.3.2 The International Period

In the late 19th century, the US and European countries began to negotiate the issue of providing an international framework to protect IPRs influenced by the explosion of international trade and the increase of competition related to technology. The spread of free-riding practices was another reason that induced countries to enter into bilateral agreements to protect intellectual property owners from such practices.[177]

Consequently, a world exposition for inventions was organized in Vienna in 1873 to adopt an international convention for industrial property. The US and German exhibitors refrained from contributing and exhibiting their ideas in the Vienna's exhibition fearing their commercial exploitation in other countries.[178] Despite the opposition to the notion of patent protection, the majority view was in favour of conferring monopoly rights to inventors. The subsequent negotiations between 1878 and 1880 to organize an international convention for the protection of new inventions culminated in the adoption of the Paris Convention for the Protection of Industrial property in 1883.[179]

Developing countries did not concede to the Paris Convention fearing restriction of their accessibility to essential medicines. Forty-nine member states to this convention also excluded pharmaceutical patents. Due to the global significance of patents and the need to find an international framework that sets substantive and procedural rules for protecting IPRs, the developed countries insisted on drafting another treaty that provides for an effective harmonized

[177] Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (Ashgate Publishing 2003) 54-55. **See also**, John Braithwaite and Peter Drahos, *Global Business Regulations* (Cambridge University Press 2000) 58. **See also**, Samuel Ricketson, *The Berne Convention for the Protection of Literary and Artistic Works:1886 to 1986* (Centre for Commercial Law Studies, Queen Mary Collage, University of London 1987) 25-38

[178] WIPO, 'WIPO Treaties – General Information: Major Events 1883 to 2002' < http://www.wipo.int/treaties/en/general > accessed 10 April 2019. **See also**, Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 11-12

[179] Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, entered into force 7 July 1884) 21 UST 1583, 828 UNTS 305 (Paris Convention). **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 34

system for intellectual property.[180] This was achieved by the TRIPS Agreement which was concluded in 1994.

It is noteworthy that another multinational agreement was adopted for the protection of Literary and Artistic work (Berne Convention) in 1886 as a result of the demand for an international framework for IP protection. However, this is beyond the purview of this dissertation and shall not be dwelt on.

#### 2.3.2.1 The Paris Convention for the Protection of Industrial Property

Adopted in 1883 and revised several times till it was last amended in 1979, the Paris Convention is considered the first multilateral treaty providing for industrial property protection, of which patent protection is a part. The convention established an international organization named Paris Union for the Protection of Industrial Property to administer its issues. Later, the administering body became the WIPO which is one of the specialized agencies of the United Nations. The WIPO covers not only the industrial property, but also all other forms of IPRs.[181]

The key principle of the convention is the national treatment in which a country member to the convention cannot discriminate, regarding the protection of industrial property, between its nationals and nationals of another member state to the convention.[182] Thus, patent applicants from all member states to the convention should have the same advantages as a national patent applicant with respect to legal rights and remedies.[183]

The convention also addressed the issue of the priority date, in which the first application for a patent in a member state gives priority right to the applicant for 12 months, starting from the date of the first filling of a patent right in other member states. During such period, a third party

[180] Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (Routledge London and New York 2002) 10. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 35-38

[181] Tanya Aplin and Jennifer Davis, *Intellectual property Law: Text, Cases and Materials* (2nd edn, Oxford University Press 2013) 546. **See also**, Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, entered into force 7 July 1884) 21 UST 1583, 828 UNTS 305 (Paris Convention) art 1

[182] Tanya Aplin and Jennifer Davis, *Intellectual property Law: Text, Cases and Materials* (2nd edn, Oxford University Press 2013) 546-547

[183] Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, entered into force 7 July 1884) 21 UST 1583, 828 UNTS 305 (Paris Convention) art 2

cannot obtain a patent on the same invention, thus preventing intervening acts from receiving a patent protection on similar inventions.[184]

The Paris Convention prohibited refusing or invalidating a patent due to domestic legal restrictions or limitations on the sale of the patented product, i.e., restrictions on importation.[185] Nevertheless, it included substantive rules on revocation of patents and granting compulsory licences in case the patents are not locally worked. The convention allowed each state to grant non-exclusive and non-transferable compulsory license to prevent the patent proprietor from abusing the exclusive rights conferred by the patent, like refusing to grant a license without a legitimate reason or inability to supply the market with sufficient amounts of the patented product (failure to work or insufficient working of the patent).[186] But the compulsory licence can only be granted after a specific time from granting the patent or filling its application, whichever period expires last, and it could be refused if the patentee justified the inaction on the grounds of legitimate interests.[187] If the compulsory licences were not sufficient to prevent patents abuses, then they could be forfeited as stipulated by the Paris Convention.[188]

However, the convention was criticized for several issues. First; it did not harmonize national patent laws, i.e., an application for a national patent in a member state shall be independent from any other patent obtained for the same invention in another state even if it is not a state member. Thus, national patents remain independent from each other concerning their validity and grant.[189] Second; the agreement failed to set out any criteria on the patentability of an invention or the exceptions from patentability, leaving every member state to exclude on its own will areas from patentability without any means of harmonization. This resulted in excluding pharmaceuticals from patent protection in some countries, like India and Brazil, in order to maintain accessibility to drugs at competitive prices. This lack of harmonization resulted in ineffective protection.[190] Third; it did not include any definition for a patent, nor did it set a minimum patent period. Fourth; the agreement also allowed compulsory licences without expressly providing for payment of any compensation to the patentee whenever a compulsory

[184] Ibid, art 4. **See also**, Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (Ashgate Publishing 2003) 57
[185] Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, entered into force 7 July 1884) 21 UST 1583, 828 UNTS 305 (Paris Convention) art 4 quarter
[186] Ibid, art 5(A)(2)
[187] Ibid, art 5(A)(4)
[188] Ibid, art 5(A)(3)
[189] Ibid, art 4bis
[190] Duncan Matthews, *Intellectual Property, Human Rights and Development: The Role of NGOs and Social Movements* (Edward Elgar UK 2011) 16

license is granted.[191] Finally, the convention did not establish standards for national enforcement nor had an effective enforcement mechanism regarding the obligations of member states. Although the disputes concerning the interpretation or the application of its provisions could be brought to the International Court of Justice (hereinafter referred as ICJ), it was not an effective mechanism. The few member states which ratified the Stockholm revision of the Paris Convention are the only states bound by its provisions.[192]

Accordingly, several pharmaceutical manufacturers and research associations in industrialised countries exerted aggressive efforts to establish a more robust patent system. The EU and the US argued that the GATT treaty is ideal for increasing patent protection instead of the weak enforcement mechanism of the WIPO which administers the Paris Convention.[193]

#### 2.3.2.2 Patents and the US Antitrust Policy

Until the mid-1970s, the US was not always supportive of the patent system. Doubts about the patent system and monopoly rights increased in the late 19th century and were heightened by the emergence of patent-based cartels and the usage of patents by big US enterprises to control market competition. Edwin J. Prindle, the President of the New York Patent Law Association and the Chairman of the Patent Committee of the American Chemical Society at that time, wrote a series of articles on "Patents in Manufacturing Business" showing that enterprises used patent licences to set their own prices, divide markets and reap great financial rewards. The articles played an important role in making the US government to critically scrutinize the whole US patent system.[194] The Congress enacted a number of antitrust legislations which allowed the Justice Department's Antitrust Division to initiate several antitrust actions between the period of 1938 and 1942. During the same period, the Congress hearings showed several

[191] Frederick M. Abbott, 'Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework' (1989) 22(4) Vanderbilt Journal of Transnational Law 689, 703-704
[192] Daniel J. Gervais, *The TRIPS Agreement: Drafting History and Analysis* (2nd edn, Sweet & Maxwell UK 2003) 9-10. **See also**, Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (Routledge London and New York 2002) 22. **See also**, Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, entered into force 7 July 1884) 21 UST 1583, 828 UNTS 305 (Paris Convention) art 28
[193] Patrick L. Wojahn, 'A Conflict of Rights: Intellectual Property under TRIPS, the Right to Health and AIDS Drugs' (2001-2002) 6(2) UCLA Journal of International Law and Foreign Affairs 463, 477
[194] Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy* (Earthscan Publications 2002) 44 < https://www.researchgate.net/publication/246471223_Information_Feudalism_Who_Owns_the_Knowledge_Economy> accessed 26 July 2019

condemnations to the patent system and called for shifting back to the compulsory licensing system.[195]

The US Supreme Court also showed distrust towards the patent system starting from overruling the *Henry v A.B. Dick Company* case in 1917 till the 1980s. In the case, the Supreme Court in 1912 upheld patent licensing restrictions, like tie-in practices, which require the purchaser of a patented product to restrict its usage to supplies purchased from the patentee. According to the case, the Dick company sued Henry for selling supplies of ink to be used with a patented mimeograph machine designed to print multiple paper copies. The plaintiff proved that the defendant knew that there was a licence restriction requiring that the machine be used only with supplies made by the company. The Supreme Court relied on the natural rights arguments that justify intellectual property, where the patentee owns the invention as a form of property. It stated that it was the inherent right of the company, as a patent owner, to restrict the usage of the invention on any terms and conditions or even lawfully refuse to license its patent at all.[196]

In 1917, the US Supreme Court overruled the previous decision in the case of *Motion Picture Patents Company v. Universal Film Manufacturing Company,*[197] which represent a noticeable court decision on the misuse of patented products. The court held that, by virtue of the patent law, the patent is limited to the invention described in the written description of the patent. The law does not " empower the patent owner, by notices attached to the things patented, to extend the scope of the patent monopoly by restricting their use to materials necessary for their operation but forming no part of the patented invention."[198] The Supreme court clarified that patent law gives the right to patentees to restrain others from manufacturing, using or selling their patented inventions, but does not give them the right to place restrictions that hinder the usage of the patented products after sale. The court concluded that the tie-ins practices allowed patentees to obtain monopolies over non-patented claims by extending their patent rights to cover non-patented products. Such practices interfere with the primary purpose of the patent law to promote the progress of science and useful arts conforming with the US constitution. Those practices create private fortunes and hamper free competition.[199]

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[195] Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (Ashgate Publishing 2003) 113
[196] *Henry v A.B. Dick Company*, 224 US 1 (1912)
[197] *Motion Picture Patents Company v Universal Film Manufacturing Company*, 243 US 502 (1917)
[198] Ibid, 502
[199] Ibid. **See also**, Lawrence G. Kastriner, 'The Revival of Confidence in the Patent System' (1991) 73(1) Journal of Patents and Trademark Office Society 5, 6. **See also**, James B. Kobak, Jr, 'The Misuse Defense and

Consequently, it can be inferred that the US policy in the 20th century viewed patents as a monopoly right rather than necessary incentives for innovation. The US courts often invalidated presumed patents in an attempt to confront the concept of patents misuse.[200] The anti-patent view of the courts began to change in the 1980s when patents were no longer construed as a method of hampering free competition.

#### 2.3.2.3 Patents and Developing Countries

Starting from the second half of the 20th century, patents became one of the most essential aspects of industry. Developed countries depicted them as incentives for R&D and a tool to promote and facilitate technology transfer. Economic philosophers in the western world invoked the utilitarian and the economic incentives-based theories to justify patent protection rather than the national rights arguments. Developed countries perceived the Paris Convention as an inadequate platform for patent protection, as previously shown, due to its weak enforcement mechanism and the reluctance of many developing countries to sign it.[201]

Developing countries found that the Paris Convention framework did not offer a suitable solution for the vast inequities in technological development. The patented inventions in those countries were predominantly owned by foreign companies or foreign nationals. A research conducted in 1973 showed that foreign companies in developing countries owned nearly 90% of the patents granted for new inventions including pharmaceuticals. This facilitated national market dominance by those companies.[202]

It was also argued that the patent system in the Paris Convention did not contribute to transferring the technology to developing countries because the patented products were not manufactured in the developing countries that granted the patents. This represents a contradiction to one of the justifications for the patent system being a tool for technology

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Intellectual Property Litigation' (1995) 1 Boston University Journal of Science and Technology Law, paras 4-5 < http://www.bu.edu/law/journals-archive/scitech/volume1/kobak.pdf> accessed 26 July 2019

[200] Susan K. Sell, *Private Power, Private Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press 2003) 65

[201] Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (Routledge London and New York 2002) 10. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 36-37

[202] Constantine Vaitsos, 'Patents Revisited: Their Function in Developing Countries' (1972) 9(1) The Journal of Development Studies 71, 79. **See also**, Edith Penrose, 'International Patenting and the Less-Developed Countries' (1973) 83(331) The Economic Journal 768, 769

transfer.[203] Moreover, foreign patents in developing countries were mostly used to prevent such countries from manufacturing local products, *inter alia*, pharmaceuticals, from alternative sources at a cheaper price.[204] A lucid example is the manufacture of generic antibiotics. When developing countries were seeking to import the suitable substances and technology for antibiotics production, foreign patent holders of such medicines were able to block the imports.[205]

While distrust regarding patent system increased gradually in developing countries, many of them neither joined the Paris Convention nor wished to embrace stronger international standards on patent systems. On the contrary, many patent legislations in developing countries included compulsory licensing provisions to prevent the abuses of patent rights, *inter alia*, restricting imports from alternative sources, as well as blocking other potential manufacturers.[206] A note prepared by the International Bureau of the WIPO in 1988 showed that many national provisions in developing countries provided for compulsory licensing for several reasons. For example, public interest as in Brazil, India, Mexico and Jordan; the abuse of monopoly rights and the violation of anti-trust law as in Colombia, Nigeria, South Africa, and Thailand; to safeguard the affordability and accessibility to medicines and to protect the public health like in India, Philippines, Zambia, Zimbabwe, and Singapore.[207] Developing countries perceived the intellectual property system as a "part of common heritage" that belongs to all human beings. As such, they did not allow pharmaceutical patents fearing that the monopoly rights granted to patentees would render the prices of medicines unaffordable for a large sector of their population. Developing countries with pharmaceutical manufacturing capacities, like India and Brazil, did not grant patents to pharmaceuticals so as not to oblige their pharmaceutical industry to stop producing cheap generic medicines. This allowed them to ensure the accessibility and affordability of essential medicines.[208]

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[203] Constantine Vaitsos, 'Patents Revisited: Their Function in Developing Countries' (1972) 9(1) The Journal of Development Studies 71, 80-81
[204] Edith Penrose, 'International Patenting and the Less-Developed Countries' (1973) 83(331) The Economic Journal 768, 776
[205] Constantine Vaitsos, 'Patents Revisited: Their Function in Developing Countries' (1972) 9(1) The Journal of Development Studies 71, 81
[206] Edith Penrose, 'International Patenting and the Less-Developed Countries' (1973) 83(331) The Economic Journal 768, 777
[207] Negotiating Group on TRIPS, Including Trade in Counterfeit Goods, 'Existence, Scope, and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual property: Note Prepared by the International Bureau of WIPO' (5 May 1988) MTN.GNG/NG11/W/24, p 11-12
[208] Susan K. Sell, 'Intellectual Property as a Trade Issue: From the Paris Convention to GATT' (1989) 13(4) Legal Studies Forum Journal 407, 410 < https://heinonline.org/HOL/LandingPage?handle=hein.journals/lstf13&div=35&id=&page= > accessed 17 April

India, known as the pharmacy of the developing world due to its thriving generic manufactory, is considered the biggest supplier of cheap generic drugs to developing countries. About 67% of its exports are medicines to these countries.[209] India considered that the free flow of technology and information is indispensable for preventing monopolies by foreign companies and for adjusting the prices of medicines whenever they increase. It refused to join the Paris Convention due to the restrictions it posed in promoting its economic and social development.[210] To restrict fields of patentability, India adopted the Patent Act 1970 which granted patents only for processes and for a limited time (7 years for pharmaceuticals). It did not shed any protection on pharmaceutical products, but rather, it allowed for free copying and local marketing of patented medicines from all over the world. Alongside with encouraging its domestic pharmaceutical sector, India put restriction on imported medicines by levying high taxes and restricting finished formulation. It also controlled the drug prices by obliging companies to generate less profits when selling medicines in the internal market. The elaborate system of licenses stipulated in the Patent Act ensured an adequate local working of the patent. Consequently, India managed to keep drug prices low and succeeded in preventing foreign companies from monopolizing the pharmaceutical market. Therefore, such companies found no interest in the Indian market which allowed national Indian firms to dominate and monopolize the local market.[211]

India was not the only country which restricted patentability in the pharmaceutical industry to serve its public interests. The Brazilian Industrial property legislation in 1945 was amended to exclude the protection of inventions relating to several issues, *inter alia*, medicines and substances obtained by chemical processes. It was amended again in 1969 to completely

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2019. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) xxxiv (Introduction)

[209] Jean Olson Lanjouw, 'The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?' (1998) National Bureau of Economic Research Working Paper 6366, 3 < http://www.dklevine.com/archive/lanjouw.pdf > accessed 15 April 2019. **See also**, Oxfam New Zealand, 'Rich Countries Betraying Their Obligations to Help Poor Countries Protect Public Health' (14 November 2006, Oxfam New Zealand) < https://www.oxfam.org.nz/news-media/media-releases/rich-countries-betraying-their-obligations-to-help-poor-countries-protect-public-health/ > accessed 16 April 2019

[210] Anitha Ramanna, 'Interest Groups and Patent Reform in India' (2009) E-Social Sciences Working Paper, 3-4 < http://www.esocialsciences.org/Articles/Show_Article.aspx?qs=ebKFqzOKbXo7se0+tFTcFgB/Qg9lMx8H7EcQyowRRVZ0EY1ajlgLHXfAf4Wg4kc9uuQBP/T5nsVG2x4L7FxRuLEqqJOArmSgOS3R0iOGFX8=> accessed 24 April 2019

[211] Ibid. **See also**, Jean Olson Lanjouw, 'The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?' (1998) National Bureau of Economic Research Working Paper 6366, 3-4 < http://www.dklevine.com/archive/lanjouw.pdf > accessed 15 April 2019

eliminate pharmaceutical patents.[212] Prohibiting pharmaceutical patents continued to exist through the 1980s because the Brazilian regime was linking, with the aid of media, human rights and access to medicine on one side and protection of IPRs on the other. The Brazilian media and activists played an important role in convincing the government to enact a law that guarantee the accessibility to affordable medicines to Brazilian citizens and to issue compulsory licences due to the spread of HIV/AIDS and other epidemic diseases.[213]

Adversely, developed countries viewed intellectual property system as private property.[214] They argued for a robust patent protection to inventions to protect the economic investments and the efforts exerted in R&D. Otherwise, third world producers would be able to free-ride such inventions and profit from the knowledge without contributing to the huge expenses incurred in the relevant R&D. Such practice is described by Michael Spence as "reaping without sowing." A practice that discourages inventors from future production.[215]

Due to the existing disparity between developed countries and developing countries, there were serious attempts to revise the international patent system in the Paris Convention and replace it with a more globalised framework for an effective and adequate IP protection. Conferences for the revision of the Paris Convention were held between 1980 and 1984 with the participation of developing countries led by India and Brazil. They insisted on applying the notion of intellectual property as a common heritage by including provisions that would allow them to incorporate exclusive compulsory licensing in case of failure to locally work the patent. They also demanded the inclusion of provisions that provide for better accessibility to technology to increase their manufacturing capacities.[216]

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[212] Maria Auxiliadora Oliveira et al, 'Brazilian Intellectual Property Legislation' in Jorge A. Z. Bermudez and Maria Auxiliadora Oliveira (eds), *Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for the Public Health* (WHO/PAHO Collaborating Centre for Pharmaceutical Policies & Oswaldo Cruz Foundation Rio de Janeiro 2004) 151, 152

[213] Gabriela Costa Chaves et al, 'Access to Medicines and Intellectual Property in Brazil: Reflections and Strategies of Civil society' (2008) 5(8) Sur International Journal on Human Rights 163, 163-166, 172 <https://sur.conectas.org/wp-content/uploads/2017/11/sur8-eng-full.pdf > accessed 16 April 2019

[214] Susan K. Sell, 'Intellectual Property as a Trade Issue: From the Paris Convention to GATT' (1989) 13(4) Legal Studies Forum 407, 410 < https://heinonline.org/HOL/LandingPage?handle=hein.journals/lstf13&div=35&id=&page= > accessed 17 April 2019

[215] Jerome H. Reichman, 'Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection' (1989) 22 Vanderbilt Journal of Transnational Law 747, 756. **See also**, Michael Spence, 'Which Intellectual Property Rights are Trade-Related?' in Francesco Francioni (ed), *Environment, Human Rights and International Trade* (Hart Publishing Oxford 2001) 263, 278

[216] Peter Drahos, 'Intellectual Property and Human Rights' (1999) 3 Intellectual Property Quarterly 349, 352-357. **See also**, Susan K. Sell, 'Intellectual Property as a Trade Issue: From the Paris Convention to GATT' (1989) 13(4) Legal Studies Forum 407, 409 <

From the other side, developed countries led by the US rejected such perspectives and called for a more stringent patent protection invoking the economic based notions. They insisted on perceiving patents as a tool to encourage inventors to produce and disseminate more inventions and to promote international trade.

The difference in views between both camps were insurmountable resulting to end of the negotiations in 1984 without any agreement.[217] A major change in the international patent system, against the will of developing countries, occurred afterwards and culminated in the adoption of the TRIPS agreement as shall be demonstrated.

### 2.3.3 The Global period

With the increase of international trade and the growing importance of IPRs in 1980s, businesses sought out to develop the concept of controlling knowledge as a new area of industry. Big businesses demanded intellectual property protection for creative labour in different sources of innovation, including pharmaceuticals, due to the loss of profits from acts of free riding or copying. The pharmaceutical manufacturers and the R&D industry claimed that the monopolistic pricing resulting from a robust patent protection would let them recoup their investments in the pharmaceutical sector. They argued that they lost a lot of profits due to the sale of generic medicines in developing countries with pharmaceutical industrial capacities like Brazil and India. Such countries had no domestic patent system for pharmaceuticals and their companies were free to copy and sell patented medicines without the consent of the companies owning the patent rights. The European Union also claimed that compulsory licensing of pharmaceuticals harmed the market potential of patented medicines which hamper and discourage investments in the pharmaceutical field.[218]

Alongside with the failure of multilateral negotiations between 1980 and 1984 and the disparity of thoughts between developing and developed countries regarding a standardized protection of

https://heinonline.org/HOL/LandingPage?handle=hein.journals/lstf13&div=35&id=&page= > accessed 17 April 2019

[217] Susan K. Sell, 'Intellectual Property as a Trade Issue: From the Paris Convention to GATT' (1989) 13(4) Legal Studies Forum 407, 407 < https://heinonline.org/HOL/LandingPage?handle=hein.journals/lstf13&div=35&id=&page= > accessed 17 April 2019

[218] Patrick L. Wojahn, 'A Conflict of Rights: Intellectual Property under TRIPS, the Right to Health and AIDS Drugs' (2001-2002) 6(2) UCLA Journal of International Law and Foreign Affairs 463, 476-477. **See also**, Robert Weissman, 'A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rule, and the Remaining WTO Legal Alternatives Available to Third World Countries' (1996) 17 University of Pennsylvania Journal of International Economic Law 1069, 1072

intellectual property with a robust enforcement mechanism, the industrialized countries resorted to unilateral pressure on developing countries.

The US and the European countries withdrew trade benefits granted to specific developing countries in case they failed to offer adequate intellectual property protection to their products.[219] The US threatened to impose trade sanctions on countries, mainly developing countries, which did not provide adequate protection to US intellectual property. By virtue of section 301 of the US Trade Act 1974, the US Trade Representative (USTR) had the authority to place those countries on "watch lists" and "priority watch lists," where they are notified that, if they did not amend their patent laws, the US would impose trade sanctions upon them. By virtue of the 1988 US Trade Act amendments, the "section 301" was further strengthened by adding the "Special 301" process. Accordingly, the USTR was given the authority to impose trade sanctions on countries denying adequate and effective intellectual property protection. In the pharmaceutical field, for instance, the countries that were exposed to section 301 are mainly the large developing countries with pharmaceutical manufacturing capacities that had started to develop their domestic industries in order to compete the US pharmaceutical industry in their domestic market, like India, Argentina, South Korea and Thailand. The first country to be exposed to the US trade sanctions "Special 301" in such field was Brazil in 1988 due to its refusal to grant patent protection to pharmaceuticals.[220]

As the US businesses continued to thrive in pharmaceuticals and technological products, intellectual property protection was placed on the top of the trade agenda and was invoked as a hot topic in the international arena. When few developing countries tried to acquire technological capacities and enact tailored national laws of patenting that would serve their local industry, the US companies lobbied to impede their attempts. The US pharmaceutical companies demanded more vigorous protection to their products in developing countries. Failing to grant such protection was depicted as distortion to international trade. The whole view of the patent system that was envisaged by the US courts as an impediment to trade and incompatible with

[219] Marco C.E.J. Bronckers, 'The Impact of TRIPS: Intellectual Property Protection in Developing Countries' in Marco C.E.J. Bronckers, *A Cross-Section of WTO Law* (Cameron May Ltd 2001) 185, 188

[220] 19 US Code § 2411, Title III ch 1, 88 Stat 2041 (Section 301 of the Trade Act of 1974). **See also**, Peter Drahos, 'Four Lessons for Developing Countries from Trade Negotiations over Access to Medicines' (2007) 28(1) Liverpool Law Review 11, 15-16. **See also**, Frederick M. Abbott, 'Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework' (1989) 22(4) Vanderbilt Journal of Transnational Law 689, 710. **See also**, Robert Weissman, 'A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rule, and the Remaining WTO Legal Alternatives Available to Third World Countries' (1996) 17 University of Pennsylvania Journal of International Economic Law 1069, 1078

the US antitrust law had changed. The patent system became a tool to foster innovation and promote international trade and flow of technology. This was supported by using the notion of "individual property right" by US businesses to justify intellectual property protection and by describing the acts of free riding, that was acceptable in international law at that time, as a piracy practice.[221]

The lobby of the US pharmaceutical companies manifested its influence in two major issues, the inclusion of intellectual property protection in both the North America Free Trade Agreement (NAFTA)[222] concluded in 1992 and the Uruguay round of GATT negotiations that began in 1986.

Regarding the NAFTA, Canada resisted the changing of its patent law that allowed compulsory licensing. The pressure from the US pharmaceutical companies through their branches and subsidiaries in Canada succeeded in making Canada to amend its patent law in 1987 providing patent protection for 7 to 10 years before issuing compulsory licences. In 1992, Canada enacted Bill C-91, the Patent Act Amendment Act, which replaces its compulsory licence system with that of the US system. The new Canadian Patent Act obligated patent holders to grant non-exclusive licenses to any entity that wants to use the patent in exchange for reasonable licensing fees. This amendment came after an acrimonious fight between Canadian patent law opponents, including generic drug industry and consumer advocates invoking the expected hiking prices of medicines after imposing the Bill C-91, and patent proponents including the Canadian Federal Government and the pharmaceutical multinational corporations. Finally, the Patent proponents succeeded to include patent protection in the NAFTA. Accordingly, the Canadian Bill C-91 entered into force on 4 February 1993, after receiving the Royal assent, representing a victory for the US pharmaceutical industry.[223]

The GATT negotiations represent another victory for the US pharmaceutical manufacturers and research associations. They exploited the success achieved by the NAFTA to seek for a global patent protection through a comprehensive agreement. So, they convinced several US-based multilateral corporations to create an intellectual property committee to promote the opinion

[221] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 18

[222] North American Free Trade Agreement (signed in US-Canada-Mexico 17 December 1992, entered into force 1 January 1994) 32 ILM 289 and 32 ILM 605 (NAFTA)

[223] Robert Weissman, 'A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rule, and the Remaining WTO Legal Alternatives Available to Third World Countries' (1996) 17 University of Pennsylvania Journal of International Economic Law 1069, 1080-1082. **See also**, The Patent Act Amendment Act (Bill C-91), 1992, SC1993, c 2

depicting the GATT as a suitable forum for the international regulation of intellectual property. Also, the US government argued that since intellectual property protection is related to the flow of international trade, then it should be addressed as a trade subject within the GATT forum. Both rallied their allies from Europe and Japan to negotiate a comprehensive agreement on intellectual property in the GATT rounds of multilateral trade negotiations. They contended that the GATT treaty was ideal for increasing patent protection due to its great power in international trade and its enforcement mechanism compared to the weak enforcement mechanism of the WIPO which administers the Paris Convention.[224]

In contrast, developing countries strongly favoured the WIPO for intellectual property negotiations noting that it is the sole platform to handle such matter. They felt that they would exercise greater influence if the negotiations were under the WIPO than they would in the GATT. The strong objections from developing countries vis-à-vis the insistence of developed countries led by the US on confining the negotiations to the GATT culminated in introducing the intellectual property subject in the GATT round of multilateral trade negotiations held at Punta Del Este – Uruguay in 1986.[225]

#### 2.3.3.1 The Negotiation Process of the TRIPS Agreement Regarding Pharmaceuticals

During the negotiations of the TRIPS agreement, developing countries argued for a weaker or more flexible patent protection for pharmaceuticals fearing restriction of generic drugs production which may cause public health concerns. By continuing to manufacture cheap generics, developing countries would maintain the price level of essential medicines at a low level rendering them accessible and affordable to all people. Further, large sectors of citizens would not afford the high prices of medicines resulting from patenting under the new global regime of intellectual property.[226]

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[224] Patrick L. Wojahn, 'A Conflict of Rights: Intellectual Property under TRIPS, the Right to Health and AIDS Drugs' (2001-2002) 6(2) UCLA Journal of International Law and Foreign Affairs 463, 477-478. **See also**, Robert Weissman, 'A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rule, and the Remaining WTO Legal Alternatives Available to Third World Countries' (1996) 17 University of Pennsylvania Journal of International Economic Law 1069, 1083-1084

[225] Peter Drahos, 'Four Lessons for Developing Countries from Trade Negotiations over Access to Medicines' (2007) 28(1) Liverpool Law Review 11, 15. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 44

[226] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 11, 76

On the contrary, the US and the European industrialized countries maintained a firm stance to adopt a standardized pharmaceutical patent protection system. The US regarded minimum period for patent protection as a pre-requisite for free trade.[227] They provided several reasons for such standard patent system, *inter alia*, that separate patent standards constitute trade distortions that curb the GATT objectives which provide for liberalizing global trade, and that free-riding practices over inventions destroy the incentives to invent. Big pharmaceutical corporations led by Pfizer contributed to drafting the strategy of pharmaceutical patenting which was presented during the negotiations.[228]

The developed countries suggested inclusion of a new 'trade-related' agreement which gathers all forms of intellectual property under the WTO. They offered developing countries trade concessions in return for accepting to accede to such agreement arguing that such concessions cannot be offered within the WIPO forum. Most likely, developed countries tried to find a strategic reason to convince developing countries to include intellectual property protection in the WTO rather than the WIPO to guarantee an effective protection under the robust enforcement mechanism of the WTO. That is why they claimed the presence of a substantive link between intellectual property law and trade law, although traditionally both systems have been regarded as separate from each other. The negotiations were complicated, and the discussions included substantive matters of intellectual property, like non-discrimination, patentable subject matter, compulsory licensing, local working requirements, patents term and pharmaceutical patents.[229]

Another reason that influenced the negotiations towards convincing the developing countries to accept the TRIPS agreement was the expectation of technological transfer. Developed countries

[227] Negotiating Group on TRIPS, Including Trade in Counterfeit Goods, 'Suggestion by the US for Achieving the Negotiating Objective' (17 October 1988) MTN.GNG/NG11/W/14/Rev.1, para III.A.2. **See also**, Negotiating Group on TRIPS, Including Trade in Counterfeit Goods, 'Meeting of Negotiating Group of 11, 12, and 14 December 1989' (23 January 1990) MTN.GNG/NG11/17, para 37. **See also**, Negotiating Group on TRIPS, Including Trade in Counterfeit Goods, 'Secretariat Note on the Meeting of 25 March 1987' (10 April 1987) MTN.GNG/NG11/1, paras 3, 4, 5, 9

[228] Robert Weissman, 'A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rule, and the Remaining WTO Legal Alternatives Available to Third World Countries' (1996) 17 University of Pennsylvania Journal of International Economic Law 1069, 1082-1085

[229] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 46, 47. **See also**, David W. Leebron, 'Linkages' (2002) 96(1) American Journal of International Law 5

argued that an adequate standard of protection and enforcement of IPRs were prerequisites to the transfer of technology and attraction of foreign direct investments to developing countries.[230]

After 7 years of long and arduous negotiations (between 1986 and 1993) and at sometimes acrimonious, states signed a full new agreement by the end of the Uruguay round on 15 April 1994, namely, the Final Act embodying the results of the Uruguay Round of Multilateral Trade Negotiations and the Marrakesh Agreement Establishing the WTO agreement, which includes several multilateral trade agreements, *inter alia*, the GATT 1994 and the TRIPS Agreement. The rules and procedures governing the settlement of WTO disputes are set forth in annex 2 of the WTO agreement, known as the WTO Dispute Settlement Understanding. WTO member States do not have a choice to pick and choose from the WTO agreements, i.e., it is a single package approach, either adopt all of them or choose not to be a member in the organization.[231]

Drahos, observed that the negotiating process was not democratic because it lacked three conditions that must be met in order to qualify as being democratic. He confined such conditions to representation of all relevant interests in the negotiations, offering full information to all states about the consequences of various possible outcomes, and one state party must not coerce the others. Drahos argued that none of the three conditions were met in the TRIPS negotiations. The genuine negotiations were mainly comprised of the US, Europe, and Japan, while the participation of developing countries was excluded. Even when they were present, most developing countries were not exactly aware of the possible outcomes of concluding the agreement due to lack of qualified legal experts specialized in intellectual property law.[232]

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[230] Sandra Bartelt, 'Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health' (2003) 6(2) Journal of World Intellectual Property 283, 286

[231] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 44, 45. **See also**, Duncan Matthews, *Globalising Intellectual property Rights: The TRIPS Agreement* (Routledge London and New York 2002) 7- 28. **See also**, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (15 April 1994) 1867 UNTS 14, 33 ILM 1143. **See also**, Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement). **See also**, Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU). **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS). **See also**, General Agreement on Tariffs and Trade, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187, 33 ILM 1153 (GATT 1994)

[232] Peter Drahos and John Braithwaite, *Information Feudalism: WHO Owns the Knowledge Economy* (Earthscan UK 2002) 187-197 <https://www.researchgate.net/publication/246471223_Information_Feudalism_Who_Owns_the_Knowledge_Economy > accessed 26 July 2019

Consequently, it could be inferred that the developing countries were forced to sign the TRIPS agreement due to the pressure put on them during the negotiation process. This resulted in narrowing their sovereignty to determine suitable levels of intellectual property protection that fit their needs, thus affecting the basic rights of their people, *inter alia*, the right to access to affordable medicines.

This previous backdrop is important because the dissertation will show in the following sub-section that the drafting of the TRIPS Agreement took into consideration the previous circumstances to convince and push the developing countries to accede to the agreement.

#### 2.3.3.2 The TRIPS Agreement

The TRIPS agreement, which came into effect on 1 January 1995, is to date the most comprehensive multilateral agreement on IPRs. It forms a part (Annex 1C) of the WTO Agreement that was signed in Marrakesh, Morocco on 15 April 1994 during the Final Act of the Uruguay round of talks on the GATT.[233]

The agreement represents a significant step in the globalisation of IPRs, where it incorporates the key provisions of the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits. While it stipulated that there is no derogation from the existing obligations that members may have towards each other under the previous conventions, it exceeded this by setting a global minimum standard for IPRs protection. The TRIPS objectives include providing a multilateral framework for an effective and adequate intellectual property protection, liberalizing trade by reducing international trade distortions, promoting technological innovation, and disseminating and transferring technology. All WTO members are obliged to amend their national legislations on IPRs protection and implement minimum standards of protection to conform with the TRIPS obligations. Otherwise, they would be subject to the WTO dispute settlement mechanism.[234]

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[233] Tanya Aplin and Jennifer Davis, *Intellectual property Law: Text, Cases and Materials* (2nd edn, Oxford University Press 2013) 550. **See also**, WTO, 'Overview: The TRIPS Agreement' < https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> accessed 10 March 2019

[234] Olufunmilayo Arewa, 'TRIPS and Traditional Knowledge: Local Communities, Local Knowledge and Global Intellectual Property Frameworks' (2006) 10(2) Marquette Intellectual Property Law Review 154, 156. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) arts 2, 27-34

The subjects of the TRIPS agreement are the right-holders, whether persons, institutions, or corporations. The TRIPS agreement seeks to achieve its objectives by specifically protecting the private property rights of individuals and corporations. This differs from other WTO agreements which seek to reduce trade restrictions between states by prohibiting any kind of discrimination related to foreign goods and services. In other words, TRIPS agreement protects the right-holders, while other WTO agreements safeguard the interests of the beneficiaries (WTO member states).[235]

Consequently, the influence of the TRIPS agreement on national policies relies on the national systems rather than the TRIPS agreement *per se*, while the influence of other WTO agreements on national policies depends directly on the obligations enshrined in the provisions of such agreements.[236] By protecting the private rights of individuals rather than states interests, the TRIPS agreement gave a chance to the holders of such rights to try to gain priority in safeguarding important national or individual values over public rights. This was emphasized by Petersmann when he noted that the TRIPS negotiations resulted in "one-sided protection of producer rights" and "may be inconsistent with the human rights interests of consumers in maximum equal liberty and open markets."[237]

This development demonstrates that the globalisation of intellectual property is inevitable. The proliferation of international agreements covering this area is crucial evidence of such globalisation. However, this proliferation constitutes an extraterritorial tension between users and owner groups. A tension also appeared between states obligations to protect pharmaceutical patents and their obligations towards human rights and the public good of the whole international society. The dissertation shall address in the following sub-section the efforts exerted to balance the private rights of producers in the TRIPS agreement with the human rights interests.

Before the TRIPS adoption, every state retained free latitude in determining its national intellectual property system as long as it treated foreign nationals similar to its nationals. However, after the TRIPS adoption, all WTO members are obliged to provide the same level of

[235] Matthew StillWell and Elisabeth Tuerk, 'Towards a Full Review of the WTO'S TRIPS Agreement Under Article 71.1' (April 2001) Centre for International Environmental Law Research Paper, 12 < https://www.ciel.org/wp-content/uploads/2015/03/Assessment_Trips_article711.pdf> accessed 19 March 2019
[236] Hans Morten Haugen, *The Right to Food and the TRIPS Agreement with Particular Emphasis on Developing Countries' Measures for Food production and Distribution* (Martinus Nijhoff Publishers Leiden Netherlands 2007) 216-217
[237] Ernst-Ulrich Petersmann, 'Human Rights and International Economic Law in the 21st Century: The Need to Clarify Their Interrelationships' (2001) 4(1) Journal of International Economic Law 3, 27

intellectual property protection independently of their level of development. Although the agreement attempts to harmonize intellectual property laws, its provisions did not oblige member states to adopt harmonized national laws. It only imposed minimum standards of protection leaving members free to provide more extensive protection of intellectual property provided that such limit of protection does not contravene the obligations set forth in the agreement.[238]

Furthermore, the TRIPS granted developing and least-developed countries transitional periods to delay their TRIPS obligations in all intellectual property fields including patents. This period has since expired and developing countries are obliged to fully implement the TRIPS provisions.[239] For the least-developed countries, the transitional period was extended, with respect to pharmaceuticals, to 1 January 2016,[240] then further extended to 1 January 2033.[241] To help least-developed countries during the transitional period, the agreement obliged developed countries to provide incentives to their national enterprises to encourage them to transfer technology to least –developing countries. As such, they help them to "create a sound and viable technological base."[242]

Another distinctive feature of the TRIPS agreement is that it brings disputes regarding intellectual property protection under the robust enforcement mechanism for dispute settlement stipulated in the WTO DSU.[243] By virtue of the DSU, any dispute relating to compliance with the TRIPS norms may be brought to the WTO adjudicating bodies (WTO panels and Appellate

[238] Peter K. Yu, 'TRIPS and its Achilles' Heel' (2011) 18 Journal of Intellectual property Law 479, 504. **See also**, Peter Drahos, 'Four Lessons for Developing Countries from Trade Negotiations over Access to Medicines' (2007) 28(1) Liverpool Law Review 11, 15-17. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 1(1)

[239] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) arts 65, 66(1)

[240] Extension of the Transitional Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products (1 July 2002) WTO Doc IP/C/25 (TRIPS Council Decision of 27 June 2002)

[241] Extension of the Transitional Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products (6 November 2015) WTO Doc IP/C/73 (TRIPS Council Decision of 6 November 2015). **See also**, WTO, 'WTO Members agree to extend Drug Patent Exemption for Poorest Members' < https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm > accessed 15 July 2019

[242] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 66(2). **See also**, Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press New York 2007) 8

[243] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 64(1)

Body). Such mechanism is not found in the Paris Convention. This was one of the main reasons that made developed countries move to the WTO for intellectual property protection instead of the weak enforcement mechanism of the WIPO.

The disputes between WTO members regarding the interpretation or the implementation of the TRIPS agreement provisions take as a starting point national legislation. The disputes arise due to lack of legislations providing IPRs protection, insufficient standards for protection, or the unjustified legislative exceptions which undermines the enjoyment of the rights even if there is no discrimination between national and foreign right holders. However, the disputes relating to other WTO agreements arise only due to discriminatory practices, *inter alia*, subsidies, any form of trade barriers, or other effects of market distortion.[244] The dissertation shall demonstrate later in chapter 5 the jurisdiction of the WTO adjudicating bodies and the WTO DSU jurisprudence in order to examine whether the WTO system took into account non-WTO treaties, specifically human rights, when clarifying WTO provisions in the context of WTO disputes or otherwise.

### 2.3.4 The Post-TRIPS Period

#### 2.3.4.1 The Doha Declaration

After the adoption of the TRIPS agreement, its potential impact on public health became a serious concern. Problems emerged after the application of the TRIPS, particularly the effect of restricting compulsory licences on the accessibility to essential medicines and the absence of a precise definition in the agreement as to what constitutes an essential medicine. Multi-national pharmaceutical companies, with the help of US and European countries, initiated aggressive campaigns to discourage the efforts of developing countries to utilize the TRIPS flexibilities for public health issues.

Two prominent cases show the strife between both camps; the first is the the South African Medicines and Related Substances Control Amendment Act, and the second is related to the Brazilian patent law.[245]

[244] Hans Morten Haugen, *The Right to Food and the TRIPS Agreement with Particular Emphasis on Developing Countries' Measures for Food production and Distribution* (Martinus Nijhoff Publishers Leiden Netherlands 2007) 217-218

[245] Laurence R. Helfer and Graeme W. Austin, *Human Rights and Intellectual property: Mapping the Global Interface* (Cambridge University Press 2011) 146

The South African Medicines and Related Substances Control Amendment Act issued on 12 December 1997 is one of the cases that received big attention. The Act, passed by the South African National Assembly, granted the Health Minister the authority to prescribe conditions for the parallel imports of patented medicines, especially HIV/AIDS drugs, in order to " supply more affordable medicines in certain circumstances to protect the health of the public."[246] The Act was an attempt by the South African government to provide affordable access to medicines, particularly those for HIV/AIDS, after the AIDS crisis in the country had reached epidemic proportions, putting South African population in danger of being extinct.[247]

The South African Act was criticized by the US, EU and major pharmaceutical companies because it gave the South African Health Minister the authority to restrict pharmaceutical patents. They argued that the Act violates the TRIPS obligations because it allowed the health minister to issue compulsory licences and to use parallel imports without limits.[248] The US imposed trade pressure on South Africa and withheld preferential tariff treatment. It put South Africa on its 'Special 301' watch list arguing that the Act granted the Minister of Health an ill-defined power to issue compulsory licences and to authorize parallel importation, thus abrogating international patent rights.[249]

Further, the pharmaceutical firms challenged the Act in front of the High Court of South Africa arguing that it violates the South African Constitution which protects property rights and is inconsistent with article 27 of the TRIPS agreement as it allegedly discriminates against patent rights in the pharmaceutical field.[250] The South African government defended by stating that, according to the constitution, the parliament has the right to declare the AIDS crisis a national emergency and to oblige the government to act respectively to protect the citizens' right to health.[251] By virtue of article 31(c) of the TRIPS agreement, the government argued, TRIPS

[246] Ibid. **See also**, Medicines and Related Substances Control Amendment Act, Act No 90 of 1997, amending the Medicines and Related Substances Control Act No 101 of 1965, Republic of South Africa Government Gazette No 18505 (12 December 1997) Sec 15/C

[247] Patrick Marc, 'Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?' (2001) 21 New York Law School Journal of International and Comparative Law 109, 118-119

[248] Laurence R. Helfer and Graeme W. Austin, *Human Rights and Intellectual property: Mapping the Global Interface* (Cambridge University Press 2011) 146

[249] Patrick Marc, 'Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?' (2001) 21 New York Law School Journal of International and Comparative Law 109, 119-121

[250] *Pharmaceutical Manufacturers' Association of South Africa et al v President of the Republic of South Africa et al,* High Court of South Africa (Transvaal Provincial Division), Case No 4183/98, Notice of Motion (1998) paras 2.3, 2.4

[251] Constitution of the Republic of South Africa, 10 December 1996, art 37(1). The article states that "A state of emergency may be declared only in terms of an Act of Parliament, and only when the life of nation is threatened

member states have the right to issue compulsory licences without the authorization of the patent holder with the proviso that the manufactured drug under compulsory licence is limited to the purpose for which it was authorized. Ironically, the US was one of the biggest critics of the South African amendment Act, yet it was the country which suggested the inclusion of article 31 in the TRIPS.[252]

Later the lawsuit was withdrawn due to the heated debate about it and the unbearable pressure from activists, media and NGOs, signifying that the right to health has to precede patent rights. With the mediation of the UN Secretary-General, pharmaceutical companies acknowledged that the amended Medicine Act was consistent with the TRIPS, and announced its commitment to jointly work with the South African government to promote public health. Further, due to the AIDS activists demonstrations against the US opposition to the South African Act, both countries reached a temporary agreement on 16 September 1999 requiring the US to withdraw its threat to impose trade sanctions and to favour the efforts of South Africa to provide affordable health care for its people.[253]

The other prominent case is the WTO dispute settlement proceedings initiated by the US against Brazil. The US claimed that the Brazilian Industrial Property Law 1996 was incompatible with article 27(1) of the TRIPS because it authorized the government to grant compulsory licences upon failure to locally work the patents, either products or processes. Thus, the Brazilian law discriminated regarding the enjoyment of patent rights whether the products are imported or locally produced. Brazil argued that such licenses are necessary to pursue its free HIV/AIDS treatment program initiated in 1996 and to allow better accessibility to HIV/AIDS drugs.[254]

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by war, invasion, general insurrection, disorder, natural disaster or other public emergency; and the declaration is necessary to restore peace and order."

[252] Patrick Marc, 'Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?' (2001) 21 New York Law School Journal of International and Comparative Law 109, 123. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 27(3)

[253] *Pharmaceutical Manufacturers' Association of South Africa et al v President of the Republic of South Africa et al*, Constitutional Court of South Africa, (CCT31/99) [2000] ZACC 1; 2000 (2) SA 674; 2000 (3) BCLR 241 (25 February 2000). **See also**, Rosalyn S. Park, 'The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients' (2002) 11(1) Minnesota Journal of Global Trade 125, 136-139. **See also**, Matthew Leis, 'Death by Treaty: South Africa's Medicines and Related Substances Amendment Act of 1997 and the Agreement on Trade Related Aspects of Intellectual Property Rights' (2004) 3(1) Journal of International Business and Law 221, 222-223. **See also**, Steven Lee Myers, 'South Africa and U.S. End Dispute Over Drugs' (The New York Times, 18 September 1999) < https://www.nytimes.com/1999/09/18/world/south-africa-and-us-end-dispute-over-drugs.html> accessed 11 March 2019

[254] Brazil Industrial Property Law No 9.279 of 14 May 1996, art 68(1). This article stated several reasons for compulsory licences authorization, *inter alia*, if the patentee exercises his rights in an abusive manner, failure to exploit the subject matter of the patent in the Brazilian territory, failure to manufacture the product, or failure to

Later, a satisfactory solution was reached, and the case was withdrawn due to the reputational damages that the pharmaceutical companies in the US would face, if they insisted on their position, and the pressure from human rights activists, media and international organizations.[255]

In addition to the two previous cases, Bristol Mayers, one of the biggest pharmaceutical corporations and a patent holder for "Videx" medicine used to treat HIV/AIDS, objected Thailand's attempt to issue a compulsory licence for the production of this drug at a 50 percent discount. Médecins Sans Frontières or Doctors Without borders, a humanitarian organization that was awarded the Nobel Prize in 1999, defended Thailand's right to grant compulsory licensing according to the TRIPS to remedy national crises. The organization followed the steps of UNAIDS, which is a joint effort of UNICEF, and the WHO in declaring HIV/AIDS as a national emergency. They emphasized that granting compulsory licences to produce AIDS drugs complies with the TRIPS provisions.[256]

The US also supported the pharmaceutical companies view that patents were not an obstacle to better accessibility to medicine. Since the price of medicines was only one factor in the public health system, the usage of the TRIPS flexibilities should be very limited.[257] This argument was rebutted after the emergence of the Anthrax threat in September 2001. Many people were infected and became ill or died after being exposed to mails from the US holding the Anthrax bacteria. Canada announced that it will issue a compulsory licence to an Indian pharmaceutical company to produce a generic version of an Antibiotic called Cipro. This medicine was patented by Bayer pharmaceutical company and known to be effective against Anthrax. The generic drug was called Cipla, and its price was half the price of the patented drug Cipro. Bayer company threatened that it would resort to litigation, but Canada defended its right to buy generic drugs at a low price for the public health of its people. This case attracted the attention of the WTO to the tension between TRIPS agreement and accessibility to medicine. It showed that "no

fully use the patented process. **See also**, Request for the Establishment of a Panel by the United States, *Brazil - Measures Affecting Patent Protection* (9 January 2001) WTO Doc WT/DS199/3

[255] Laurence R. Helfer and Graeme W. Austin, *Human Rights and Intellectual property: Mapping the Global Interface* (Cambridge University Press 2011) 157. **See also**, Notification of Mutually Agreed Solution, *Brazil - Measures Affecting Patent Protection* (19 July 2001) WTO Doc WT/DS199/4, G/L/454, IP/D/23/Add.1

[256] Patrick Marc, 'Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?' (2001) 21 New York Law School Journal of International and Comparative Law 109, 122-123

[257] Frederick M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lightening a Dark Corner at the WTO' (2002) 5 Journal of International Economic Law 469, 485

responsible government with a choice would place the public health of its citizens below the interests of a few patent holders."[258]

Influenced by the previous cases in addition to the price inflation of essential medicines after adopting the TRIPS agreement, the NGOs flagged the problem of accessibility to medicines in TRIPS agreement in international fora.[259] Developing countries sought an official confirmation that the WTO dispute settlement mechanism would not be used against them if they adopted specific measures according to the TRIPS flexibilities to protect public health.[260] By conducting a series of negotiations and conferences, the NGOs succeeded in urging the WTO to call for a Ministerial Conference in Doha in 2001 to negotiate public health issues within the TRIPS provisions and the measures that could be taken to ensure better accessibility to medicines in developing countries. The Doha Declaration was adopted on 14 November 2001,[261] and it was considered a victory for NGOs and developing countries and an important step in balancing between pharmaceutical patents under the TRIPS agreement and public health.

The Doha Declaration recognized the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.[262] As such, the declaration is not limited to certain diseases but rather it is applicable to all public health diseases. The inclusion of specific epidemics in the declaration is only for illustration.[263]

The declaration emphasized that the TRIPS should be part of the national and international action to address public health problems.[264] While it recognized that intellectual property protection is indispensable for pharmaceutical industry, it also recognized "the concerns about its effects on prices."[265] This recognition reflects the acknowledgment that patents can be an impediment to access to medicines.

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[258] Ibid, 488. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 16
[259] Valbona Muzaka, *The Politics of Intellectual Property Rights and Access to Medicines* (Palgrave Macmillan UK *2011) 60*
[260] Susan K. Sell, *Private Power, Private Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press 2003) 158
[261] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration)
[262] Ibid, para 1
[263] WHO, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health/ Carlos M. Correa' (June 2002) WHO Doc WHO/EDM/PAR/2002.3, 5
[264] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration) para 2
[265] Ibid, para 3

Further, the declaration reiterated the rights of developing countries to use the flexibilities in the TRIPS agreement to balance between pharmaceutical patenting and the accessibility to essential medicines. It asserted that each state has the right to determine what constitutes national emergency or other circumstances of extreme urgency, establish its own regime of exhaustion of IPRs and consequently permit or prohibit the parallel importation, and right to grant compulsory licences according to the conditions it determined. It also asserted that the TRIPS agreement should not prevent states from taking measures to protect public health.[266] However, the declaration failed to allow health concerns to prevail over TRIPS obligations because it stated that the interpretation and implementation of the TRIPS provisions, in a manner supportive of WTO members' right to protect public health and promote access to medicine, should not contravene with the TRIPS obligations.[267]

This was a controversial provision during the negotiations of the declaration. Developing countries were hoping for a statement similar to the general exceptions in article XX of the GATT stipulating that nothing in the GATT shall be construed to prevent states from adopting or enforcing measures necessary to protect human health.[268] Their target was to obtain recognition that nothing in the TRIPS shall be interpreted in a manner that could prevent them from adopting measures necessary to protect public health. This would render ineffective the last part of the sentence in article 8(1) of the TRIPS which restrict using public health flexibilities in the TRIPS unless they are consistent with its provisions. On the other hand, developed countries did not view the TRIPS agreement as an impediment to the achievement of public health objectives. As such, they did not want to undermine any of the TRIPS obligations.[269]

An important achievement in the Doha Declaration is the recognition of the difficulties facing WTO members, with insufficient or no manufacturing capacities in the pharmaceutical sector, when they use the compulsory licensing system under the TRIPS. Instead of proposing a solution to this problem, paragraph 6 of the Doha Declaration instructed the TRIPS Council to find an expeditious solution to it and report to the General Council before the end of 2002. Practically, such countries were not able to exercise their rights in using the compulsory

[266] Ibid, paras 4, 5
[267] Ibid, para 4. **See also**, WHO, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health/ Carlos M. Correa' (June 2002) WHO Doc WHO/EDM/PAR/2002.3, 9
[268] General Agreement on Tariffs and Trade, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187, 33 ILM 1153 (GATT 1994) art XX
[269] WHO, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health/ Carlos M. Correa' (June 2002) WHO Doc WHO/EDM/PAR/2002.3, 9-10

licensing system under the TRIPS provisions. On one side, they lack the manufacturing capacities needed to produce pharmaceuticals. On the other, they cannot import the needed medicines from another country because article 31(f) of the TRIPS required that the generic medicines produced according to compulsory licences should be authorized predominantly for the supply of the domestic market of the authorizing country. Once a state begins to export more than 50% of the medicines it manufactures, it exposes itself to arguments of breaching its obligation under article 31 of the TRIPS.[270]

Most of the public health advocates have generally hailed the Doha Declaration as an important achievement towards the protection of public health against private intellectual property.[271] It was considered a breakthrough in attracting the international attention to the tension between TRIPS and public health.[272] Notably, in a symposium on Global Health marking the 10th anniversary of the Doha Declaration, Pascal Lamy, the former WTO Director-General, mentioned that the declaration changed the perception that TRIPS agreement and pharmaceutical patents were obstacles to public health. The declaration affirmed that they are consistent with each other. Lamy asserted that "the TRIPS agreement does not and should not prevent members from taking measures to protect public health."[273]

On the contrary, a few public health supporters criticized the Doha Declaration for refraining from establishing any sort of automatic or mandatory primacy of access to medicine over the pharmaceutical patent protection obligation in the TRIPS agreement as shown above.[274]

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[270] Ellen 't Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha' (2002) 3(1) Chicago Journal of International Law 27, 40-46. **See also**, Peter Drahos, 'Four Lessons for Developing Countries from Trade Negotiations over Access to Medicines' (2007) 28(1) Liverpool Law Review 11, 11-12. **See also**, Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration) para 6. **See also**, Developing Country Group, 'TRIPS and Public Health Paper submitted to the TRIPS Council for the Special Discussion on Intellectual Property and Access to Medicines' (19 June 2001) WTO Doc IP/C/W/296 < https://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm > accessed 17 April 2019

[271] Ellen 't Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha' (2002) 3(1) Chicago Journal of International Law 27, 28. **See also**, Tshimanga Kongolo, 'TRIPS, the Doha Declaration and Public Health' (2003) 6(2) Journal of World Intellectual property 373, 378

[272] Elena Ghanotakis, 'How the U.S. Interpretation of Flexibilities Inherent in TRIPS Affects Access to Medicines for Developing Countries' (2004) 7(4) Journal of World Intellectual Property 563, 579

[273] WTO, '10-Year-Old WTO Declaration has Reinforced Health Policy Choices: Lamy Tells Symposium' (2011) WTO New Items < https://www.wto.org/english/news_e/news11_e/trip_23nov11_e.htm> accessed 3 July 2019

[274] Roger Kampf, 'Patents Versus Patients?' (2002) 40(1) Archiv Des Völkerrechts 90, 98 < https://www.jstor.org/stable/40800024?seq=1#metadata_info_tab_contents> accessed 3 February 2020

Most commentators and scholars considered that the Doha Declaration is merely a political and moral statement with practical implications. It emphasized the right of developing countries to adopt measures necessary to ensure accessibility to medicines and created political obstacles to bring disputes against states that use the TRIPS flexibilities to respond to public health emergencies. Also, it clarified some of the uncertainty in the interpretation of the TRIPS provisions, *inter alia*, the question of permissibility of the exhaustion of patent rights which allow developing countries to resort to parallel importation of generic versions of patented medicines in response to public health emergencies. However, the declaration has insignificant legal implications in WTO law framework because it only restricted the exercise of patent rights and emphasized the flexibilities that already exist in the TRIPS agreement without creating new legal obligations other than those mentioned in the TRIPS.[275]

A few scholars, however, argued that the declaration is a legally binding instrument like the decisions taken by the TRIPS Council. Carlos Correa argued that the Doha Declaration is a "ministerial decision with legal effects on the members and on the WTO bodies, particularly the Dispute Settlement Body and the Council for TRIPS." He considered that the declaration has the same effect as an authoritative interpretation, particularly, in "providing an agreed understanding on certain aspects of the TRIPS agreement" and in "creating a binding precedent for future panels and Appellate Body reports."[276] Fredrick Abbott asserted that it is a legal instrument which "prove significant in supporting interpretations that promote the protection of public health."[277]

The argument considering the Doha Declaration a binding authoritative interpretation of the TRIPS agreement cannot be tenable. By virtue of article IX (2) of the WTO Agreement, only the "Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of the WTO Agreement and of the Multilateral Trade Agreements… The decision to adopt an interpretation shall be taken by a three-fourths majority of the Members."[278]

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[275] Ibid, 125. **See also**, Jeffrey J. Schott, 'Comment on the Doha Ministerial' (2002) 5(1) Journal of International Economic Law 191, 195. **See also**, Paul Vandoren and Jean Charles Van Eeckhaute, 'The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making it Work' (2003) 6(6) Journal of World Intellectual Property 779, 780. **See also**, Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 307

[276] WHO, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health/ Carlos M. Correa' (June 2002) WHO Doc WHO/EDM/PAR/2002.3, viii, 44

[277] Fredrick M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 Journal of International Economic Law 469, 470

[278] Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement) art IX(2)

However, the declaration was adopted at a Ministerial Conference in Doha, yet it did not take the three-fourths majority required to adopt an authoritative interpretation. If the Doha Declaration is not an authoritative interpretation which requires a procedure less onerous than the procedures for treaty amendments stipulated in article X of the WTO Agreement, then, *a fortiori*, the declaration is not an amendment of the TRIPS Agreement. As such, it is not a binding instrument, but rather it could be considered a non-binding authoritative interpretation supporting the right of WTO members to promote accessibility to medicines.[279]

Later in chapter 5, the dissertation shall address the rules of interpretation according to the VCLT. It shall show that non-binding authoritative interpretations do not amount to subsequent agreements or subsequent practice within the meaning of articles 31(3)(a)(b) of the VCLT. As Ehlermann and Ehring explained, non-binding authoritative interpretations are only a mere reference or confirmation of legal findings the WTO panels and Appellate Body have developed independently of such interpretative interpretation.[280] Notably, the WTO DSU required the interpretation of WTO agreements in compliance with customary rules of interpretation of public international law. The WTO jurisprudence considered the VCLT a codification of such customary rules.[281]

Generally, the Doha Declaration was considered a victory to developing countries regardless of its legal status issue. The dissertation shall explain in the following sub-section why such victory was watered down afterwards by the drafting of the 30 August 2003 Decision.

#### 2.3.4.2 The 30 August 2003 Decision

The 30 August Decision was drafted to implement paragraph 6 of the Doha Declaration which sought to find a solution for an effective usage of the compulsory licence system under the

[279] Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 307-308

[280] Claus-Dieter Ehlermann and Lothar Ehring, 'The Authoritative Interpretation Under Article Ix:2 of the Agreement Establishing the World Trade Organization: Current Law, Practice and Possible Improvements' (2005) 8(4) Journal of International Economic law 803, 807-808

[281] WTO Appellate Body Report, *United States - Standards for Reformulated and Conventional Gasoline* (adopted 20 May 1996) WTO Doc WT/DS2/AB/R, 17. **See also**, WTO Appellate Body Report, *Japan - Taxes on Alcoholic Beverages* (adopted 1 November 1996) WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, 10-11. **See also**, Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 3(2). **See also**, Ian Sinclair, *The Vienna Convention on the Law of Treaties* (2nd edn, Manchester University Press 1984) 153. **See also**, Daya Shanker, 'The Vienna Convention on the Law of Treaties: The Dispute Settlement System of the WTO and the Doha Declaration on the TRIPS Agreement' (2002) 36(4) Journal of World Trade 721, 728-730

TRIPS agreement for countries with no or insufficient pharmaceutical manufacturing capabilities. It is also known as the TRIPS waiver Decision because it provided for waivers of states obligations under article 31(f) and (h) of the TRIPS agreement with respect to pharmaceutical products.[282]

Before adoption of the decision, there was much controversy regarding the mechanism to be adopted to implement paragraph 6 of the Doha Declaration and the scope of diseases to be covered by such mechanism. Developing countries were seeking an authoritative interpretation of the limited exceptions to the pharmaceutical patents, stipulated in article 30 of the TRIPS agreement, to be adopted by the WTO General Council. They opined that such mechanism was capable of authorizing generic manufacturers, without the consent of the patentee, to make, sell and export patented medicines to address public health needs in another country. They argued that such solution would not "unreasonably prejudice the legitimate interests of the patent owner," as required in article 30 of the TRIPS, since the act of "exporting" is not listed among the exclusive rights conferred to patentees by virtue of article 28 of the TRIPS.[283] Also, developing countries proposed that the diseases to be covered by the adopted mechanism should include chronic diseases, like diabetes, cancer, asthma, cardiovascular diseases and chronic respiratory disease. They considered them diseases that affect public health in developing countries.[284]

On the other hand, developed countries proposed a solution either based on the amendment of article 31(f) of the TRIPS agreement or a waiver that provides certainty to the manufacturing countries that their pharmaceutical production and export shall not be subject to challenge. Further, developed countries refused to expand the scope of medicines to include chronic diseases. They insisted that the exemption should be limited to what was mentioned in the Doha

[282] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision). **See also**, Carlos M. Correa, 'Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?' (January 2019) South Centre Policy Brief No 57, 2 < https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf> accessed 12 April 2020

[283] WTO TRIPS Council, 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Communication from the Permanent Mission of Brazil on Behalf of the Delegations of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela' (24 June 2002) WTO Doc IP/C/W/355, paras 8, 10

[284] Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 314-315. **See also**, Duncan Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) 7(1) Journal of International Economic Law 73, 83-85. **See also,** Council for TRIPS, 'Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation' (11 July 2002) WTO Doc IP/C/W/363, 4

Declaration, i.e., covering only grave public health problems afflicting developing and least-developed countries, particularly those resulting from HIV/AIDS, Tuberculosis, Malaria, in addition to other epidemic diseases.[285]

Responding to the demands of developed countries, the 30 August Decision was adopted as a waiver of states obligations, regarding pharmaceutical patents, under article 31(f) and (h) of the TRIPS agreement.

The decision allowed pharmaceuticals made under compulsory licence to be exported to countries lacking manufacturing capacities. It waived the obligation under article 31(f) stipulating that such pharmaceuticals should be predominantly for the supply of domestic market of the member authorizing the compulsory licence. As such an exporting member can issue compulsory licences "to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)."[286]

Further, the decision dealt with the problem of double remuneration to the patentees. By virtue of article 31(h) of the TRIPS, patentees have the right to obtain adequate remuneration whenever the compulsory licensing system is used to produce generic versions of patented medicines. Thus, they receive remuneration from the exporting and importing countries according to the economic value of the compulsory licence authorization. The decision waived such obligation on eligible importing members and confined it to the exporting members. As such, the exporting members who granted compulsory licences according to the decision are obliged to pay adequate remuneration to the patent holders pursuant to article 31(h) of the TRIPS "taking into account the economic value to the importing member of the use that has been authorized in the exporting member."[287]

Moreover, the scope of medicines to be covered under the decision is restricted to those mentioned in the Doha Declaration, i.e., HIV/AIDS, Tuberculosis, Malaria, and other epidemic diseases.[288] In order to ensure that the medicines imported under the compulsory licence system set out in the decision are used for public health purposes only, the declaration obliged eligible importing members to take adequate measures to prevent re-exportation of such medicines.[289]

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[285] Ibid
[286] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision) para 2
[287] Ibid, para 3
[288] Ibid, para 1(a)
[289] Ibid, para 4

Unlike the TRIPS agreement which did not differentiate between different types of developing countries, the 30 August Decision introduced a new distinction between developing countries. The decision considered that the least-developed countries are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector, thus they are the only eligible importing members to use the waiver. Developing countries or other countries are not allowed to use the waiver unless they notify the TRIPS Council of their intention to use the waiver as an importer. This notification is only in cases of "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."[290]

This differentiation was criticized by the NGOs for denying the equal rights of accessibility to generic medicines for many developing countries that are not considered least-developed countries and at the same time they could not produce generic versions of patented drugs for themselves.[291] The differentiation between potential beneficiary countries was not mentioned in paragraph 6 of the Doha Declaration which simply refers to "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector." Thus, the decision failed to implement precisely what was mentioned in paragraph 6 of the Doha Declaration.

Moreover, the 30 August Decision stated a group of robust requirements to utilize the compulsory licences under the waiver. Those requirements were designed to ensure that the generic versions of patented drugs, directed to eligible importing countries, would not be diverted to developed country markets. However, such requirements were onerous and rendered utilizing the waiver burdensome for eligible countries due to the intricate procedures resulting in lengthy delays and high financial costs. It obliged the eligible importing member to make a notification to the TRIPS Council about several requirements, *inter alia*, the names and expected quantities of medicines. On the other side, the exporting member has to notify the TRIPS Council of the grant of the compulsory licence and the licence should include several requirements, *inter alia*, the quantities, labelling, shape and colour of the drugs.[292]

The NGOs expressed their alarm at the decision because it was overly inefficient and failed to address the economic realities of the production of generic medicines. Instead of increasing the accessibility to medicines, there were signs of steep price increases in newer medicines, like

[290] Ibid, para 1(b), Annex
[291] Duncan Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) 7(1) Journal of International Economic Law 73, 87
[292] Ibid, 96-97. **See also**, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision) para 2

second-line AIDS drugs. The decision showed that the WTO ignored the problem of affordable and accessible essential medicines to all people.[293] On the contrary, the pharmaceutical industry voiced its contentment with the decision because it favoured its interests.

Consequently, the 30 August 2003 Decision was considered a defeat for developing countries because it required several intricate procedures to utilize the compulsory licence system.[294] Indeed, it watered down the wording of the Doha Declaration due to failure to resolve the outstanding issue of generic medicines. It showed the persistence of developed countries to limit the scope of any waiver or flexibility, under the TRIPS agreement, that would allow better accessibility to medicines for developing countries. It emphasized the view of developed countries and pharmaceutical companies that the TRIPS agreement is not an impediment to public health but rather an effective mechanism necessary for maintaining a robust patent protection for pharmaceuticals. The dissertation shall show later in this chapter the decision's cumbersome requirements for utilizing the compulsory licensing system.

It is worth noting that the 30 August Decision instructed the TRIPS Council to initiate by the end of 2003, work on transforming its contents into a permanent amendment to the TRIPS agreement with a view to its adoption within six months. The 30 August Decision, including the waivers granted, "shall terminate for each member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member."[295]

Consequently, the WTO General Council adopted a Decision on 6 December 2005 to amend article 31 of the TRIPS agreement. The amendment is in the form of a Protocol which inserts new article 31 *bis* after article 31of the TRIPS agreement and an Annex after article 73 of the TRIPS agreement. The content of the amendment follows the exact wording of the 30 August 2003 Decision. Article 31 *bis* exempts WTO members from their obligations under article 31(f) of the TRIPS agreement, when granting a compulsory licence, to the extent necessary to produce

[293] 'Amendment to WTO TRIPS Agreement Makes Access to Affordable Medicines Even More Bleak' (Médecins Sans Frontières, 6 December 2005) < https://www.msf.org/amendment-wto-trips-agreement-makes-access-affordable-medicines-even-more-bleak> accessed 2 March 2020

[294] Peter Drahos, 'Four Lessons for Developing Countries from Trade Negotiations over Access to Medicines' (2007) 28(1) Liverpool Law Review 11, 14. **See also**, Brook K. Baker, 'Arthritic Flexibilities: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (2004) 14(3) Indiana International and Comparative Law Review 613, 633-635, 655. **See also,** Duncan Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) 7(1) Journal of International Economic Law 73, 96-97, 105-106

[295] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision) para 11

pharmaceutical products and their export to an eligible importing WTO member. It also obliges the exporting country to pay adequate remuneration to the patent holder as stated in article 31(h) of the TRIPS agreement. The Annex inserted after article 73 of the TRIPS contains the definitions, notification procedures and conditions for exemption that were mentioned in the 30 August Decision. Article 31 *bis* and the Annex do not prejudice the rights, obligations and flexibilities that states members have under the TRIPS provisions other than article 31 paragraphs (f) and (h).[296]

Accordingly, any WTO member willing to benefit from the permanent amendment, which allow exporting pharmaceutical products made under compulsory licence system, should accept the amendment in addition to changing its own patent law to allow it to do so.[297]

The entry into force of this amendment (protocol) requires the acceptance of two-thirds majority of the WTO member states in accordance with article X (3) of the WTO Agreement. After being accepted by the said majority, the amendment becomes immediate effective for only the WTO member states that accepted it. It becomes effective after that for each WTO member upon acceptance by it.[298] The deadline was set for 1 December 2007 then it was extended by the General Council several times because it was not accepted by the two-thirds majority. As such, the deadline was extended to 31 December 2009, then to 31 December 2011, and so on every 2 years until 31 December 2021.[299]

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[296] Amendment of the TRIPS Agreement (8 December 2005) WT/L/641 (Decision of 6 December 2005). **See also**, WTO, 'Members OK Amendment to Make Health Flexibility Permanent' (6 December 2005) Press/426 < https://www.wto.org/english/news_e/pres05_e/pr426_e.htm> accessed 5 March 2020

[297] WTO, 'Members OK Amendment to Make Health Flexibility Permanent' (6 December 2005) Press/426 < https://www.wto.org/english/news_e/pres05_e/pr426_e.htm> accessed 5 March 2020

[298] Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement) art X(3)

[299] Amendment of the TRIPS Agreement –Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement (21 December 2007) WT/L/711 (Decision of 18 December 2007). **See also**, Amendment of the TRIPS Agreement – Second Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement (21 December 2009) WT/L/785 (Decision of 17 December 2009). **See also**, Amendment of the TRIPS Agreement – Third Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement (5 December 2011) WT/L/829 (Decision of 30 November 2011). **See also**, Amendment of the TRIPS Agreement – Fourth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement (27 November 2011) WT/L/899 (Decision of 26 November 2013). **See also**, Amendment of the TRIPS Agreement – Fifth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement (2 December 2015) WT/L/965 (Decision of 30 November 2015). **See also,** Amendment of the TRIPS Agreement – Sixth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement (1 December 2017) WT/L/1024 (Decision of 30 November 2017). **See also**, Amendment of the TRIPS Agreement – Seventh Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement (11 December 2019) WT/L/1081 (Decision of 10 December 2019)

On 23 January 2017, the amendment protocol was formally built into the TRIPS after acceptance by two-thirds of the WTO members. As such, the amendment replaced the 30 August 2003 waiver decision, but only for the members who had accepted the amendment. For the remaining WTO members, they currently have until 31 December 2021 to accept the amendment. For such members, the waiver shall continue to apply until they accept the amendment.[300]

Eventually, since the amendment of the TRIPS agreement is identical to the wording of the 30 August 2003 Decision, then all the criticism directed to the decision, either those previously explicated or those that will be shown later when analysing the compulsory licences flexibilities, are the same criticisms directed to the TRIPS amendment. Indeed, the amendment of the TRIPS agreement did not solve the problem of accessibility to medicines for WTO members with insufficient or no manufacturing capacity, either least-developed countries or developing ones. The problem started from the time they became obliged to grant pharmaceutical patents according to the TRIPS obligations.

#### 2.3.4.3 TRIPS - Plus Era and Public Health

Developed countries sought to conclude FTAs which impose higher level of protection to IPRs than required by the TRIPS agreement. Such FTAs are often referred to as "TRIPS-Plus."[301] Several studies flagged up concerns regarding such agreements, warning that they not only narrow the policy space provided by the TRIPS and erode the TRIPS flexibilities, but also impose additional obligations on states which hamper their capacity to ensure better accessibility to medicine.[302]

A joint study conducted by the WIPO, WTO and WHO shows that the FTAs affect the pharmaceutical sector in various ways. These include provision of patents to new uses of known

[300] WTO, 'Intellectual Property: TRIPS and Public Health: Amendment of the TRIPS Agreement' < https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 24 May 2020. **See also**, TRIPS Agreement (as amended on 23 January 2017) < https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm#:~:text=(as%20amended%20on%2023%20January,force%20on%2023%20January%202017> accessed 24 May 2020

[301] Peter Drahos, 'BITS and BIPS: Bilateralism in Intellectual property' (2001) 4 The Journal of World Intellectual Property 791, 792-793

[302] Ibid, 791-808. **See also**, Fredrick M. Abbot, 'The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements' (27 December 2011) Quaker UN Office (Geneva) (QUNO), Occasional Paper No 14, April 2004 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1977300> accessed 27 June 2019. **See also**, Carlos M. Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines' (2006) 84(5) Bulletin of the WHO 399, 399-402

products, limiting compulsory licences, impeding parallel importation, data exclusivity, and extending the terms of patents.[303]

One of the obligations required by the FTAs is granting patents to second uses of pharmaceutical products. If a pharmaceutical compound that is effective for one disease is found to treat another disease, such second use should be patented by virtue of FTAs provisions. This would encourage filling patent applications for modified versions of older medicines resulting in expanding the scope and term of patents and curbing the innovation of new medicines.[304] The new FTAs provisions run counter to article 27(3) of the TRIPS agreement which provided for the possibility of excluding methods of medical treatment from patentability. This means that the TRIPS neither obliged nor prohibited patenting second medical uses.[305] Developing countries use such TRIPS permission to avoid patenting second medical applications.[306]

Further, FTAs allow patent owners to prevent parallel importation which is permitted as one of the flexibilities in the TRIPS agreement. It was shown above that the TRIPS agreement and the Doha Declaration gave WTO member states the freedom to adopt the system of exhaustion of IP rights that they prefer. Developing countries permitted international exhaustion of pharmaceutical patents in order to retain flexibility to obtain patented medicines at the lowest price through parallel importation. Consequently, developed countries resorted to FTAs to secure provisions that prohibit parallel importation of medicines, for example the bilateral agreements between the US and countries of Australia, Singapore, and Morocco.[307]

Moreover, FTAs restricted the grounds for granting compulsory licences to public non-commercial use, national emergency or other cases of extreme urgency. This restriction has a negative effect on accessibility to medicines. Also, many FTAs required their parties to extend

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[303] WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade* (WIPO Publications 2013) 186-190 < https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf> accessed 19 April 2019

[304] Carlos M. Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines' (2006) 84(5) WHO Bulletin 399, 401

[305] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 27(3)

[306] Clara Ducimetière, 'Second Medical Use Patents - Legal Treatment and Public Health Issues' (December 2019) South Centre Research paper No 101, 19-20 < https://www.southcentre.int/wp-content/uploads/2019/12/RP101_Second-Medical-Use-Patents-Legal-Treatment-and-Public-Health-Issues_EN.pdf > accessed 12 August 2020

[307] Duncan Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements' (2005) 27(11) European Intellectual Property Review 420, 426-427. **See also,** Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration) para 5(d)

the patent term for more than the 20 years stated in the TRIPS agreement to "compensate for delays in marketing approval processes and in the examination of patent applications." The increase of the patent term would result in delaying the introduction of generic versions of medicines with expired patent term, thus impeding access to medicines.[308]

Finally, the TRIPS agreement obliged states to protect undisclosed test data from unfair commercial use, however it did not oblige them to confer exclusive rights over such data for a fixed period.[309] FTAs went beyond what is required in TRIPS, when they provided for granting exclusive rights for clinical data associated with pharmaceutical products for a fixed period, starting from the date of approval of the product. During such period, no pharmaceutical company can use the data to seek approval of a generic medicine. Remarkably, test data exclusivity is applied to all pharmaceutical products whether patented or not. Thus, FTAs provisions providing for data exclusivity significantly delay the registration of generic drugs because generic manufacturers would not be able to utilize the data submitted by the original applicant for regulatory approval of the generic drug until the expiration of the period of data exclusivity, even if the patent term of the product itself has been expired.[310] Also, the data exclusivity has an indirect negative effect on compulsory licensing because generic manufacturers utilizing the licences are also prevented from using the test data for regulatory approval of the generic drug till the period of data exclusivity of the original product expires. Hence, the financial incentives for generic companies might be insufficient to fulfil the compulsory licences obligations. Examples of data exclusivity provisions in FTAs are the bilateral FTAs between US and several countries, *inter alia*, Australia, Jordon, Chile, Morocco and Singapore.[311] Inevitably, impeding the competition of generic drugs severely constrains the ability of developing countries to use the TRIPS flexibilities to provide better accessibility to essential medicines.

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[308] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 27-28. **See also**, Carlos M. Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines' (2006) 84(5) WHO Bulletin 399, 400-401

[309] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 39(3)

[310] Carlos M. Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines' (2006) 84(5) WHO Bulletin 399, 401. **See also**, Duncan Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements' (2005) 27(11) European Intellectual Property Review 420, 426

[311] Duncan Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements' (2005) 27(11) European Intellectual Property Review 420, 426-427

Accordingly, it has been observed that the TRIPS-Plus requirements hinder developing countries from utilizing the TRIPS flexibilities to create national polices for better accessibility to medicines. It has been cautioned that the TRIPS-Plus standards are highly likely to lead to hiking of prices in medicines in developing countries, and delay access to generic drugs.[312]

Indeed, Frederick Abbott opined that the TRIPS-Plus is designed to "inhibit the marketing of generic products."[313] Similarly, Pascal Lamy, the former WTO Director-General, commented on the pressure put on developing countries to adopt substantive TRIPS-Plus standards by stating that the TRIPS flexibilities "should not be taken away through the back door" since such standards curtail the ability to use the TRIPS flexibilities.[314] An Oxfam study in 2007 estimated that the data exclusivity provision required in the FTA between US and Jordan resulted in delaying market entry of 79% of generics between the period 2002-2006, thus resulting in the increase of medicine prices by 20% since the conclusion of the agreement.[315]

#### 2.3.4.4 Public Health and Intellectual Property

WIPO and WHO conducted several discussions on the relation between intellectual property and public health. The WIPO General Assembly adopted a Development Agenda in October 2007 containing forty-five recommendations that echoes the concerns of developing countries regarding the TRIPS agreement, *inter alia*, its negative effect on the accessibility to medicines and the usage of flexibilities stipulated in the agreement.[316] To implement such recommendations, the WIPO established the Committee on Development and Intellectual Property (CDIP) in 2008 in order to set a work program for implementing the Development Agenda recommendations and to monitor, assess and report the implementation of the

[312] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 28
[313] Frederick M. Abbott, 'Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism' (2005) 8(1) Journal of International Economic Law 77, 92
[314] Pascal Lamy, 'Trade-Related Aspects of Intellectual Property Rights: Ten Years Later' (2004) 38(6) Journal of World Trade 923, 934
[315] Oxford Committee for Famine Relief (OXFAM), 'All costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines' (March 2007) Oxfam Briefing Paper, 9, 12 < https://oxfamilibrary.openrepository.com/bitstream/handle/10546/114080/bp102-all-costs-no-benefits-trips-210307-en.pdf?sequence=1> accessed 5 May 2019
[316] WIPO, 'The 45 Adopted Recommendations under the WIPO Development Agenda' < https://www.wipo.int/ip-development/en/agenda/recommendations.html> accessed 19 November 2019

recommendations and coordinate with the relevant WIPO bodies in this regard. Since then, the Committee issues annual recommendations to the WIPO General Assembly.[317]

Further, the WHO played a substantial role in the discussions concerning patents and access to medicines. It established the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) in 2003. The CIPIH is mandated to "collect data and proposals from the different actors involved and produce an analysis of IPRs, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries."[318]

The CIPIH focussed exclusively on the application of IPRs to pharmaceuticals. In 2006, it issued a report that demonstrated with plenty of evidence that the current pharmaceutical patent system is fundamentally flawed leaving huge health needs of developing countries unmet because it favours only commercial incentives of pharmaceutical companies in developed world and the financing of medical R&D. The report also recognized that the patent system does not provide an effective incentive system to boost R&D in the pharmaceutical sector in developing countries because of the limited market demand of these countries. Moreover, the report drew attention to the fact that patents may impede innovation by restricting access to research tools. It warned against FTAs that include TRIPS-Plus measures as they may reduce access to medicines in developing countries. Finally, the report issued some recommendations to provide better accessibility to medicines. The most important are the necessity of providing other incentives and financial mechanisms in the field of pharmaceuticals, improving mechanisms that promote pharmaceutical research responding to the needs of developing countries, resorting to compulsory licensing, and lastly, applying research exemptions as potential solutions to overcome patenting barriers.[319]

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[317] WIPO, 'Committee on Development and Intellectual Property (CDIP)' < https://www.wipo.int/policy/en/cdip> accessed 19 November 2019

[318] Commission on Intellectual Property Rights, Innovation and Public Health, *Public health, Innovation and Intellectual Property Rights* (WHO Geneva 2006) iv < http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> accessed 12 February 2019

[319] Ellen 't Hoen, 'Report of the Commission on Intellectual Property Rights, Innovation and Public Health: A Call to Governments' (2006) 84(5) Bulletin of the World Trade Organization 421, 421-422 < https://www.researchgate.net/publication/7070305_Public_Health_Innovation_and_Intellectual_Property_Rights_Report_of_the_Commission_on_Intellectual_Property_Rights_Innovation_and_Public_Health> accessed 19 November 2019. **See also**, Commission on Intellectual Property Rights, Innovation and Public Health, *Public health, Innovation and Intellectual Property Rights* (WHO Geneva 2006) < http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> accessed 12 February 2019

To implement the recommendations of the CIPIH report, the WHO established an Intergovernmental Working Group on Public Health, Innovation and Intellectual property in 2006 to adopt a global strategy and action plan to secure, inter alia, essential health R&D relevant to diseases affecting developing countries.[320] The strategy recognized that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being." It emphasized the Doha Declaration that "the intellectual property rights do not and should not prevent members from taking measures to protect public health." It realized that IPRs represent a crucial incentive in the development of new health care products, yet it does not alone "meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain."[321]

Ultimately, the historical account demonstrated that states utilized patents as a legal tool to achieve social objectives at first, then patents were adjusted in response to the technological development to be a tool for promoting the economic development of states and their public welfare. The exclusive rights granted by patents often invited debates about the tension between private interests in inventions and public access to such inventions. In the past, patent system was opposed by developed countries because of its negative effect on free trade. On the other hand, developing countries envisaged patents as a system that could encourage free flow of technology and information to them. However, modern patenting systems attempted to harmonize robust standards of patent protection via a legal framework that achieve social objectives like promoting technological development and facilitating the transfer of knowledge. Also, patents are considered as inevitable incentives for R&D. Each country is free to determine the scope and level of patent protection which is suitable for its industrial development and would achieve its public interests, with the proviso that there is no discrimination between nationals and foreigners regarding rights and remedies.

Medicines were excluded from patentability in many European countries as well as developing countries due to the arguments stating that the basic needs should not be subject to exclusive rights. However, in the TRIPS era, all WTO members were obliged to extend the scope and term of patent protection to pharmaceuticals resulting in negative impacts on public health. The monopoly rights conferred to patent holders resulted in overpricing of patented drugs rendering

[320] World Health Assembly, 'Resolution 59.24: Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action' (27 May 2006) WHA 59.24, para 3(1)

[321] World Health Assembly, 'Resolution 61.21: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property' (24 May 2008) WHA 61.21, Annex paras 7, 8, 16

them inaccessible to developing countries. Such concerns were flagged in several International fora.

The Doha Declaration was considered an important step in balancing between pharmaceutical patents under the TRIPS agreement and public health. However, the 30 August Decision, and afterwards the TRIPS amendment after being accepted by the majority of WTO members, watered down the wording of the Doha Declaration due to failure to resolve the outstanding issue of generic medicines. Adopting FTAs represents a setback to the accessibility to medicines in developing countries because it led to hiking medicine prices and delayed access to generics.

In the following part, the underlying justifications for patents shall be analysed in order to explore the approach that could provide room to invoke the accessibility to medicines. It shall be shown that the previous findings in the historical account conform with the philosophy of the patent law.

### 2.4 Philosophical Justifications for Patent Protection

Patent rights are generally characterized as non-physical properties over ideas or knowledge which are the product of cognitive processes. Patent rights are not directed towards the abstract non-physical ideas *per se*, rather, they protect the right to ideas by granting such protection to the physical embodiment or expression of those ideas.[322]

The logic underlying patent creation is recognizable. While society wants knowledge to be always in the public domain, inventors seek a standardized system of protection to incentivize them for future innovation and creativity and enable the industry to recoup its investment in R&D. Such protection withholds the knowledge specifying the invention, keeping it out of the public domain, thus restricting others from copying or free riding. But at the same time, it encourages inventors to release their inventions for the public benefit in return for the royalties they earn during the protection period. Thus, patents represent a compromise between providing protection to inventors in the form of licences, allowing them to preclude others from using or

[322] Adam D. Moore, 'Intellectual Property, Innovation and Social Progress: The Case Against Incentive Based Arguments' (2003) 26(3) Hamline Law Review 602, 604

copying the information underlying the patented inventions, and allowing the public to commercially use the patented products.[323]

Any justification for property in knowledge or ideas has to deal with their distinctive features of non-excludability. While the effective usage of a tangible object requires exclusive right over that object precluding others from using it, knowledge or ideas, in contrast, are abstract or intangible objects which can be used and shared by many people at the same time. They are not exhausted by consumption and can occupy many places concurrently.[324] Yet, sharing knowledge or ideas may hinder the original possessor from profiting when selling them. Edwin Hettinger claims that the non-exclusive characteristic of knowledge provides "a strong prima-facie case against the wisdom of private and exclusive intellectual property rights."[325] Therefore, any argument about a strong protection for patents must include convincing reasons showing the necessity of granting exclusive rights over abstract objects when such objects by their nature do not restrict several people from using them concurrently.

Various philosophical arguments have been put forward in the debate about granting patent protection. Opponents to the notion of allowing property rights for intangible objects argued that patents increased the prices of invented products rendering them inaccessible for specific sectors of people. It diluted the principle of free trade because the owner is the only one who gains the economic benefits from the invention and precludes others from using it without his consent. In contrast, proponents to patent rights argued that patents are indispensable to incentivize and support costly R&D programs in industry to produce new products. It also encourages inventors to disclose valuable technical information to the public, otherwise it would have remained secret. Such argument is derived from the general assumption that justify intellectual property protection as an inducement to scientific and technological development which eventually contributes to the improvement of the social and economic welfare.[326]

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[323] Robert Weissman, 'A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rule, and the Remaining WTO Legal Alternatives Available to Third World Countries' (1996) 17 University of Pennsylvania Journal of International Economic Law 1069, 1071-1072

[324] Lionel Bently and Brad Sherman, *Intellectual Property Law* (2nd edn, Oxford University Press 2004) 1

[325] Edwin C. Hettinger, 'Justifying Intellectual Property' (1989) 18(1) Philosophy and Public Affairs 31, 32

[326] Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (Routledge London and New York 2002) 9-10. **See also**, Philippe Cullet, 'Patents and Medicines: The Relationship between TRIPS and Human Rights to Health' (2003) 79(1) International Affairs 139, 140-141. **See also**, Edwin C. Hettinger, 'Justifying Intellectual property' (1989) 18(1) Philosophy and Public Affairs 31-32. **See also,** Lionel Bently and Brad Sherman, *Intellectual Property Law* (2nd edn, Oxford University Press 2004) 4, 5, 379, 380

Further, patents proponents invoked the general concept of unjust enrichment to justify granting patent rights. They argued that people who benefit from others work are, as Michael Spence described them, "reaping without sowing." Nevertheless, this description is morally objected to and cannot be relied upon to justify granting patent rights. Many people benefit from each other's work, either with an explicit or implicit consent, and justify such benefit as a form of enhancement to the previous work or as a kind of imitation. Also, Spence gave owners the right to exclude others from utilizing their work.[327]

Patent proponents also argued that resources are scarce rendering them impossible to be shared, thus, it is necessary to grant exclusive rights over resources or in other words, monopoly rights to proprietors.[328] This concept also falls short of justifying inhibiting people from using others intellectual work. As clarified by Thomas Jefferson, ideas and knowledge are not scarce like tangible resources, thus the usage of an idea or knowledge shall not deprive the original possessor of such idea from using it.[329]

The following part shall review the most prevailing arguments for granting patent protection, namely, the moral argument, the utilitarian argument, and the economic incentive argument. It shall demonstrate the different perspectives underpinning each argument and analyse the reasoning behind each of them. Even though the current national patent system is largely justified by the utilitarian argument,[330] it shall be argued that combining moral rights argument with economic incentive argument would provide a room for invoking human rights instruments into the patent system. This is due to the close relation between human rights and natural rights.

### 2.4.1 The Moral Argument

The earliest and most invoked perspective for the moral argument is the natural rights perspective. It implies that individuals have natural property rights in their ideas. Such natural rights are pre-societal, where their existence does not depend on positive laws. Therefore, it is

[327] Karsten Schubert and Daniel McClean, *Dear Images: Art, Copyright and Culture* (Ridinghouse London 2002) 389-395
[328] Lionel Bently and Brad Sherman, *Intellectual Property Law* (2nd edn, Oxford University Press 2004) 4
[329] Norman Stephan Kinsella, 'Against Intellectual Property' (2001) 15(2) Journal of Libertarian Studies 1, 22-23
[330] Tanya Aplin and Jennifer Davis, *Intellectual Property law: Text, cases and Materials* (2nd edn, Oxford University Press 2013) 539. **See also**, Edwin C. Hettinger, 'Justifying Intellectual Property' (1989) 18(1) Philosophy and Public Affairs 31, 47. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 29, 31. **See also**, Lionel Bently and Brad Sherman, *Intellectual Property Law* (2nd edn, Oxford University Press 2004) 379

the moral duty of the society and the state to recognize and protect such rights and to preclude others from using them without the owners' authorization. The only appropriate way to recognize the natural rights of inventors is by enforcing exclusivity in the use of the patented invention.[331]

The natural rights perspective was the *raison d'etre* for the French Patent Act of 1791 and is echoed in its preamble. The above section of the historical development of the patent system illustrated that natural rights argument was among the ideas that established the modern French intellectual property system. The preamble of the Act stated that "every novel idea whose realization or development can become useful to society belongs primarily to him who conceived it, and it would be a violation of the rights of man in their very essence if an industrial invention was not regarded as the property of its creator."[332] However, the French Patent Act was only an exception rather than a norm in the stages of patent development because most countries envisaged patent rights as a privilege granted by the crown in the medieval era and a legal tool to promote social utility in the modern era.

The natural rights perspective can be traced back to the writings of John Locke in the 17th century which represent the foundation for natural property rights in both intellectual and material objects. John Locke offered what is known as "the labour theory of acquisition." Locke stated that God has created the earth and everything on it to the benefit of man. Principally, no one owns anything because all the resources are allowed in common for the use of man. However, if an object is removed from nature and mixed with men's labour, he owns a natural right in the fruits of his labour. Property arises from mixing his labour with an unappropriated object because he released its common feature, thus others are deprived from using it. Locke claimed that every person owns his body which entails him the right to protect his mind labour and to have a natural property right over the fruits of his effort. When a person mixes his intellectual labour with something in the common, such as an idea or knowledge, it becomes his property which entitles him to protect it from thieves willing to exploit, amend or copy it. But he stated two provisos that must be fulfilled. The first is the sufficiency condition in which the property can only be appropriated, where there is 'enough and as good' left in common for

[331] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 34. **See also**, Tanya Aplin and Jennifer Davis, *Intellectual Property law: Text, cases and Materials* (2nd edn, Oxford University Press 2013) 539, 540. **See also**, William W. Fisher, 'Theories of Intellectual Property' in Stephen R. Munzer (ed), *New Essays in the Legal and Political Theory of Property* (Cambridge University Press 2001) 168, 169

[332] Fritz Machlup and Edith Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10(1) Journal of Economic History 1, 11. This article cites the French patent Act 1791

others. The second is the non-waste condition, where the person cannot appropriate more than his requirement from the advantage.[333]

Locke's theory of natural rights in intellectual objects due to labour was supported by many scholars because it gives incentives to inventors and motivates them to continue innovation, and at the same time leaves good for others to share in common. Among the proponents of Locke's theory is Justin Hughes, who provided many reasons for which IPRs are better justified under Locke's theory. First, ideas are produced by mixing one's labour with the common, thus appropriating these ideas and removing them from the common shall not significantly decrease the value of the common because the ideas were not existing in the common from the beginning. Second, property rights on ideas suit the Lockean theory which links property to the product of one's labour since ideas emanate from the mental labour of persons. Third, conferring property rights to more ideas expands the intellectual common by adding new ideas, therefore, private appropriation of ideas successfully deals with the sufficiency condition of the Lockean theory. Finally, granting exclusive IPRs over ideas do not violate the two provisos of sufficiency and non-waste. Ideas are not subject to waste as they are imperishable, thus they can be appropriated without violating the non-waste condition. Also, ideas are abundant enough that they do not leave others worsened by private appropriation.[334] John Locke natural rights theory (labour theory) seems to advocate for the claim saying, "I invented it, then its mine and no one else."[335]

Other scholars argued that the Lockean theory cannot be used to justify IPRs. From their perspective, the theory was mainly addressing the legitimacy of political government and the physical property derived from manual labour. It is highly debatable that John Locke's labour theory could be used with intangible property rights and the requirements of novelty and creativity to grant exclusive rights to invention.[336] They criticized the natural right theory for

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[333] John Locke, *Second Treatise of Government* (Watchmaker Publishing 2011) 10,11. **See also**, Adam D. Moore, 'A Lockean Theory of Intellectual property Revisited' (2012) 49 San Diego Law Review 1069, 1071. **See also**, Tanya Aplin and Jennifer Davis, *Intellectual Property law: Text, cases and Materials* (2nd edn, Oxford University Press 2013) 540. **See also**, William W. Fisher, 'Theories of Intellectual Property' in Stephen R. Munzer (ed), *New Essays in the Legal and Political Theory of Property* (Cambridge University Press 2001) 168, 172. **See also,** Stavroula Karapapa and Luke McDonagh, *Intellectual Property Law* (Oxford University Press 2019) 13, 14, 368

[334] Justin Hughes, 'The Philosophy of Intellectual Property' (1988) 77 Georgetown Law Journal 287, 300-328 <https://cyber.harvard.edu/IPCoop/88hugh.html> accessed 25 November 2019

[335] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 36

[336] Stavroula Karapapa and Luke McDonagh, *Intellectual Property Law* (Oxford University Press 2019) 368. **See also**, Alex Tuckness, 'Locke's Political Philosophy', *Stanford Encyclopedia of Philosophy* (6 October 2020) < http://plato.stanford.edu/entries/locke-political/> accessed 14 January 2021. **See also**, Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 35. **See also**, Hans Morten Haugen, *The Right to Food and the TRIPS Agreement with Particular*

several reasons. First, since the person removes something from the common and adds his labour to it, then it is unclear why he is entitled to the ownership of the whole work and not the added part only. An initial distinction has to be made between the value of the object used in labour and the value of the labour itself. If such distinction is made, then the share of both, the value attributed to the inventor's labour and the value attributed to the prior knowledge owned by early contributors, have to be determined.[337]

Second, it is doubtful to attribute an intellectual invention solely to a person's labour. Most of the subject matter of patents is inspired by previous inventions rendering it almost impossible to separate between the mental work of the inventor and the knowledge left in common which he used. Inventors are not living on isolated islands, but rather, they build on previous ideas and knowledge and the prior experience of others when they create their own work. Applying the natural property right theory requires that the early contributors also have a natural right in their prior knowledge, thus allowing them to share the market value of the invention, rather than to attribute it all to the last contributor.[338] This contradicts with the current patent system which recognizes only the right of the first applicant of a patent.

Third, even if there are no early contributors, things left in common unappropriated, do not have any value. According to Lock's theory, when labour is mixed with unappropriated objects, it gives value to it. The theory only explains the added value rather than the reason for the whole value of the object. Finally, commentators argued that the two provisos stated by Locke render the natural rights notion inconsistent with the patent system. Since patent rights can be assigned or transferred between people, as stated in article 28(2) of the TRIPS, without affecting their shares, then it could be deduced that such provisos were not intended to be applied to patents.[339]

Consequently, natural rights proponents derived another version of the labour based Lockean theory to justify private appropriation to inventions. The new version is called the "No Harm" theory. According to such theory, if someone adds his labour to an appropriated object, then his

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*Emphasis on Developing Countries' Measures for Food production and Distribution* (Martinus Nijhoff Publishers Leiden 2007) 41

[337] Sigrid Sterckx, 'The Ethics of Patenting: Uneasy Justifications' in Peter Drahos (ed), *Death of Patents* (Law Text Publishing Limited in association with Queen Mary Intellectual Property Research Institute 2005) 175, 182

[338] Robert P. Merges, Peter S. Menell and Mark A. Lemley, *Intellectual Property in the New Technological Age* (Aspen Law and Business US 2000) 4. **See also**, Sigrid Sterckx, 'The Ethics of Patenting: Uneasy Justifications' in Peter Drahos (ed), *Death of Patents* (Law Text Publishing Limited in association with Queen Mary Intellectual Property Research Institute 2005) 175, 182

[339] William Dibble, 'Justifying Intellectual Property' [1994] University College London Jurisprudence Review 74, 76

labour becomes appropriated as well because he has a moral duty not to harm others who appropriate the object before him. In other words, he has an obligation to leave the appropriated object that holds his labour to the early proprietor. In patents, this could be interpreted as an obligation not to copy others' inventions. But also, this theory failed to give a proper explanation to the right over intangible objects because it did not give a clear definition to what constitutes a harm.[340]

Another theory that was derived from Lock's theory is the "Just Deserts" theory, where Robert Nozick, tried to explain why a person should own something found in common when he mixed it with his labour.[341] He started with the same idea of John Locke with its two provisos but noted that there are instances, where mixing one's labour with something in common results in losing the labour without making any gain. To illustrate, he provided the example of a can of tomato juice in the sea, where he stated that if a person owns a can of tomato juice and pours it in the sea so that the juice mingles throughout the sea water, that does not entitle him to own the sea. He only wasted the tomato juice. Thus, Nozick suggested that what Locke meant from his theory is not the ownership or appropriation of the full resulting product of one's labour, but rather, it is the value added to the original product found in common before adding the labour. He exemplified his view by stating that when a medical researcher discovers a new substance from materials found in common, he is entitled to the property of the new substance only, meanwhile the raw materials are still available to others in common.[342] So, the inventor has a natural right only in protecting the part that he added to the product found in nature. Only the part he invented entitles him to deprive others from gaining unfair advantage from free-riding or copying it.

Further, Nozick argued that granting a patent right to the inventor encourages him to reveal his invention to the society which would not exist without his effort. Therefore, the interests of the consumers are achieved rather than harmed by the grant of the patent. However, there are two limitations to the inventor's entitlement. First, people who subsequently invented the same invention independently must have the right to produce it and sell it, otherwise granting patent right to the first inventor only would leave them in a worse condition. Second, patent rights

[340] Ibid, 77
[341] Robert Nozick and Thomas Nagel, *Anarchy, State, And Utopia* (Basic Books New York 2013) 174, 175
[342] Ibid, 174, 175, 181. **See also**, Alejandra Mancilla, 'A Can of Tomato Juice in the Sea' (2015) 107 Philosophy Now Magazine < https://philosophynow.org/issues/107/A_Can_of_Tomato_Juice_in_the_Sea > accessed 17 February 2019

should not last for a long time in order to enable others who have the same knowledge to produce similar inventions independently after the expiration of the patent term.[343]

Moreover, Nozick argued that the two provisos of the Lockean theory are meant to prohibit worsening others by depriving them of things left in common. As patents did not deprive others of common good because the inventions exist only after using human labour, thus patent rights can be justified under the natural rights theory of Locke.[344] Among the supporters of the "Just Deserts" theory is Lawrence Becker. He argued that the theory takes into account the Lockean provisos ensuring that the benefits achieved from the usage of resources are compatible with the product's value without worsening the situation of others.[345]

But again, applying Nozick's version of the natural right theory with its two limitations would mandate the recognition of the natural right of all persons coming up with the same intellectual invention, either at the same time or subsequently. This would require a substantial reform of the current patent system which provided a patent term for at least 20 years and does not allow granting patent rights to persons inventing similar inventions. Alternatively, it sets an obligation on inventors who build on earlier patented invention to pay a reward for the patentee to be able to use the invention. Also, patent law excludes others from using a patented product or process which contradicts with Nozick's idea that the ownership of a specific object does not necessarily worsen others' situation if there is a sufficient number of unappropriated objects left in common to be used. Other people may want to put their labour in the specific appropriated object; however, they are prohibited from doing so under patent law.[346] As such, it is suggested that the current patent framework cannot be justified under natural rights arguments.

Moreover, Edwin Hettinger and Peter Drahos criticized Nozick's notion stating that the inventor has a natural right to the market value of the added part resulting from his labour to the original product. They argued that the market value is not based on natural rights rather it depends on multiple factors, *inter alia*, consumers conditions and demand, and government regulations. Market value is a "socially created phenomenon," thus, there is a salient difference between

[343] William W. Fisher, 'Theories of Intellectual Property' in Stephen R. Munzer (ed), *New Essays in the Legal and Political Theory of Property* (Cambridge University Press 2001) 168, 170
[344] Robert Nozick and Thomas Nagel, *Anarchy, State, And Utopia* (Basic Books New York 2013) 174, 175, 182
[345] Lawrence C. Becker, 'The Labour Theory of Property Acquisition' (1976) 73(18) The Journal of Philosophy 653, 653-664
[346] Sigrid Sterckx, 'The Ethics of Patenting: Uneasy Justifications' in Peter Drahos (ed), *Death of Patents* (Law Text Publishing Limited in association with Queen Mary Intellectual Property Research Institute 2005) 175, 185

natural right to the fruits of one's labour and the market value of one's invention.[347] The current patent system entitles the patentee to a certain period to control the use and sell of the patented invention in the market and to reap its profits solely by excluding others from using and selling it without his authorization. As such, the patent system cannot be vindicated by the natural right notion of Nozick.

Furthermore, Seana Shiffrin counter argued Nozick's notion of private property. She contended that even though intellectual inventions are partly based on intellectual common, the non-excludable nature of intellectual inventions renders natural right to patents groundless, as they can be used and shared by many people at the same time and are not exhausted by consumption. Patents have little reason to depart from the common ownership presumption. Also, she viewed the common ownership as a reflection of the "equal moral status of individuals." Thus, unless the nature of an assigned invention requires exclusive control or use, such invention, from a moral aspect, should become part of the common to be available for others.[348] As such, Shiffrin's notion contradicts with Nozick's notion which gives primacy to private property as long as no one is worsened or harmed by being deprived of the available objects found in common.

Ultimately, the moral argument with its natural property right perspective may explain the moral rights of creators mentioned in both the Universal Declaration of Human Rights (hereinafter referred as UDHR) and the ICESCR. The instruments stipulate that everyone has the right "to benefit from the protection of the moral interests resulting from any scientific, literary or artistic production of which he is the author."[349]

Nevertheless, due to their contentious features, doubts have been casted on the moral arguments to justify granting patent rights for new inventions. As such, scholars searched for another justification considering the necessity of rewarding the inventors for their intellectual work. They invoked both the UDHR and ICESCR since they contain provisions about the right to benefit from the protection of the material interests not only the moral interests.[350]

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[347] Edwin C. Hettinger, 'Justifying Intellectual Property' (1989) 18(1) Philosophy and Public Affairs 31, 38-40. **See also**, Peter Drahos, *A Philosophy of Intellectual Property* (Australian National University E-Text 2016) 52 < https://press-files.anu.edu.au/downloads/press/n1902/pdf/book.pdf > accessed 20 April 2019

[348] Seana Valentine Shiffrin, 'Lockean Arguments for Private Intellectual property' in Stephen R. Munzer (ed), *New Essays in the Legal and Political Theory of Property* (Cambridge University Press 2001) 138, 158-167

[349] Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) art 27(2). **See also**, International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 15(1)(c)

[350] Ibid

Thomas Jefferson, the first administrator of the US patent system, was a prominent supporter of the justification for granting patents to inventors as a reward from the society for their useful inventions. He stated that inventions cannot be subject of natural property because ideas should be freely spread to all people for the benefit of everyone. However, as a means of encouragement to inventors, the society may assign to them an exclusive right to the profits gained from their inventions. Such tool depends on the will of the society without claims or complains from anyone.[351]

Another less important perspective for the moral argument is the personality perspective which echoes the natural property right perspective. This perspective was derived from both Kant and Hegel who emphasized that private property rights are basic entitlements to human fundamental needs. Each invention is an extension of its inventor's personality. The governments should find suitable means to create and allocate entitlements to resources in order to enable people to satisfy their needs. Inventors are entitled to private property rights because of their contribution to the society's prosperity.[352]

The personality perspective emphasizes the natural right of inventors and the moral obligation of the society to reward the inventor for his contribution. It can be envisaged as a statutory expression to both the moral and the economic rights of creators.[353]

### 2.4.2 The Utilitarian Argument

The utilitarian argument addresses the idea of what is beneficial for the society and people rather than the notion of natural property rights and labour entitling the inventor to the ownership of the fruits of his labour.

The main supporter of the Utilitarian theory was Jeremy Bentham who rejected the notion that laws are derived from natural rights. Instead, he assumed that the social policies have to be justified in light of their capability of bringing more happiness and benefits to the maximum number of people. He always used the term "the greatest happiness" which he borrowed from

[351] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 44

[352] William W. Fisher, 'Theories of Intellectual Property' in Stephen R. Munzer (ed), *New Essays in the Legal and Political Theory of Property* (Cambridge University Press 2001) 168, 171. **See also**, Stavroula Karapapa and Luke McDonagh, *Intellectual Property Law* (Oxford University Press 2019) 13

[353] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 67

Hume to justify his perspective to the usefulness of things [354] Bentham assumed that the hedonistic value of people's activities is measured by the pleasure achieved, its duration, and the potential benefit or harm it produced. He opined that the happiness of the society in general is achieved when the total number of interests or utilities of the individuals in this society is accomplished. He drew an example by stating that punishing offenders deter criminal actions because it balances the apparent harm resulted from the crime with the public benefit.[355]

Theorists used Bentham's theory to justify patents. They argued that producing and disseminating inventions of a valuable utility to the society entitles inventors to a reward. This reward forms what is called a social contract between the inventor and the society, in which the inventor agrees to disclose his invention to the society and in return the society protects such invention by granting the inventor a monopoly right (patent right). So, the society acknowledges that its general interest necessitates granting legal protection for inventions after fulfilling certain requirements.[356]

This argument is in line with the TRIPS agreement stating that an "applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."[357] This is the *quid pro quo* principle of patent protection, where in exchange for the disclosure of an invention to others instead of keeping it secret, the inventor is granted a temporary right to exclude others. The US courts and the US constitution neglected other theories of patent law and relied on this justification as the primary reason for the patent system.[358] The Supreme Court in the US stated that the disclosure of an invention is the "*quid pro quo* of the right to exclude."[359] Also, the US constitution granted the Congress the power to "promote the progress of science and useful arts, by securing for limited times to inventors the exclusive right to their respective discoveries."[360]

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[354] Tanya Aplin and Jennifer Davis, *Intellectual Property law: Text, cases and Materials* (2nd edn, Oxford University Press 2013) 11
[355] William Sweet, 'Jeremy Bentham (1748-1832)', *Internet Encyclopedia of Philosophy* < http://www.iep.utm.edu/bentham/ > accessed 10 March 2019
[356] H. I. Dutton, *The Patent System and Inventive Activity During the Industrial Revolution 1750-1852* **(**Manchester University Press 1984) 22. **See also**, Timothy R. Holbrook, 'Possession in Patent Law' (2006) 59(1) Southern Methodist University Law Review 123, 131. **See also**, Stavroula Karapapa and Luke McDonagh, *Intellectual Property Law* (Oxford University Press 2019) 369
[357] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 29(1)
[358] Timothy R. Holbrook, 'Possession in Patent Law' (2006) 59(1) Southern Methodist University Law Review 123, 131-132. **See also**, Tanya Aplin and Jennifer Davis, *Intellectual Property law: Text, cases and Materials* (2nd edn, Oxford University Press 2013) 11
[359] *J. E. M. Ag Supply Inc et al v Pioneer Hi-Bred International Inc,* 534 US 124 (2001), 142
[360] US Constitution, art 1 sec 8, cl 8

Moreover, utilitarian proponents contended that such legal protection is needed to adjust the market failure because it provides incentives that urge inventors to produce more useful inventions and assure them that their time and labour in producing such work will not go in vain, but they will find an appropriate compensation. Without patents, others will be able to free-ride or copy an invention easily and compete without investing any time or money or exerting any effort in R&D (reaping without sowing). This would discourage inventors from future production and consequently no new inventions would be developed which would harm the social and economic welfare.[361]

Similarly, if sufficient incentives were not awarded to inventors, they would keep their inventions without disclosure and the society would lose the new public benefit.[362] However, monopoly rights may prevent inventions from being available in the public domain, yet the happiness of the society will occur by encouraging inventors to produce and disseminate more creative inventions. Eventually, the monopoly period will expire, and the invention will be released to the public domain where it can be easily used. Thus, the interests of both the inventors and the society shall be met.[363]

One of the remarkable philosophers who also supported the utilitarian theory and built on the writings of Bentham is John Stewart Mill. He supported the idea of granting exclusive privileges to people to promote the happiness of the society in general. He stated that happiness is a pleasure and people's work is right as long as it promotes happiness and wrong if it resulted in pain.[364] Another proponent to the utilitarian theory is Edward Hettinger, who argued that granting patent rights to inventors restrict the current availability and use of inventions for the purpose of encouraging inventors to increase their production, which will ensure future availability and use of new inventions.[365]

The current national patent laws are chiefly justified by the utilitarian theory, yet this rationale has not gone uncriticised. Arguments are legion in this regard. First, there is no empirical

[361] Conor Shelvin, 'The Difficulties in Finding a Single Theory to Fully Justify Copyright' (2015) 3 North East Law Review 49, 51. **See also**, William M. Landes and Richard A. Posner, 'An Economic Analysis of Copyright Law' (1989) 18(2) The Journal of Legal Studies 325

[362] Fritz Machlup and Edith Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10(1) Journal of Economic History 1, 10-11. **See also**, Stavroula Karapapa and Luke McDonagh, *Intellectual Property Law* (Oxford University Press 2019) 369

[363] Michael Falgoust, 'The Incentives Argument Revisited: A Millean Account of Copyright' (2014) 52(2) The Southern Journal of Philosophy 163, 171

[364] Christopher Macleod, 'John Stuart Mill', *Stanford Encyclopedia of Philosophy* (25 August 2016) < https://plato.stanford.edu/entries/mill/ > accessed 20 March 2019

[365] Edwin C. Hettinger, 'Justifying Intellectual Property' (1989) 18(1) Philosophy and Public Affairs 31, 47-51

evidence showing that inventors would not create if they were not granted exclusive rights to their creations. Second, incentives are not the only tool to encourage inventors. Many useful inventions were invented without adequate monetary compensation, where only honour and moral prizes were conferred. The law itself, in some instances, might not offer protection, like immoral inventions or contrary to public policy.[366] Third, patents encourage monopoly. It gives privileges for certain people for their benefit in a way that inhibits the flow of technology to the public resulting in a welfare loss such as increasing the prices of products.[367] Fourth, excessive patenting may impede future innovation because it precludes other inventors from pursuing further R&D on the inventive work without paying a cost for such usage. [368] Fifth, granting patents is not in itself an incentive that will help in correcting the market failure because the public will still have to pay for the price of the invention.[369] Sixth, sometimes patents deter inventors from disclosing their ideas to the public at an earlier stage till they apply for the patent. On the contrary, researchers would disclose their ideas earlier seeking only for fame and recognition. Finally, it is paradoxical and unrealistic to justify the patent system by arguing, like Hettinger, that hampering the diffusion of invented ideas is necessary to increase market production and ensure future availability and use of inventions. An argument based on contradiction cannot be suitable for justifying an ideal patent system.

Better alternatives to patents can be applied to increase production of inventions without restricting their use and availability. For example, government funding of intellectual work and transfer of its ownership to the public, or the governmental funding of universities' R&D where the results become public property. This would encourage innovation without depriving people of using inventions. [370] Therefore, the diffusion of knowledge is not qualified as a convincing reason for granting patent protection.

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[366] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 32. **See also**, Tanya Aplin and Jennifer Davis, *Intellectual Property law: Text, cases and Materials* (2nd edn, Oxford University Press 2013) 13

[367] Tanya Aplin and Jennifer Davis, *Intellectual Property law: Text, cases and Materials* (2nd edn, Oxford University Press 2013) 542. **See also**, Michael A. Heller and Rebecca S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280(5364) Journal of the American Association for the Advancement of Science 698, 698-700

[368] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 32.

[369] Lionel Bently and Brad Sherman, *Intellectual Property Law* (2nd edn, Oxford University Press 2004) 36

[370] Tanya Aplin and Jennifer Davis, *Intellectual Property law: Text, cases and Materials* (2nd edn, Oxford University Press 2013) 12-13. **See also**, Robert P. Merges, Peter S. Menell and Mark A. Lemley, *Intellectual Property in the New Technological Age* (Aspen Law and Business US 2000) 11-13

### 2.4.3 The Economic Incentive Argument

The economic incentive argument addresses the market incentives needed to grant patent protection. Proponents of economic argument justify granting patents to new inventions by stating that if there is no adequate protection for intellectual inventions, the needs of the market shall not be met as there would be no incentives to encourage inventions and innovation or to promote industrial progress.[371]

Such incentives mechanisms are necessary for persuading investors to be more willing to provide funds for R&D resulting in more creations and production of new inventions which will inevitably benefit the public. Thus, patents act as a vector that links technical and scientific research with commercial aspects.[372] Further, without patents, there would be unfair competition between people who copy inventions and others who invested time and money in R&D. Patents allow companies who invested in R&D to recoup their investments, rendering inventions a profitable business.[373] Moreover, granting patent rights is necessary to stimulate extra economic investments in inventions to be put on the market for commercial use.

Another argument is that patent rights improve the competitive economic advantage of states because they promote the transfer of technology from developed to developing countries with the encouragement of foreign investments.[374]

Such arguments were also criticized. The patent system is paradoxical. Whereas it is an incentive for inventors, patents for third parties are considered disincentive because they increase the prices of invention making them inaccessible to many people.[375] Also, the practices of big private entities may stifle research activities by impeding the sharing of scientific progress and technological creations in order to prevent others from obtaining a patent on a new invention which may erode their own competitiveness in the market.[376] This was confirmed by Stephen Glazier who stated that "invention is not the point of most valuable patent. Instead, most patents

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[371] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 68

[372] Lionel Bently and Brad Sherman, *Intellectual property law* (4th edn, Oxford University Press 2014) 380

[373] Robert P. Merges, Peter S. Menell and Mark A. Lemley, *Intellectual Property in the New Technological Age* (Aspen Law and Business US 2000) 12. **See also**, William M. Landes and Richard A. Posner, *The Economic Structure of Intellectual Property Law* (Harvard University Press 2003) 13

[374] Audrey Chapman, 'Approaching Intellectual Property as a Human Right' (2001) 35(3) UNESCO Copyright Bulletin 4, 8 < https://unesdoc.unesco.org/ark:/48223/pf0000125509> accessed 9 April 2019

[375] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 69

[376] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 47. **See also**, William M. Landes and Richard A. Posner, *The Economic Structure of Intellectual Property Law* (Harvard University Press 2003) 320-321

are obtained for the proper business purpose of keeping competitors away from the market for a new product or service."[377]

Furthermore, even though the patent system is meant to increase inventions, it impedes further innovation. Research activities and innovation depend and build on each other. In articulating such an important feature of innovation, Suzanne Scotchmer resorted to the famous scientist Isaac Newton, who acknowledged this fact by stating that "I have seen so far because of standing on the shoulders of giants." She noted that any technological progress builds on information provided from earlier inventions.[378] As such, patents stifle innovation because they prohibit other inventors from gaining any knowledge regarding previous inventions to develop new ones. Such new inventions may increase the social benefit exactly like the old ones.[379]

Moreover, according to economics, free market competition ensures the efficient allocation of resources. When granting patent rights to inventors, they become entitled to set the highest possible prices for their inventions which the market can bear. Such prices exceed the marginal cost of production, rendering the inventions accessible to only few people than if it was supplied in a competitive market environment.[380]

Another perspective of the economic incentive argument is the prospect theory which was advanced by Edmund Kitch to justify granting patent rights. He used the term prospect to mean "a particular opportunity to develop a known technological possibility."[381] According to this theory, patents are considered tools to promote investment in innovation. Kitch alleged that patents are usually granted before the patentee forms a clear idea about the exploitation of the patent. It provides him with the opportunity to investigate market opportunities and seek for venture capital.[382] Once a patent has been granted to an invention, others shall know about it and redirect their efforts and research to different innovative work to avoid duplicate investment, or they may seek to purchase a licence from the patentee if they are interested in researching the

[377] Stephen C. Glazier, *Patents Strategies for Business* (3rd edn, Law and Business Institute Washington 2003) 321-322
[378] Suzanne Scotchmer, 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law" (1991) 5(1) The Journal of Economic Perspectives 29, 29-30
[379] Michael A. Heller and Rebecca S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280(5364) Journal of the American Association for the Advancement of Science 698, 698-699
[380] Robert P. Merges, Peter S. Menell and Mark A. Lemley, *Intellectual Property in the New Technological Age* (Aspen Law and Business US 2000) 13
[381] Edmund W. Kitch, 'The Nature and Function of the Patent System' (1977) 20(2) Journal of Law and Economics 265, 266-267
[382] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 33

same work. Thus, broad patents prevent the wasteful duplication of similar efforts and reduce the amount of duplicate investment in innovation. This would help to divide the profits between early inventors and subsequent ones.[383]

Although the theory was credited from the aspect of the search and exploitation of market opportunities,[384] it was contested because granting broader patents to earlier inventions might generate patent races regarding who shall be the first to gain a patent right and get rewarded. Robert Merges and Richard Nelson criticized the prospect argument stating that it might delay or block further innovation because subsequent innovators are obliged to obtain licenses from earlier patent holders, otherwise they would be violating the patent laws.[385] In biomedical research particularly, the proliferation of patents has been a considerable source of concern. As biomedical research is increasingly subject to patent rights, patentees exclude others from scarce resources which may deter life-saving innovations due to the high prices of obtaining licenses in the biomedical field.[386] Thus, it was recommended in research environment, especially in pharmaceuticals, to narrow the breadth of patent rights whenever the new invention is deemed to be an important contribution to innovation or a new improved product.[387] In the same context, the patentability requirements of novelty and inventive step, which are stipulated in the TRIPS agreement,[388] should be applied strictly when considering granting patent rights to new inventions, especially pharmaceuticals, so as to avoid the proliferation of patents.

Eisenberg, the former chairperson of the US National Institute of Health, criticized the broad patenting practices in the biomedical field. He articulated that pharmaceutical and biotechnology researchers encounter difficulties in accessing patented research tools. They have

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[383] Edmund W. Kitch, 'The Nature and Function of the Patent System' (1977) 20(2) Journal of Law and Economics 265, 275-279. **See also**, Suzanne Scotchmer, 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law" (1991) 5(1) The Journal of Economic Perspectives 29, 37-40

[384] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 33

[385] William M. Landes and Richard A. Posner, *The Economic Structure of Intellectual Property Law* (Harvard University Press 2003) 319 -320. **See also**, Robert P. Merges and Richard R. Nelson, 'On the Complex Economics of Patent Scope' (1990) 90(4) Colombia Law Review 839, 860-862

[386] Stephen A. Merrill and Anne-Marie Mazza et al (eds), *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* ( The National Academies press 2006) 2-3 < https://www.nap.edu/catalog/11487/reaping-the-benefits-of-genomic-and-proteomic-research-intellectual-property > accessed 21 April 2019. **See also**, Michael A. Heller and Rebecca S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280(5364) Journal of the American Association for the Advancement of Science 698, 699

[387] Robert Mazzoleni and Richard R. Nelson, 'The Benefits and Costs of Strong patent Protection: A Contribution to the Current Debate' (1998) 27(3) Research policy Journal 273, 281-282

[388] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 27(1)

to bargain with multiple patent holders and pay high costs, resulting in delay in transferring such tools. This impedes biomedical R&D of drugs.[389]

When examining the objectives of the TRIPS agreement, it can be noticed that it justified IPRs in general according to both the utilitarian and the economic incentive arguments. The TRIPS objectives are the "dissemination of IPRs to the mutual advantage of both the user and producer in a manner conducive to the social and economic welfare."[390] It is clear from the language of the article, namely, dissemination, social and economic welfare, and the balance between rights and obligation, that the TRIPS envisages IPRs principally as economic rights with social functions not moral rights.

This finding was emphasized by the 2002 Report of the Commission on Intellectual Property Rights which demonstrated that the TRIPS agreement treats IPRs as private socio-economic rights rather than natural rights or human rights. The report explained that the TRIPS recognizes the need to strike a balance between the private rights of inventors to protect their inventions and the rights of the users to access such inventions as stipulated in article 7 of the TRIPS. The TRIPS referred only to the inventor's private right to protect his technological innovation. It neglected his human right to such protection (the right to protect the moral and material interests resulting from the scientific production as stipulated in article 27/1 of the UDHR and article 15/1/c of the ICESCR). This infers that the TRIPS agreement envisages IPRs as private rights with material benefits placing it at a higher position than human rights. Therefore, the private right and the private material interests of the inventor are derived at the expense of the consumer.[391] In developing countries, where many consumers do not have adequate accessibility to pharmaceuticals, this may appear to interfere with the human right to health. This constitutes a serious problem especially when the IP system under the TRIPS agreement does not allow discrimination as to the field of technology, i.e., health-related inventions, like pharmaceuticals, are treated the same as other inventions related to any field of technology.

In chapter 3, the dissertation will demonstrate that the nature of human rights is totally different from that of IPRs. Where the former are fundamental, inalienable, and universal entitlements

[389] Michael A. Heller and Rebecca S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280(5364) Journal of the American Association for the Advancement of Science 698, 700-701

[390] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 7

[391] Commission on Intellectual Property Rights, 'Report of the Commission on Integrating Intellectual Property Rights and Development Policy' (Commission on Intellectual Property Rights, September 2002) 6 < http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 1 May 2019

belonging to individuals, the latter are of a temporary nature, and can be revoked, licensed or assigned to someone else. Thus, both rights cannot be treated alike.

Similarly, the report of the High Commissioner of the Human Right Commission commenting on the impact of TRIPS on human rights confirmed that IPRs could be justified under the economic incentive argument. The report stated that "the overall thrust of the TRIPS Agreement is the promotion of innovation through the provision of commercial incentives."[392]

Ultimately, it could be argued that justifying patent protection according to both the moral rights and the economic incentive perspective provides a room for invoking human rights instruments into the patent system, considering the close relation between human rights and natural rights. On the one hand, the moral rights promote public accessibility to inventions by encouraging inventors to disclose their ideas and creation. Also, they promote the trade and foreign direct investment by diffusion of science and technology. On the other hand, economic incentives are essential for the globalization of patent protection under TRIPS and for inducing investments in innovations which enhance the progress of technology.

Relying on the economic incentives only may have a significant impact on the pharmaceutical sector. Commercial activities and international trade and investment may impede the sharing of scientific progress by utilizing the monopoly rights granted to them to block research and control prices. To elaborate, a patent system relying on economic incentives only creates monopoly rights over resources, *inter alia*, chemical compounds, that is used to manufacture medicines which are indispensable for human health. Such monopoly rights entitle the patent owner to control the accessibility to such chemical compounds creating a dependent relationship not only between the patent owner and the chemical compounds but also between him and others who seek the usage of such compounds to produce medicines. The latter relationship is represented by an authorization from the patent owner in order to access such compounds and produce medicines. Thus, either pay the high costs of the licences that the patent owner sets or restrict the freedom to produce medicines.

Inevitably, it is crucial to invoke human values beside economic incentives in drafting patent law and policy in medicines. Given the effect of patenting medicines on people's health, the

[392] UN Sub-Commission on the Promotion and Protection of Human Rights, 'Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights' (27 June 2001) UN Doc E/CN.4/Sub.2/2001/13, para 22

patent system should be guided by moral rights, which are considered universal, beside the economic incentives.

The TRIPS agreement sets a standard level of harmonization for international patent protection. It aims to promote an adequate and effective intellectual property protection by reducing impediments to international trade for the welfare of people.[393] Consequently, the TRIPS should be flexible enough to deal with not only trade regime distortions, like the acts of copying and free riding on inventions, but also with the human rights regime. It is important to strike a balance between weak and strong patent protection. If the protection is weak, it will impede more creations. If the protection is too strong, it will block public access to inventions and neglect human health considerations rendering patents merely a corporate profit.

In essence, the TRIPS agreement has to take into account human rights norms, not only trade law. The dissertation shall continue to explore whether or not the flexibilities stipulated in the TRIPS provide room for invoking human rights considerations.

### 2.5 The Peculiarity of Pharmaceutical Patents

The pharmaceutical industry needs robust patent protection to retrieve the high costs of R&D. It was estimated that the R&D cost for producing a new drug was around 2 billion dollars in 2011, a tenfold increase from the 1980 estimate of approximately 200 million dollars.[394] Before the 1980s, most of the basic drug researches for treatment of many diseases including cancer, tuberculosis and HIV/AIDS were almost publicly funded at in-house government facilities, public research institutions, and universities in Europe, North America and Japan.[395] A UNDP research indicated that 70% of the medicines produced in the US between 1981 and 1991 and having therapeutic gains were produced with government involvement.[396] Since then, a steep decline in governmental funding in major industrialized countries on pharmaceutical R&D

[393] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) preamble, art 7

[394] Jorge Mestre-Ferrandiz et al, *The R&D Cost of a New Medicine* (Office of Health Economics UK 2012) <https://www.ohe.org/publications/rd-cost-new-medicine#> accessed 12 March 2020

[395] Diana Smith et al, 'Fatal Imbalance: The Crises in Research and Development for Drugs for Neglected Diseases' (Médecins Sans Frontières Access to Essential Medicines Campaign & The Drugs for Neglected Diseases Working Group, September 2001) 20 < https://www.msfaccess.org/sites/default/files/MSF_assets/NegDis/Docs/NEGDIS_report_FatalImbalance_CrisisInR&D_ENG_2001.pdf> accessed 11 July 2019

[396] UN Development Program, *Human Development Report 1999* (Oxford University Press New York 1999) 69 < http://hdr.undp.org/sites/default/files/reports/260/hdr_1999_en_nostats.pdf > accessed 11 July 2019

made the private sector responsible for the largest part of global funding in the field.[397] Unlike the public sector, the private one is dominated by profit-making objectives where it found that the acquisition policy and the enforcement of a robust patent system worldwide is the only means to recoup their expenditures on R&D programs.[398]

Patent system was doing its role in protecting new drugs and therefore allowing the private sector to recover the investments on R&D and providing incentives to inventors.[399] Recently, it has diverged from its purpose and instead of protecting only genuinely new pharmaceutical products, many patents are granted to pharmaceutical-related inventions covering incremental minor developments or poor-quality inventions with broad claims of innovation.[400] Therefore, the innovation "has shifted away from models based on absolute novelty and first improvement towards a model in which innovation is no longer driven by technological breakthroughs but by the routine exploitation of existing technologies."[401] This divergence was illustrated in a study issued by the US National Institute for Health Care Management in 2002. The study pointed out that for over a 12-year period (1989 till 2000), nearly two-thirds of the drugs approved by the FDA were either existing drugs or modified versions of them. These drugs are connected with incremental modifications of older ones which do not provide significant clinical improvement, for example, minor features such as inert ingredients and the form, colour, and scoring of tablets. Therefore, they discourage generic companies from trying to develop competitive cheaper products.[402]

Multi-national pharmaceutical companies had exploited patents instruments in TRIPS agreement and the weak procedures in patent offices. They applied different strategies to offensively utilize patents in obstructing the development of competitive or generic products

[397] Carlos M. Correa, 'Ownership of knowledge: The role of patents in pharmaceutical R&D' (2004) 82(10) International Journal of public Health 784, 784-785 < http://apps.who.int/iris/bitstream/10665/72867/1/bulletin_2004_82%2810%29_784-790.pdf> accessed 11 July 2019
[398] Ibid
[399] WHO Commission on Macroeconomics and Health, *Report on Macroeconomics and Health: Investing in Health for Economic Development* (WHO publications 2001) 126 < http://www1.worldbank.org/publicsector/pe/PEAMMarch2005/CMHReport.pdf > accessed 12 July 2019
[400] Carlos M. Correa, 'Ownership of knowledge: The role of patents in pharmaceutical R&D' (2004) 82(10) International Journal of public Health 784, 784-785 < http://apps.who.int/iris/bitstream/10665/72867/1/bulletin_2004_82%2810%29_784-790.pdf> accessed 11 July 2019
[401] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed Books 2000) 126
[402] 'Changing Patterns of Pharmaceutical Innovation' (EURACTIV, 29 January 2010) < https://www.euractiv.com/section/health-consumers/opinion/changing-patterns-of-pharmaceutical-innovation/ > accessed 12 July 2019

and to detract public domain knowledge used by many researchers to explore several inventive opportunities.[403] Examples of those strategies are "blanketing" which aims to protect every step of the manufacturing process with patent rights claiming minor modifications; "surrounding" which occurs "when an important central patent can be fenced in or surrounded by other patents, which are individually less important but collectively block the effective commercial use of the central patent, even after its expiration," "fencing" which is multiple patents on the same product in order to "block certain lines or directions of R&D," and "flooding" which is based on the acquisition of several patents on minor or incremental variations on technology developed by another company.[404]

Patent offices in many countries, including developed ones, grant patents without adequate examination due to the absence of experts capable of examining complex patent applications. Even where such offices have the experts, they are overburdened by the large number of received applications.[405] This was emphasized by the Council of the Royal Society in London, where it expressed its concerns, in one of its reports, regarding the development in patent applications in Europe. Several reasons for these concerns were stated in the report, *inter alia*, many major patent offices have "a significant backlog of patent applications to search and examine and conduct searches on," patent offices are satisfying applicants' wishes for the grant of their patent application which may "carry the risk that the important public interest task of examining patents to a consistent high standard is subordinated to meeting the wishes of applicants," and finally examiners lack skill and experience needed to examine patent applications in new areas of science, or they do not fully understand the science, or have access to all the prior art.[406] Accordingly, the council recommended that governments should make it clear to their respective patent offices that "their primary goal is to examine patent applications

[403] John H. Barton, 'Research-Tool Patents: Issues for Health in the Developing World' (2002) 80(2) Bulletin of the WHO 121, 122 < http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2567728/pdf/11953790.pdf > accessed 12 July 2019. **See also**, 'Changing Patterns of Pharmaceutical Innovation' (EURACTIV**,** 29 January 2010) < https://www.euractiv.com/section/health-consumers/opinion/changing-patterns-of-pharmaceutical-innovation/ > accessed 12 July 2019

[404] Carlos M. Correa, 'Ownership of knowledge: The role of patents in pharmaceutical R&D' (2004) 82(10) International Journal of public Health 784, 785 < http://apps.who.int/iris/bitstream/10665/72867/1/bulletin_2004_82%2810%29_784-790.pdf> accessed 11 July 2019

[405] Frederick M. Abbott, 'Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (Cambridge University Press UK 2005) 393, 408-409

[406] The Royal Society Working Group on Intellectual Property, 'Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science' ( Council of the Royal Society, 14 April 2003 ) 11 < https://royalsociety.org/-/media/Royal_Society_Content/policy/publications/2003/9845.pdf > accessed 30 September 2021

appropriately rather than to strive to grant as many patents as possible." Also, the council underscored the importance of providing training programs to patent office examiners and widening the novelty searches of patents applications.[407]

Two distinctive instruments in the pharmaceutical industry, stipulated in the TRIPS agreement, were used by pharmaceutical companies to gain market exclusivity for a longer term after the expiration of the patent term. These are the regulatory data protection or data exclusivity, and the supplementary protection. Before demonstrating the two instruments, it is worth explaining the market authorization of new medicines to understand the concept of each instrument.

There are significant regulatory and scientific requirements that must be fulfilled before the national authorities approve placement of any new drug in the market. Many rigorous experiments have to be conducted to ensure the safety and effectiveness of the new medicine for consumer use. In order to conduct such experiments, the pharmaceutical company that innovated the medicine has to disclose and provide the national authorities with all the data about such medicine including its composition and manufacturing process. The national authorities also require data from pre-clinical and clinical trials. Clinical trials are expensive and contribute significantly to setting the price of the new medicine. Also, the process from discovering the new molecule of the active substance in the drug, and the filing of a patent application, until obtaining market approval and releasing the product in the market can take up to 15 years.[408]

After gaining market authorization, the pharmaceutical company owning the patent loses the commercial value of a significant part of the patent term (20 years) during which the clinical experiments are conducted.[409] As stated by Susan Finston, the co-finder and director at Indian biomedicine start-up Amirta therapeutics and a strategic consultant, every company can protect trade data by virtue of trade secret laws, but pharmaceutical companies "actually face an additional requirement to disclose trade secrets, in the form of regulatory data" to national authorities and wait for a long time till gaining market authorization as previously shown. Finston explained that "a typical food and beverage company can hold trade secrets on their

[407] Ibid
[408] James Killick et al, 'The special Regime of Intellectual Property for the Pharmaceutical Industry' (Stockholm Network Experts' Series on Pharmaceutical Intellectual property Rights, 26 August 2009) 3 < https://issuu.com/stockholmnetwork/docs/the_special_ip_regime_for_pharmaceuticals> accessed 11 July 2019. **See also**, Jack Ellis, 'Supporting Innovation in Next-Generation Medicines' (2017) 3 WIPO Magazine 37, 37
[409] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 33

recipes and so forth, and they can do that in perpetuity. But if you are a biopharma innovator, you have to disclose to regulators what your 'cookbook' is."[410] Traditionally, generic producers have to only demonstrate that their medicines are bioequivalent to the original drugs, i.e., equally safe and equivalent, rather than repeating the whole regulatory process. Consequently, the generics entry to market relies on the clinical data already provided by the originators. This situation puts patent owners at a competitive disadvantage because a generic producer might use the disclosed data and enter the market once the patent term expires.[411] To offset the time that had passed after granting the patent right until receiving market authorization and to recoup the cost of R&D investments before the patent protection expires, the regulatory data protection (data exclusivity) and the Supplementary Protection Certificate instruments were used to delay a generic producer from relying on the originator's data in his application for marketing approval for similar or identical product. During the period of protection in both instruments, the generic producer is not allowed to rely on the originator's market approval. Instead, he either has to generate equivalent clinical data, or accept postponement of regulatory approval.[412] The following sub-section will demonstrate both instruments and their usage in EU.

### 2.5.1 The Regulatory Data protection (Data Exclusivity)

The first instrument to extend market exclusivity for patent holders is the regulatory data protection which may provide protection to commercially valuable information, including trade secrets.[413] Regulatory data protection refers to the period during which pharmaceutical firms enjoy proprietary rights over the clinical data related to the medicines they produce. The clinical data is the data generated by the research conducted by the company to demonstrate the safety and efficacy of the new medicine. Protecting the regulatory data prevents generic manufacturers

[410] Jack Ellis, 'Why Regulatory Data protection Matters for Medicines' (11 July 2017, Geneva Network for International Innovation, Trade and Development Policy) < https://geneva-network.com/research/regulatory-data-protection-matters-medicines/ > accessed 2 October 2021. **See also**, Jack Ellis, 'Supporting Innovation in Next-Generation Medicines' (2017) 3 WIPO Magazine 37, 38

[411] Lisa Diependaele, Julian Cockbain and Sigrid Sterckx, 'Raising the Barriers to Access to Medicines in the Developing World – The Relentless Push for Data Exclusivity' (2017) 17(1) Developing World Bioethics Journal 11, 12. **See also**, Jack Ellis, 'Supporting Innovation in Next-Generation Medicines' (2017) 3 WIPO Magazine 37, 38

[412] Lisa Diependaele, Julian Cockbain and Sigrid Sterckx, 'Raising the Barriers to Access to Medicines in the Developing World – The Relentless Push for Data Exclusivity' (2017) 17(1) Developing World Bioethics Journal 11, 12

[413] Wael Armouti and Mohamed Nsour, 'Test Data Protection: Different Approaches and Implementation in Pharmaceuticals' (2016) 20(2) Marquette Intellectual Property Law Review 267, 278. **See also**, Amit Singh and Paramita DasGupta, 'Pharmaceutical Test Data Protection and Demands for Data-Exclusivity: Issues and Concerns of Developing Countries and India's Position' (2019) 24 Journal of Intellectual Property Rights 69, 72-74

from utilizing it, throughout the protection period when they apply for market authorization of generic medicines.[414] Accordingly, the regulatory data protection allows pharmaceutical companies to recoup their investments before release of generic versions of the original medicines.

The TRIPS agreement allowed regulatory data protection, but it did not specify a period for such protection. It required the protection of the test data submitted to governmental authorities for market authorization of new medicines against disclosure and unfair commercial use, except when it is necessary to protect the public or when the data is otherwise protected against unfair commercial use.[415] The regulatory data protection became a requirement for all WTO members according to the TRIPS provisions, except the least-developed countries. However, many countries are yet to implement it.

The regulatory data protection was first introduced in the EU in 1987 by virtue of the Council Directive 87/22/EEC[416] which was amended in 1993 by the Council Regulation (EEC) No. 2309/93,[417] then in 2001 by the Directive 2001/83/EC of the European parliament and of the Council.[418] There was disparity in the period of data exclusivity in the previous EU instruments, as to whether a product had been registered through a mutual recognition procedure or through the centralized system. While the Council Regulation 2309/93 provided 10 years of regulatory data protection for pharmaceutical products which were authorized by the EC via the centralized procedure, the Directive 2001/83/EC provided only a period of 6 years which could be extended to 10 years by a single decision from the EU member state when it considers this extension necessary for public health interests.[419]

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[414] James Killick et al, 'The special Regime of Intellectual Property for the Pharmaceutical Industry' (Stockholm Network Experts' Series on Pharmaceutical Intellectual property Rights, 26 August 2009) 9 < https://issuu.com/stockholmnetwork/docs/the_special_ip_regime_for_pharmaceuticals> accessed 11 July 2019

[415] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 39(1)(3)

[416] Council Directive 87/22/EEC of 22 December 1986 on the Approximation of National Measures Relating to the Placing on the Market of High-Technology Medicinal Products, Particularly Those Derived from Biotechnology [1987] OJ L15/38

[417] Council Regulation (EEC) No 2309/93 of 22 July 1993 Laying Down Community Procedures for the Authorization and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Agency for the Evaluation of Medicinal Product [1993] OJ L214/1

[418] Council Directive 2001/83/EC of the European Parliament and of the Council 2 December of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use [2001] OJ L311/67

[419] Ibid, art 10(1)(a)(iii). **See also**, Council Regulation (EEC) No 2309/93 of 22 July 1993 Laying Down Community Procedures for the Authorization and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Agency for the Evaluation of Medicinal Product [1993] OJ L214/1 art 13(4)

Such disparity was abolished by the new EC Regulation Number 726/2004.[420] It created a harmonised EU data exclusivity period "8+2+1." Accordingly, the data would remain undisclosed for 8 years starting from the initial authorization of the product in the EU. This would be followed by an additional 2 years of market protection, where the pharmaceutical companies producing generic medicines can utilize the regulatory data but cannot place the generic medicine in the market for such period. Finally, an extension of one year over the 10 years could be given, if during the first 8 years the marketing authorization holder obtained an authorization for a new therapeutic indication bringing an important clinical benefit in comparison with the existing therapies, or he makes an application for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.[421]

The regulatory data protection is crucial for pharmaceutical companies. It gives them additional time to offset the time lost from granting patent rights over medicines until releasing them on the market. This time, which can reach up to 15 years, renders the period left before the expiry of the patent term insufficient for pharmaceutical companies to recoup their investments. Adversely, for developing countries, regulatory data protection is detrimental because it restricts generics production which their market relies on, and it does not promote R&D. Thus, the practice prevents possible reductions in the cost of medicines in developing countries.[422]

The generic industry tried to utilize the clinical data in performing the experimental use before the expiry of the patent term to decrease the time required to gain market approval. However, such activities were invalidated in the case of *Roche Products v. Bolar Pharmaceutical Co.* by the US Court of Appeal of the Federal Circuit. In the case, Bolar, a generic manufacturer, used the patented data of the active ingredient of a drug called Dalmane produced by Roche to

[420] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency [2004] OJ L136/1

[421] Ibid, art 14(11). **See also**, Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use [2004] OJ L136/34 art 10(1)

[422] Commission on Intellectual Property Rights, Innovation and Public Health, *Public health, Innovation and Intellectual Property Rights* (WHO Geneva 2006) 125 < http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> accessed 12 February 2019. **See also**, James Killick et al, 'The special Regime of Intellectual Property for the Pharmaceutical Industry' (Stockholm Network Experts' Series on Pharmaceutical Intellectual property Rights, 26 August 2009) 10 < https://issuu.com/stockholmnetwork/docs/the_special_ip_regime_for_pharmaceuticals> accessed 11 July 2019. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 27(1)

determine whether or not the generic version is bioequivalent to the patented one before applying for FDA approval. Bolar argued that such usage does not constitute any infringement to patent rights since it is not meant for commercial purposes, but rather, it is meant for making generic versions of Dalmane available immediately once its patent term expires. If the right to use the active ingredient data was restricted, as Bolar contended, the monopoly rights of Roche would be extended beyond the date of expiration of the patent and would restrict the production of the generic version of Dalmane. However, the Court of Appeal rejected the arguments stating that Bolar company used the patented data to gain market approval and sell the product in the market right after the patent term of Roche's medicine expires, i.e., it was not an experimental use.[423] It shall be shown later when addressing the flexibilities in the TRIPS agreement, namely the limited exceptions provided under article 30, that the "Bolar exemption" had a significant impact on the rapid production of generic medicines.

Eventually, limiting the protection of regulatory data is important for balancing between the need of inventors to recoup their investments by extending market exclusivity, and the need of public health entities and generic manufacturers to allow generic versions of the patented medicine to appear on the market after the patent term expires without any delay.

### 2.5.2 The SPC

The SPC for medicinal products is another instrument intended to offset the time that had passed after granting the patent right until receiving market authorization. It is referred to as a *sui generis* instrument for pharmaceutical patent protection.[424] As earlier noted, testing medicines and conducting pre-clinical and clinical trials is a time-consuming process that could last, in some instances, up to 15 years. As such, most of the patent term (20 years as stipulated in TRIPS), would be used up before placing the patented medicine on the market.

The SPC was first introduced in the EU in 1992 by virtue of the Council Regulation (EEC) No 1768/92.[425] The regulation extended the patent term for medicines up to 5 years maximum starting from the expiry of the patent term.[426] Its aim is to compensate the research-based

[423] *Roche Products Inc v Bolar Pharmaceutical Co Inc*, 733 F2d 858 (Fed Cir 1984)
[424] Guy Tritton, *Intellectual Property in Europe* (2nd edn, Sweet & Maxwell UK 2002) 177
[425] Council Regulation (EEC) No 1768/92 of 18 June 1992 Concerning the Creation of a Supplementary Protection Certificate for Medicinal Products [1992] OJ L182/1
[426] Ibid, art 13

companies for the delays in the regulatory system by giving them sufficient time to recoup their investments and make reasonable profits which could be re-invested in future R&D.[427]

To obtain an SPC, three conditions must be met. Firstly, a pharmaceutical product must be patented, and the patent term must not have expired. Secondly, the manufacturer must have been granted a valid authorization to place the medicine on the market and he should be the first one to obtain authorization for that medicine. Thirdly, the medicine must not already be a subject of an SPC since each drug can only obtain a single SPC for 5 years maximum.[428]

The SPC is considered a disadvantage to generics production and to developing countries since it delays introduction of generic versions of original drugs after expiration of the patent term. Generic manufacturers in EU cannot produce such drugs even for the purpose of exporting them outside the EU. This deprives developing countries of one of the sources to cheap medicines. However, the SPC is applied only on EU-based generic manufacturers. Those located outside the EU can still produce generic medicines once the patent term expires, which gives them a competitive advantage vis-à-vis EU-based generic manufacturers.[429]

Due to the disadvantage to EU-based generic manufacturers, the EU amended the 1992 Council Regulation several times until 11 June 2019 when the EU published the current Regulation (EU) No 933/2019 of the European Parliament and of the Council.[430] The new EU Regulation introduced an exception to the SPC for export purposes and for stockpiling.[431] The exception favours the interests of EU-based manufacturers as they would be entitled to produce generic versions of patented medicines still covered by an SPC.

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[427] James Killick et al, 'The special Regime of Intellectual Property for the Pharmaceutical Industry' (Stockholm Network Experts' Series on Pharmaceutical Intellectual property Rights, 26 August 2009) 5 < https://issuu.com/stockholmnetwork/docs/the_special_ip_regime_for_pharmaceuticals> accessed 11 July 2019. **See also**, FratiniVergano European Lawyers, 'Trade Perspectives: The EU Introduces Exceptions to the Protection of Medicines through Supplementary Protection Certificates to the Benefit of Biosimilar and Generic Medicines' Producers' (FratiniVergano European Lawyers, Issue No 12, 14 June 2019) < http://www.fratinivergano.eu/en/issue-number-12-14-june-2019/#_The_EU_introduces> accessed 12 February 2020

[428] Council Regulation (EEC) No 1768/92 of 18 June 1992 Concerning the Creation of a Supplementary Protection Certificate for Medicinal Products [1992] OJ L182/1 art 3

[429] FratiniVergano European Lawyers, 'Trade Perspectives: The EU Introduces Exceptions to the Protection of Medicines through Supplementary Protection Certificates to the Benefit of Biosimilar and Generic Medicines' Producers' (FratiniVergano European Lawyers, Issue No 12, 14 June 2019) < http://www.fratinivergano.eu/en/issue-number-12-14-june-2019/#_The_EU_introduces> accessed 12 February 2020

[430] Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 Amending Regulation (EC) No 469/2009 Concerning the Supplementary Protection Certificate for Medicinal Products [2019] OJ L153/1

[431] Ibid, art 1(2)(2)(a)

The European Commission published a study before adopting the 2019 amendment to assess the "Economic Impacts of Changing Exemption Provisions During Patent and SPC Protection in Europe." The study found that the waiver of the SPC would create additional manufacturing jobs in Europe by 2025, increase the net sales for EU-based generic manufacturers, ensure faster entry of generics in the EU after the expiry of the SPC which improve accessibility to medicines at cheaper prices, and finally enable savings in pharmaceutical expenditure due to competition.[432] This study was among other discussions and consultations that induced the EU to amend the SPC regulation to the current 2019 one.

Indeed, the recent development of the SPC in Europe which was introduced by the 2019/933 EU Regulation draws attention to the importance of balancing between the interests of patent holders and the development of generic medicines to improve accessibility to medicines. Consideration should be given not only to trade and economic values but also to public health and the affordability of medicines to patients around the world.

A famous case showing that the SPC system is sometimes misused by companies is the *AstraZeneca v. European Commission* case regarding the Ulcer medicine Losec.[433] AstraZeneca pharmaceutical company was charged in front of the European General Court for misleading representation in front of several European patent offices and for attempting to deregister the marketing authorisations for Losec to withdraw it from the European market and release an alternative medicine called Losec MUPS.[434] The court's decision, which was upheld by the ECJ,[435] was to fine AstraZeneca 60 million Euros for deliberately concealing the correct data of the first market authorization and misusing the SPC system by intending to delay or block market entry of generic medicines to Losec to maintain an artificial high price for it.[436]

The European Commission stated in the case that, although a robust patent protection is important for innovation and for retrieving the costs of R&D, generic medicines have a substantial effect in keeping drugs prices down for the benefit of the European health care

[432] Raphaël De Coninck et al, *Assessing the Economic Impacts of Changing Exemption Provisions During Patent and SPC Protection in Europe* (European Union Publication 2017) 2-3
[433] Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010] ECR II–2805
[434] Ibid, paras 1, 2, 8
[435] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012] OJ C26/2
[436] European Commission, 'Competition: Commission Fines AstraZeneca €60 Million for Misusing Patent System to Delay Market Entry of Competing Generic Drugs' (15 June 2005) IP/05/737 < http://europa.eu/rapid/press-release_IP-05-737_en.htm > accessed 21 July 2019. **See also**, *AstraZeneca* (Case COMP/A.37.507/F3) Commission Decision 2006/857/EC [2005] OJ L332/24

systems which rely on generic medicines. The Commission asserted that generics competition spurs pharmaceutical innovation after the expiry of the patent term.[437]

This case highlights the tension between the right to control accessibility to medicines for economic purposes and the right to access to medicines, as an indispensable component of the right to health, by enabling cheaper generic medicines.

### 2.6 The TRIPS Flexibilities

The TRIPS agreement envisages IPRs as private rights that need to be effectively and adequately protected. The purpose of this protection is the "promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge, and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[438] The agreement obliged member states, when they formulate or amend their intellectual property legislations to "adopt measures necessary to protect public health, … provided that such measures are consistent with the provisions of the agreement."[439] Further, the agreement required that WTO members should adopt suitable measures and regulations to "prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."[440]

This infers that the agreement tried to strike a balance between the right of inventors and the right of the users by imposing limits on the rights of the inventors for social and economic welfare reasons. Accessibility to medicines is one of the interests of the society that has to be balanced with patent obligations in the TRIPS agreement. As such, the interpretation of the TRIPS provisions has to take into consideration public health interests as one of the principles of the TRIPS agreement.

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[437] European Commission, 'Competition: Commission Fines AstraZeneca €60 Million for Misusing Patent System to Delay Market Entry of Competing Generic Drugs' (15 June 2005) IP/05/737 < http://europa.eu/rapid/press-release_IP-05-737_en.htm > accessed 21 July 2019. **See also**, *AstraZeneca* (Case COMP/A.37.507/F3) Commission Decision 2006/857/EC [2005] OJ L332/24, paras 113, 116, 363, 514, 767, 843, 869.

[438] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 7

[439] Ibid, art 8(1)

[440] Ibid, art 8(2)

This was emphasized by the Doha Declaration which stipulated that the TRIPS should be interpreted and implemented in a manner that support the right of WTO members to protect public health, particularly, accessibility to medicines. The application of customary rules of interpretation of public international law requires reading the TRIPS provisions in light of its objectives and principles that support the right to protect public health.[441]

In its 2016 report on the promotion of innovation and access to medicine, the UN Secretary-General's High-Level Panel on Access to Medicine emphasized the existence of an incoherence between the patent rights of inventors and public health. The report suggested that the relation between access to medicine and patent protection requires a better balance between the interests of the patent holder and the interests of the society which can be achieved by taking advantage of the flexibilities in the TRIPS agreement.[442]

The dissertation shall critically analyse the ex-post flexibilities that were addressed at the beginning of this chapter. Ex-post flexibilities are the flexibilities provided by the TRIPS after granting the patent right. Those flexibilities limit the exclusive rights of patent holders to promote access to medicines. The right to access to medicine can be used as an argument that favours the flexibilities supported by the objectives and principles of the TRIPS. However, developed countries and the pharmaceutical industry opting for stringent patents protection argued that the flexibilities stipulated in the TRIPS agreement should be used restrictively. A proper interpretation for using such flexibilities must consider that the TRIPS agreement is intended to provide a balance between incentivizing technological innovation and protecting the social welfare of people including accessibility to affordable medicines as a component of public health.

[441] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration) paras 4, 5(a)
[442] UN Secretary-General's High-Level Panel on Access to Medicines, 'Report on Promoting Innovation and Access to Health Technologies' (September 2016) 7, 9 < http://www.unsgaccessmeds.org/final-report> accessed 12 December 2019

### 2.6.1 The Limited Exceptions

Article 30 of the TRIPS Agreement provides for limited exceptions to the exclusive rights conferred by a patent. The vagueness of the wording of the article triggered a lot of controversies regarding its interpretation and provided a point of entry for the right to access to medicines.[443]

These limited exceptions are applied without the authorization of the patent holder. This is inferred from the heading of article 31 of the TRIPS "Other Use Without Authorization of the Right Holder" and its footnote 7 reading "Other use refers to use other than that allowed under Article 30."[444] However, the exceptions in article 30 are bound by three main important conditions which constituted a "three-step" test regarding the validity of the exceptions to the minimum standards required by the TRIPS. Firstly, there can only be "limited exceptions" to the patent rights. Secondly, these exceptions should not "unreasonably conflict" with the exploitation of the patent. Thirdly, the exceptions should not "unreasonably prejudice the legitimate interests" of the patent owner. Although the exceptions according to article 30 are limited by these conditions, the term "limited exceptions" itself is not defined.[445]

In an attempt to identify the scope of such exceptions, the WTO Fact Sheet on TRIPS and Pharmaceutical Patents recognized two kinds of exceptions used by countries. The first is related to the experimental non-commercial usage of the patented medicine to understand its composition more fully, thus the exceptions are used to advance science and technology. The second is the regulatory review exception, also known as the "Bolar exemption." It allows generic manufacturers to use the patented invention to develop information required for governmental marketing approval on generic medicines without the patentees' permission and before the patent term expires. This would not delay placing generic products on the market as soon as the patent term expires.[446] The WTO panel emphasized in *Canada- Pharmaceutical*

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[443] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 223

[444] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 31 footnote7

[445] Philippe Cullet, 'Patents and Health in Developing Countries' in John Hatchard and Amanda Perry-Kessaris (eds), *Law and Development: Facing Complexity in the 21st Century* (Cavendish Publishing Limited London 2003) 78, 82. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 31

[446] WTO, 'TRIPS and Pharmaceutical Patents' (September 2006) WTO Fact Sheet, 3 < https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf > accessed 13 October 2019. **See also**, Katri Paas, 'Compulsory licensing under the TRIPs Agreement: A Cruel Taunt for Developing Countries?' (2009) 31(12) European Intellectual Property Review 609, 610

*Patents* case that the "Bolar exemption must be an example of the type of exception that was intended to come within Article 30."[447]

Article 30 may offer an alternative solution to the domestic market usage requirement, bureaucratic procedures and political barriers related to granting compulsory licences stipulated in article 31 of the TRIPS.[448] It would authorize generic manufacturers to produce and export patented drugs to countries suffering from health crisis provided that the aforementioned conditions are fulfilled.[449] It could be used to pursue public health goals, thus balancing between the promotion of innovation and the dissemination of innovation as indicated by the objectives of the TRIPS agreement. To achieve its purpose, states should avoid unreasonably prejudicing the interest of patent owners on one side, while taking into account the legitimate interest of third parties on the other side.[450] Adopting such view, it could be argued that states facing HIV/AIDS or other epidemic crises should invoke article 30 exceptions to provide accessibility to patented life-saving medicines.

Nevertheless, the WTO adopted a very restrictive approach to article 30 in *Canada - Patent Protection of Pharmaceutical Products* case, when applying the "three-step" test on two kinds of exceptions permitted by the Canadian Patent Act.

According to this case, the European Community and their member states alleged that the Canadian Patent Act is incompatible with its TRIPS obligations because it allowed a Bolar exception and a stockpiling exception in its Patent Act. They claimed that the two exceptions did not fall under the limited exceptions provided by article 30 of the TRIPS agreement. Canada argued that the disputed exceptions were meant to achieve its long-standing policy goal of providing cheap generic medication to consumers as soon as the patent term expires. The stockpiling exception, stated in section 55.2(2) of Canada Patent Act, permits generic manufacturers to manufacture and stockpile unlimited quantities of a patented medicine during

[447] WTO Panel Report, *Canada - Patent Protection of Pharmaceutical Products* (adopted 7 April 2000) WTO Doc WT/DS114/R, para 4.15

[448] Katri Paas, 'Compulsory licensing under the TRIPs Agreement: A Cruel Taunt for Developing Countries?' (2009) 31(12) European Intellectual Property Review 609, 610-611. **See also**, Bryan C. Mercurio, 'TRIPS, Patents and Access to Life-Saving Drugs in the Developing World' (2004) 8(2) Marquette Intellectual Property Law Review 211, 231

[449] Amir Attaran, 'The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals and Options Under WTO Law' (2002) 12 Fordham Intellectual Property, Media & Entertainment Law Journal 859, 865

[450] Philippe Cullet, 'Patents and Health in Developing Countries' in John Hatchard and Amanda Perry-Kessaris (eds), *Law and Development: Facing Complexity in the 21st Century* (Cavendish Publishing Limited London 2003) 78, 82-83

the 6 months before the patent expires, which could then be sold when the patent term expires. The regulatory review exception (Bolar exception), stated in article 55.2(1), allows generic manufacturers to obtain governmental market approval for generics so as not to delay placing them on the market as soon as the patent term expires as previously illustrated. As such, Canada claimed that the two exceptions were consistent with its basic legal obligations under the TRIPS to provide 20 years of patent protection.[451]

The WTO panel applied the "three-step" test, where it strictly focused on the fulfilment of the three conditions provided by article 30. It mentioned that the three conditions are "cumulative, each being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in the article 30 exception being disallowed." Further, it stated that each of the three conditions must be presumed to mean something different from the other or else there would be redundancy.[452]

In clarifying the first condition of the "three-step" test, which is that the exceptions have to be limited, the WTO panel adopted a very narrow definition to the term "limited". It stated that the word "exception" already implies a limited derogation which is narrowed even further by adding the word "limited" to it. The limited character is to be "measured by the extent to which the exclusive rights of the patent owner, mentioned in article 28(1) of the TRIPS, have been curtailed, rather than the size or extent of the economic impact."[453]

Regarding the second condition of the "three-step" test, which is that the exceptions cannot unreasonably conflict with a normal exploitation of the patent, the WTO panel stated that "exploitation" refers to "the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent."[454] The panel viewed that the normal practice of exploitation by patent owners is to "exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity."[455]

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[451] WTO Panel Report, *Canada - Patent Protection of Pharmaceutical Products* (adopted 7 April 2000) WTO Doc WT/DS114/R, paras 7.2-7.10. **See also,** Patent Act, RSC 1985, c P-4, sec 55.2(1), 55.2(2). Note that Section 55.2(2) is repealed in 2001 by the Act to Amend the Patent Act, SC 2001, C 10. **See also**, Robert Howse, 'The Canadian Generic Medicines Panel. A Dangerous Precedent in Dangerous Times' (2005) 3(4) World Intellectual Property Journal 493, 495

[452] WTO Panel Report, *Canada - Patent Protection of Pharmaceutical Products* (adopted 7 April 2000) WTO Doc WT/DS114/R, paras 7.20, 7.21, 7.23-7.26

[453] Ibid, paras 7.29 – 7.31

[454] Ibid, para 7.54

[455] Ibid, para 7.55

In the last condition, which is that the limited exceptions should not unreasonably prejudice the legitimate interests of the patent owner, the panel found that the legitimate interest should be construed to be broader than the legal interest.[456] The legitimate interest involves "a normative claim calling for protection of interests that are justifiable in the sense that they are supported by relevant public policies or other social norms."[457]

Applying the first step of the "three-step" test on the stockpiling exception, the WTO panel found that the stockpiling exception was not a limited exception because it allowed generic manufacturers to "make" and "use" the patented medicines during the last 6 months of the patent term without imposing any limitation on production and without the authorization of the patent holder. Accordingly, the stockpiling exception substantially curtailed the exclusive rights of patent owners provided under article 28(1). The WTO panel concluded that the stockpiling exception did not satisfy the first step of the "three-step" test, thus violated the TRIPS agreement.[458] As the three conditions are cumulative, the panel did not apply the other two conditions since failure to comply with any of them suffice to invalidate the contested exception.

In contrast, the WTO panel found that the Bolar exception fell within the scope of article 30 according to the "three-step" test due to the following reasons. First, it is a limited exception because of "the narrow scope of its curtailment of article 28(1) rights." It only allowed very few acts of making and selling the patented medicine, namely, those necessary for the regulatory approval process. The exception did not allow any commercial use for the resulting final products.[459] Second, the Bolar exception does not conflict with the normal exploitation of the patent since the additional period of market exclusivity "created by using patent rights to preclude submissions for regulatory authorization" is not deemed to be part of the normal exploitation of the patent right.[460] Third, there is no compelling evidence provided by the claimant that the Bolar exception unreasonably prejudiced the legitimate interests of the patent holder.[461]

[456] Ibid, para 7.71
[457] Ibid, para 7.69
[458] Ibid, paras 7.34-7.36
[459] Ibid, para 7.45
[460] Ibid, para 7.57
[461] Ibid, para 7.81

Accordingly, the WTO panel decided that Canada should amend article 52.2(2) allowing stockpiling because it is not consistent with articles 28(1) and 30 of the TRIPS agreement. The Panel decision was upheld by the WTO DSB at its 7 April 2000 meeting.[462]

The panel report was criticized by many commentators and human rights proponents because it adopted a narrow definition to the limited exceptions provided by article 30 when examining the stockpiling exception. It favoured only the interests of the patent holder allowing them to prevail always over public health expectations. It did not take into consideration the objectives and principles of the TRIPS agreement, stipulated in articles 7 and 8, providing for adopting measures to protect public health and achieving the mutual advantage of producers and users.[463]

If the stockpiling exception is not included within the scope of the limited exceptions in article 30 of the TRIPS, there would be no chance to complete the authorization procedures for exporting and selling medicines while the patent remains in force. Such a situation would put any TRIPS amendment or any declaration regarding expanding the scope of article 30 to encompass the stockpiling exception, into legal uncertainty, unless considering that the previous WTO panel decision is exceptional.[464]

Commentators expected that the WTO panel decision in the previous Canadian case would take a new approach when interpreting the limited exceptions after the adoption of the Doha Declaration.[465] The declaration reaffirmed that the TRIPS should be interpreted and implemented in a way that should take into consideration its objectives and principles that support the right to access to medicine.[466] Thus, it may be used in future to strengthen arguments of accessibility to medicine against the more restrictive interpretations.

Eventually, article 30 of the TRIPS falls short of providing legal certainty to developing countries when utilizing the exceptions to manufacture and stockpile patented medicines in

[462] WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (adopted 7 April 2000) WTO Doc WT/DS114/R
[463] Robert Howse, 'The Canadian Generic Medicines Panel. A Dangerous Precedent in Dangerous Times' (2005) 3(4) World Intellectual Property Journal 493, 496-498. **See also**, Bryan C. Mercurio, 'TRIPS, Patents and Access to Life-Saving Drugs in the Developing World' (2004) 8(2) Marquette Intellectual Property Law Review 211, 233
[464] Bryan C. Mercurio, 'TRIPS, Patents and Access to Life-Saving Drugs in the Developing World' (2004) 8(2) Marquette Intellectual Property Law Review 211, 233-234
[465] Frederick M. Abbott and Jerome H. Reichmann, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 (4) Journal of International Economic Law 921, 986
[466] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration) paras 4, 5(a)

order to ensure faster accessibility once the patent term expires. Its usage might drag them to the WTO DSB or expose them to trade sanctions or pressure according to the stringent interpretation of article 30 adopted by the WTO panels.

From another perspective, the *Canada – Patent* case addressed the issue of whether the limited exceptions provided in article 30 constitute discrimination against the field of pharmaceutical technology or otherwise. Article 27(1) of the TRIPS stipulated that patent rights should be allowed to all inventions without discrimination as to the field of technology. Canada had argued that the non-discrimination principle was subject to the limited exceptions in article 30 of the TRIPS, thus it could establish separate rules for the pharmaceutical field.[467] Similarly, Australia contended that "it was not inconsistent with the TRIPS agreement to provide for distinct patent rules that respond to practical consequences of differences between fields of technology."[468] The WTO panel responded and pointed out that not all differential treatment of certain products is considered discrimination. The panel stated that article 27 "does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas."[469] The panel added that the meaning of the word "discriminate" certainly "extends beyond the concept of differential treatment. Discrimination may arise from explicitly different treatment, sometimes called "de jure discrimination," but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called "de facto discrimination."[470]

Scholars emphasized the distinction between differential treatment and discrimination in relation to the application of the limited exceptions in article 30. Burk and Lemley noted that while patent law is technology-neutral in theory, it is technology-specific in application. The differences between fields of technology require responses tailored to the field of technology.[471] Fredrick Abbott demonstrated that discrimination refers to unfair or unjustifiably adverse treatment which is totally different from differential treatment applied to certain pharmaceuticals or public health patents. The latter is "necessary to address important public interests; this does not constitute discrimination against the field of pharmaceutical technology.

[467] WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (adopted 7 April 2000) WTO Doc WT/DS114/R, paras 7.88-7.91
[468] Ibid, para 5.9
[469] Ibid, paras 7.92, 7.100
[470] Ibid, para 7.94
[471] Dan L. Burk and Mark A. Lemley, 'Is Patent Law Technology-Specific' (2002) 17 Berkeley Technology law Journal 1155, 1156

It constitutes recognition of legitimate public interests in differential treatment."[472] Hestermeyer affirmed what other scholars articulated that the distinction between the permissible differential treatment and impermissible discrimination allows for an interpretation that respects the TRIPS principles. This distinction gives WTO members more latitude when legislating to preserve public health than in other fields of technology.[473] Similarly, Robert Howse asserted that a WTO member state is not considered discriminating as to the field of technology, when it wishes to limit IPRs in a particular industrial sector to achieve legitimate social and economic objectives. In the pharmaceutical field, health concerns "might well argue in favour of limits that would be inappropriate to impose … on all sectors."[474]

Ultimately, the threshold between discrimination and differential treatment is determined on a case-by-case basis.[475] This adds to the legal insecurity for developing countries willing to take public health measures.

### 2.6.2 Compulsory Licences

Article 31 of the TRIPS titled "other use without authorization of the right holder" is traditionally viewed as referring to compulsory licences or non-voluntary licences.[476] In the context of pharmaceuticals, compulsory licence is a tool by which the national authority authorizes generic manufacturers to produce the patented medicines without the authorization of the patent holder.[477]

[472] Frederick M. Abbott, 'WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries' (2002) UK Commission on Intellectual property Rights Study Paper 2a, 38 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1924420> accessed 25 May 2019
[473] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 60
[474] Robert Howse, 'The Canadian Generic Medicines Panel. A Dangerous Precedent in Dangerous Times' (2005) 3(4) World Intellectual Property Journal 493, 505
[475] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 60
[476] Daniel J. Gervais, *The TRIPS Agreement: Drafting History and Analysis* (2nd edn, Sweet & Maxwell UK 2003) 250
[477] WTO, 'TRIPS and Health: Compulsory licensing of pharmaceuticals and TRIPS' <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 23 July 2019. **See also**, Tarunz Jain, 'Compulsory Licences Under TRIPS and its Obligations for Member Countries' (2009) 8(1) Journal of IPRs of the Institute of Chartered Financial Analysts of India 27. **See also**, Katri Paas, 'Compulsory licensing under the TRIPs Agreement: A Cruel Taunt for Developing Countries?' (2009) 31(12) European Intellectual Property Review 609, 610

Most scholars are of the view that the TRIPS agreement does not contain any explicit limitations to the reasons justifying the grant of compulsory licences.[478] Article 31 of the TRIPS provides several grounds for grant of such licences, namely; cases of national emergencies or other circumstances of extreme urgency, public non-commercial use,[479] and the grant of the licence as a remedy for a practice determined after judicial or administrative process to be anti-competitive.[480] Other common grounds, not stipulated in the TRIPS, include failure or insufficient working of the patented medicine, promoting competition by creating domestic competitors, safeguarding the supply of domestic market with patented medicine, breaking monopolies and cartels, and finally boosting technology transfer.[481]

Some scholars opined that the grounds for granting compulsory licences are limited to article 8(1) of the TRIPS which permits states to adopt measures necessary to achieve their public interest.[482] Others argued that the licence may only be granted when the patentee abuses the patent right. They deduced this requirement from the Paris Convention, applicable by virtue of article 2(1) of the TRIPS,[483] which permits states to grant compulsory licences "to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work the patent."[484]

It is argued that article 5(a)(2) of the Paris Convention providing for granting compulsory licence in case of failure to work the patent conflicts with the principle of non-discrimination in

[478] Paul Champ and Amir Attaran, 'Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute' (2002) 27(2) Yale Journal of International Law 365, 384. **See also**, Thomas Cottier, 'TRIPS, the Doha Declaration and Public Health' (2003) 6(2) Journal of World Intellectual Property 385, 386

[479] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 31(b)

[480] Ibid, art 31(K)

[481] Muhammad Zaheer Abbas, 'Pros and Cons of Compulsory Licensing: An Analysis of Arguments' (2013) 3(3) International Journal of Social Science and Humanity 254, 254-255. **See also**, Ebenezer Durojaye, 'Compulsory Licensing and Access to Medicines in post Doha Era: What Hope for Africa?' (2008) 55(1) Netherlands International Law Review 33,48. **See also**, Carlos M. Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) 93-94

[482] Edward Richard Gold and Danial K. Lam, 'Balancing Trade in Patents: Public Non-Commercial Use and Compulsory Licensing' (2005) 6(1) Journal of World Intellectual Property 5, 22-23

[483] Article 2(1) of the TRIPS agreement obliges states members to comply with articles 1-12, 19 of the Paris Convention

[484] Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, entered into force 7 July 1884) 21 UST 1583, 828 UNTS 305 (Paris Convention) art 5(a)(2). **See also**, Frederick M. Abbott, 'The TRIPS-Legality of Measures Taken to Address Public Health Crises: Responding to USTR-State-Industry Positions That Undermine the WTO' in Daniel L. M. Kennedy and James D. Southwick (eds), *The Political Economy of International Trade: Essays in Honour of Robert E. Hudec* (Cambridge University Press 2002) 311, 324

article 27(1) of the TRIPS.[485] Article 27(1) provides that patent rights should be granted to products on equal terms regardless of whether the patented product is imported or locally produced. Accordingly, the principle of non-discrimination is applied to compulsory licences. This argument needs more elucidation.

The Paris Convention did not put any restriction on the interpretation of failure to work the patent considering it a matter of domestic interpretation and policy. Ordinarily however, working a patent is understood to mean working it industrially by manufacturing the product rather than the importation or sale of the patented product.[486] Accordingly, if a patent holder only imported a patented product into the country that granted him the patent right without manufacturing the product in that country, a compulsory licence could be issued for that patented product if the country adopts the policy of local working of the patent. Consequently, the application of the non-discrimination principle in the field of compulsory licences would imply that any working requirement of the patent can be fulfilled entirely by imports. The local working requirement is considered illegal because it violates the non-discrimination principle in article 27(1) of TRIPS which provides equal treatment to patents irrespective of whether the underlying product is imported or locally produced. That is why some countries avoided the violation by broadly defining the term "working" to include the importation of the patented product.[487]

It has been suggested that only such an interpretation to failure to work the patent would be consistent with the wider context of article 27(1) and 31 of the TRIPS which implies that the patentee exercises his patent right when the product is placed on domestic market, either through production or through importation.[488]

The issue of the apparent conflict between article 5(a)(2) of the Paris Convention and article 27(1) of the TRIPS was raised once in the WTO in *Brazil - Patent Protection* case between US

[485] Althaf Marsoof, 'Local Working of Patents: The Perspective of Developing Countries' in Ashish Bharadwaj et al (eds), *Multi-Dimensional Approaches Towards New Technology: Insights on Innovation, Patents and Competition* (Springer Singapore 2018) 315, 317-320
[486] G.H.C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property* (WIPO Publication 1969) 71< https://www.wipo.int/edocs/pubdocs/en/intproperty/611/wipo_pub_611.pdf> accessed 12 May 2020
[487] Althaf Marsoof, 'Local Working of Patents: The Perspective of Developing Countries' in Ashish Bharadwaj et al (eds), *Multi-Dimensional Approaches Towards New Technology: Insights on Innovation, Patents and Competition* (Springer Singapore 2018) 315, 318
[488] Brand, 'Article 2- Intellectual Property Conventions' in Peter Tobias Stoll et al (eds), *WTO-Trade Related Aspects of Intellectual Property Rights* (Martinus Nijhoff Publishers 2009) 95, 140

and Brazil in 2000.[489] According to that case, the US requested consultations with Brazil regarding its Industrial Property Law which allows compulsory licensing if the patent holder did not locally work the patent. The US noted that the Brazilian law defined failure to work the patent as failure to manufacture the product. Such definition is inconsistent with Brazil's obligations under article 27 and 28 of the TRIPS. Later, the dispute was resolved by a mutually satisfactory solution.[490]

Other scholars strongly rejected the application of non-discrimination principle to compulsory licences because it leads to an undesirable consequence. Patent laws that adopt local working requirement for granting compulsory licence violate the TRIPS agreement. Meanwhile, other broader patent laws granting compulsory licence on any ground would be consistent with the TRIPS obligations.[491] It is essential to regard article 31(compulsory licence) as an exception to the principle of non-discrimination in article 27(1) and not to apply the principle in such case.[492] As such, the patentee is required to manufacture the patented medicine in the country that granted the patent rather than to merely import it, otherwise a compulsory licence would be authorized.

This last argument is supported by many national patent legislations adopting the local working requirement.[493] Further, it is supported by article 5(a)(2) of the Paris Convention which left states free to determine the definition of "failure to work" that suits its policy and domestic interpretation as previously demonstrated. Moreover, the transfer of technology as one of the objectives of TRIPS support permitting the local working as an exception from the non-discrimination principle. This argument harks back to the historical function of patent rights, where patents were used as a tool to transfer knowledge to the country that granted the patent. This was previously demonstrated in the dissertation under the sub-section of the territorial period of the patent system. Finally, the local working requirement is of particular interest to countries lacking pharmaceutical manufacturing capabilities because it ensures that the patent holder shall transfer the manufacturing technology to them. It incentivizes local production by threatening to impose compulsory licences. Developing the pharmaceutical manufacturing

[489] Notification of Mutually Agreed Solution, *Brazil - Measures Affecting Patent Protection* (19 July 2001) WTO Doc WT/DS199/4, G/L/454, IP/D/23/Add.1
[490] Ibid
[491] Paul Champ and Amir Attaran, 'Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute' (2002) 27(2) Yale Journal of International Law 365, 392
[492] Ibid, 367
[493] Ibid, 366

capabilities of developing countries has an effective impact on enhancing the accessibility to medicines.

The report of the UN High-Level Panel on Access to Medicines emphasized the last meaning. It urged states to "adopt and implement legislation that facilitates the issuance of compulsory licences. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licences for legitimate public health needs." The report emphasized that the TRIPS did not specify reasons for granting compulsory licences. The grounds for their issuance are left to each state's discretion.[494]

The Compulsory licence system was incorporated into many national laws of developed countries to guarantee the affordability of medicines to all people. The dissertation showed under the section titled "The Historical Development of the Patent System" that developed countries started to eliminate or relax this system after the emergence of the economic arguments calling for incentives for future innovation. After the adoption of the TRIPS, they abandoned the whole system due to its interference with the exclusive rights granted to patent holders. Similarly, pharmaceutical companies opposed its usage on the grounds that it discourages R&D and pharmaceutical investments. On the other hand, developing countries regarded the system as crucial for public health protection and ensuring accessibility to essential medicines.[495]

A clear example of the effect of compulsory licences is that of drug prices under the Canadian Patent Act. Before its amendment, it allowed compulsory licences for the manufacture, use and sale of patented drugs, thus maintaining low prices of medicines. It was amended in 1969 to include importation of medicine, then further amended in 1987 to restrict the use of compulsory licences. Finally, the system was totally abrogated by Bill C-91, enacted in 1992, to enable Canada to meet its obligations under the TRIPS agreement. Noticeably, the prices of medicines significantly increased after the 1987 amendment.[496]

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[494] UN Secretary-General's High-Level Panel on Access to Medicines, 'Report on Promoting Innovation and Access to Health Technologies' (September 2016) 9 < http://www.unsgaccessmeds.org/final-report> accessed 12 December 2019

[495] Carlos M. Correa, 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (Cambridge University Press UK 2005) 227, 240. **See also**, Carlos M. Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) 93

[496] Carlos M. Correa, 'Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries' (October 1999) South Centre Working Paper No 5, 19-20 < http://www.iatp.org/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf > accessed 1 August 2019

Compulsory licences seem to be one of the TRIPS flexibilities that can provide a solution to the tension between pharmaceutical patents and accessibility to affordable medicines. However, due to the intricate conditions required in article 31 to grant this license, developing and less-developed countries are unlikely to benefit from it.[497] The article contains detailed conditions and restrictions for authorizing the use of the patented invention without the consent of the patent owner. This constitutes the longest list of specific requirements for any exception to substantive IPRs in the TRIPS agreement. States should comply with such requirements otherwise the authorization of compulsory licence is deemed as violating their TRIPS obligations. The requirements enumerated in article 31 of the TRIPS are as illustrated below.

#### 2.6.2.1 The Requirements of the Compulsory Licence Flexibility

##### A. Prior Negotiation

Paragraph(b) requires that the proposed beneficiary of the compulsory licence should, before the authorization of the compulsory licence, make prior negotiations to "obtain authorization from the right holder on reasonable commercial terms and conditions." Such negotiations should be conducted for "a reasonable period of time" before concluding their failure and, accordingly, permitting the authorization. However, states "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use" may waive the requirement of reasonable period of negotiations. Nevertheless, the patentee should be notified "as soon as reasonably practicable."[498] The requirement is also waived when the grant of the licence is permitted as a remedy for a practice determined to be anti-competitive after judicial or administrative process.[499]

National emergency or other circumstances of extreme emergency could allow states to invoke accessibility to medicines since TRIPS did not include any exhaustive list of such circumstances. The broad interpretation of the circumstances is supported by the Doha

[497] WTO, 'TRIPS and Pharmaceutical Patents' (September 2006) WTO Fact Sheet, 4 < https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf > accessed 13 October 2019. **See also**, Katri Paas, 'Compulsory licensing under the TRIPs Agreement: A Cruel Taunt for Developing Countries?' (2009) 31(12) European Intellectual Property Review 609, 609-610. **See also**, Frederick M. Abbott, 'Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO After the Doha Declaration on Public Health' (February 2002) Quaker UN Office Geneva Occasional Paper No 9, 25 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1977304 > accessed 19 February 2020

[498] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 31(b)

[499] Ibid, art 31(K)

Declaration which stipulated that "each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency."[500]

In the field of pharmaceuticals, the negotiations between the patentee and the beneficiary are usually complicated, considered case-by-case according to the industry and innovation, consume a lot of time to be concluded, and are likely to encounter stiff opposition by the patentee.[501] Further, while national emergency might be a suitable solution for access to medicine, it was argued by some commentators that emergency has to be narrowly interpreted. It is not meant for long-term health problems, *inter alia*, pandemics, as they do not constitute emergency. Emergency refers only to situations with grave consequences that demand a speedy reaction with no time for negotiations.[502] However, this argument runs counter to the Doha Declaration which does not include an exhaustive list of emergency cases.

Furthermore, some countries are reluctant to declare a situation of emergency due to political and economic situations.[503] As such, some states adopted a narrow interpretation of such circumstances preferring to negotiate for a voluntary license instead of taking the risk of revocation of the license or paying a lot of compensation to the patent holder.[504]

### B. Adequate Remuneration

There is a clear obligation to compensate the patent holder with adequate remuneration after authorizing the compulsory licence as mentioned in paragraph(h). This paragraph has proven to be highly controversial because it evaluates the adequate remuneration based on the economic value of the license.

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[500] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration) para 5(c). **See also**, Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 196

[501] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 195. **See also**, ICTSD- UNCTAD, *Resource Book on TRIPS and Development* (Cambridge University Press New York 2005) 469-470 < https://unctad.org/en/PublicationsLibrary/ictsd2005d1_en.pdf> accessed 20 February 2019

[502] Sandra Bartelt, 'Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health' (2003) 6(2) Journal of World Intellectual Property 283, 295

[503] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 247

[504] Graham Dutfield and Uma Suthersanen, *Global Intellectual Property Law* (Edward Elgar Publishing Limited UK 2008) 319. **See also**, Carlos M. Correa, 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (Cambridge University Press UK 2005) 227, 248

This provision can be used by developing countries when considering the right to access to medicine. For example, Zambia, the first African country to grant a compulsory licence, granted a compulsory licence on medicine to one of its local pharmaceutical companies in 2004 for the local production of a generic HIV/AIDS medicine after failing to reach an agreement with the patent holder. It considered that the adequate remuneration should be calculated according to the low price of the generic medicine.[505] Likewise, the royalty paid by the Thai government for issuing a compulsory licence was too low and evaluated by the government itself.[506]

However, in the absence of an indication as to the adequate level of remuneration, developed countries contended that other factors have to be taken into consideration, like the interests of the patent holders. This would make the estimation depend on each case merits, creating an obstacle to granting compulsory licences if the value of remuneration was set at a high rate.[507]

Generally, the granting government is left to decide the adequate remuneration if the subject matter of the authorization shall be manufactured in its territory. However, when the product is imported from another country the situation changes. If the economic situation in the importing country differs from that of the exporting country, the relative economic strength of the two countries should be considered. The 30 August Decision and the amendment of the TRIPS agreement provided that the remuneration in general should be paid only by one country, either the importing country or the exporting one.[508]

### C. Scope and Duration

The TRIPS agreement obliges states to limit the scope and duration of the compulsory licence to the purpose for which the licence was granted. When the circumstances leading to the authorization of compulsory licence "cease to exist and are unlikely to recur," the compulsory licence has to be terminated.[509] Also, the compulsory license is non-exclusive.[510] The patentee

[505] Republic of Zambia, Ministry of Commerce, Trade and Industry, Compulsory Licence No CL 01/2004, MCT1/104/1/1c (21 September 2004) cited in Cephas Lumina, 'Free Trade or Just Trade? The World Trade Organisation, Human Rights and Development' Pt 2 (2010) 14 African Journal Online, 10 < https://repository.up.ac.za/bitstream/handle/2263/16145/Lumina_Free(2010).pdf?sequence=1> accessed 30 May 2019

[506] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 221

[507] Bryan C. Mercurio, 'TRIPS, Patents and Access to Life-Saving Drugs in the Developing World' (2004) 8(2) Marquette Intellectual Property Law Review 211, 222-223

[508] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision) paras 3, 9. **See also**, Amendment of the TRIPS Agreement (8 December 2005) WT/L/641 (Decision of 6 December 2005) art 31*bis* (2)(5)

[509] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 31(g)

[510] Ibid, art 31(d)

still enjoys his right to produce, use and licence the patent. Further, it is "non-assignable, except with that part of the enterprise or goodwill" which uses the licence.[511] As such, the patent holder has the option to continue exploiting the pharmaceutical product and compete with the compulsory licensee or even grant any voluntary license to a third party.[512]

Moreover, the TRIPS obliged member states to provide for the possibility of "judicial review or other independent review by a distinct higher authority in that member" regarding the legal validity of any decision relating to the authorization of use of the compulsory licence or any decision relating to the remuneration provided in respect of such use.[513]

### D. Domestic Supply

According to paragraph(f), the compulsory licence has to be used "predominantly for domestic market supply." The word "predominantly" refers to the major part or majority. It would generally suggest that more than 50% of the production resulting from the compulsory licence should be intended to supply the domestic market of the member state that granted the compulsory licence. It would also suggest that "the domestic market of the granting country takes the greatest share of supply as among those members receiving supplies."[514]

Noticeably, the manufacturing process itself is not required to take place within the territory of the granting country. The principle of territoriality, as implied by paragraph (f), is directed to the usage rather than the production *per se*. As such, if the granting country lacks pharmaceutical manufacturing capacities and the beneficiary does not establish such capacities, the compulsory licensee, in order to work the licence, may import medicines from a third country whether they were manufactured there by the patent holder or not.[515]

The condition of "predominantly for domestic market supply" constituted a highly contentious issue and a major limitation to accessibility to medicines in countries with insufficient or lacking manufacturing capacities or with public health needs. It restricts the compulsory licensees' ability to supply their domestic market by importing medicines from a third country, in case

[511] Ibid, art 31(e)
[512] Carlos M. Correa, 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (Cambridge University Press UK 2005) 227, 248-249.
[513] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 31(i)(j)
[514] Frederick M. Abbott, 'WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries' (2002) UK Commission on Intellectual property Rights Study Paper 2a, 17 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1924420> accessed 25 May 2019
[515] Ibid, 18

where the generic medicines are not domestically manufactured. These countries were mainly relying on foreign generic manufacturers before the implementation of the TRIPS.[516]

Further, such condition limits the flexibility of countries having pharmaceutical industrial capacities to authorize the export of compulsory-licenced drugs. According to their TRIPS obligations, if they authorized a compulsory licence for producing a generic medicine, it has to be consumed in their domestic markets.[517]

Moreover, if the domestic market is small, the compulsory licensee will not be willing to manufacture medicines because of the obligation to direct the product solely for the supply of that small domestic market. To be efficient, the compulsory licensee would need to manufacture more medicines and export the surplus production. Consequently, the condition in paragraph(f) hinders the transfer and dissemination of technology to countries with insufficient or no pharmaceutical manufacturing capacities which runs counter to the TRIPS objectives stipulated in article 7.

Indeed, the compulsory licensing system allows only the usage of a patented medicine, but it does not oblige the patent holder to transfer the knowledge and know-how needed to execute the generic medicine. Generally, the patent specification includes minimum information which is not sufficient for manufacturing generic drugs.[518]

Accordingly, to work the compulsory licence in consistency with paragraph(f), the licensee has two possible options. The first is to set up manufacturing capacities in the granting country, which is unlikely to happen given that the relevant markets are often not sufficiently large to support the pharmaceutical industry. The second option is to import from a third country making the generic drug available in the market, either due to not granting a patent to the original medicine or due to the expiry of the patent term. However, due to the expiry of the TRIPS transitional period for all developed countries with manufacturing capabilities on 1 January 2005, they became obliged to provide patent protection for all medicines. As such, the only

[516] Bryan C. Mercurio, 'TRIPS, Patents and Access to Life-Saving Drugs in the Developing World' (2004) 8(2) Marquette Intellectual Property Law Review 211, 231-232. **See also**, Graham Dutfield and Uma Suthersanen, *Global Intellectual Property Law* (Edward Elgar Publishing Limited UK 2008) 320. **See also**, WHO, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health/ Carlos M. Correa' (June 2002) WHO Doc WHO/EDM/PAR/2002.3, 19-20

[517] Frederick M. Abbott, 'WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries' (2002) UK Commission on Intellectual property Rights Study Paper 2a, 17 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1924420> accessed 25 May 2019

[518] Carlos M. Correa, 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (Cambridge University Press UK 2005) 227, 247

option left is exporting generic medicines to the granting country after the expiry of the patent term of the original medicine.

Some scholars offer another option arguing that the limited exceptions flexibility provided by article 30 of the TRIPS include permitting the production and exportation of generic medicines according to compulsory licences, in order to meet public health needs.[519] However, such argument is impermissible due to the narrow interpretation of the WTO panel to the limited exceptions in article 30 in the *Canada - Patent Protection of Pharmaceutical Products* case. As previously shown, the panel concluded that the stockpiling exception violates article 28(1) of the TRIPS agreement.

In essence, paragraph(f) caused heated debates due to its severe implications on WTO members lacking pharmaceutical manufacturing capacities. A WHO seminar about compulsory licences viewed article 31(f) as an obstacle specifically impeding developing countries with pharmaceutical manufacturing capacities, like India, from exporting sufficient quantities of medicines to least-developed countries lacking such capacity, like Togo. This makes compulsory licensing a meaningless measure for many least-developed countries.[520]

The foregoing analysis of the compulsory licence flexibility showed the burdensome conditions provided by article 31 of the TRIPS to utilize such flexibility. A literal interpretation of such conditions may, as Carlos Correa stated, "discourage the application of compulsory licences since the licensee may be exposed to the revocation of his right at any time."[521] Fulfilling the conditions stated in article 31 hampers most developing countries from utilizing the compulsory licensing system as a possible solution to promote access to medicines. This contradicts the objectives, purposes and the non-discrimination principle of the TRIPS agreement.[522]

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[519] K.M. Gopakumar, 'The WTO Deal on Cheap Drugs: A Critique' (2004) 7(1) Journal of World Intellectual property 99, 102-103

[520] Suerie Moon, 'Implementation of the Doha Declaration on the TRIPS Agreement and public Health: Technical Assistance-How To Get it Right' (WIPO Conference on the International Patent System, International Conference Centre of Geneva, 28th March 2002) 4 < https://oxfamilibrary.openrepository.com/bitstream/handle/10546/112363/implementation-doha-trips-agreement-public-health-280302-en.pdf;jsessionid=5A32CCCFD04C39083FD44FCD9891B7B5?sequence=1> accessed 10 January 2020

[521] Carlos M. Correa, 'Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries' (October 1999) South Centre Working paper No 5, 8 < http://www.iatp.org/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf > accessed 1 August 2019

[522] Carlos M. Correa, 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (Cambridge University Press UK 2005) 227, 240-241

While the right to access to medicines is a crucial argument that supports a broader and more flexible interpretation of article 31, there are other arguments pertaining to the protection of patent rights which favour a more restrictive interpretation. The human rights argument is one argument among others, and it is unclear which argument would prevail in a dispute settlement proceeding.

Due to the legal uncertainty about the interpretation of the intricate requirements of the compulsory licence flexibility and the pressure exerted by developed countries to restrict such system in the field of pharmaceuticals, developing countries have largely forgone using the system to alleviate health concerns.[523] One of the very few cases regarding compulsory licences usage is when Malaysia in 2017 issued a compulsory licence for the production of Sovaldi medicine for the treatment of Hepatitis C. This was to overcome the drug's high price set by Gilead pharmaceutical company.[524]

Previously, the dissertation demonstrated the WTO decisions to remedy the deficiencies in the pharmaceutical patent system in TRIPS. In the following sub-section, it shall highlight the problems in the Doha Declaration and the 30 August 2003 Decision regarding compulsory licence. As noted previously, the amendment of the TRIPS by virtue of article 31*bis* follows the exact wording of the 30 August Decision, thus the same problems addressed under the decision are directed to the amendment.

#### 2.6.2.2 The WTO Decisions Concerning the Compulsory Licence Flexibility

A lot of concerns were directed to Article 31(f) in the TRIPS agreement which provided that the usage of compulsory licence is predominantly for domestic consumption.[525] The Doha Declaration recognized the gravity of this issue. It gave each state the right to "grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." It

[523] Olga Gurgula & Wen Hwa Lee, 'COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?' (23 January 2021) Forthcoming in the Journal of generic Medicines 2,7 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3771935> accessed 23 March 2021

[524] 'Sofosbuvir (Sovaldi)' (Hepatitis C Online) < https://www.hepatitisc.uw.edu/page/treatment/drugs/sofosbuvir-drug#:~:text=Sofosbuvir%20is%20manufactured%20as%20Sovaldi,Pharmasset%20as%20compound%20PSI%2D7977 > accessed 11 January 2021. **See also**, Catherine Saez, 'Malaysia Grants Compulsory Licence for Generic Sofosbuvir Despite Gilead Licence' (Intellectual Property Watch, 15 September 2017) < https://www.ip-watch.org/2017/09/15/malaysia-grants-compulsory-licence-generic-sofosbuvir-despite-gilead-licence/ > accessed 11 January 2021

[525] Ebenezer Durojaye, 'Compulsory Licensing and Access to Medicines in post Doha Era: What Hope for Africa?' (2008) 55(1) Netherlands International Law Review 33, 50

also allowed WTO members to determine "what constitutes a national emergency' while explicitly mentioning that 'public health crisis, *inter alia*, HIV/AIDS, Malaria, Tuberculosis and other epidemics can represent national emergency or other circumstances of extreme urgency."[526]

Moreover, the declaration allowed the least-developed countries to delay their pharmaceutical patenting obligations under the TRIPS agreement, regarding compulsory licensing, until 1 January 2016. This period was extended to 1 January 2033 by virtue of the TRIPS Council Decision issued in November 2015.[527]

The declaration recognized the difficulties facing WTO members, with insufficient or no manufacturing capacities in the pharmaceutical sector, when using the compulsory licence system. However, it did not offer an effective solution to remedy such difficulties. It only instructed the TRIPS Council to find an expeditious solution and report it to the General Council before the end of 2002.[528] Accordingly, the TRIPS Council adopted the 30 August 2003 Decision allowing for waivers from the compulsory licensing obligation of domestic consumption stipulated in article 31(f) of the TRIPS and from the remuneration obligation stated in article 31(h).[529]

The 30 August Decision appeared to present a legitimate solution with a new compulsory licence scheme which allows member states to produce and export generic drugs to other countries without requiring that such medicines should be domestically used. However, the Decision confined the eligible importing countries to the least-developed countries and other countries that notified the TRIPS Council of their intention to utilize the exemption due to an emergency or in case of public non-commercial use. Certainly, this opened a room to invoke accessibility to medicines as an argument in emergency cases.[530]

The Decision also dealt with the problem of double remuneration, where the patent holder receives remuneration from both the exporting and importing country. The Decision waived

[526] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration) para 5(b)(c)
[527] Ibid, para 7. **See also**, WTO, 'Responding to Least Developed Countries' Special Needs in Intellectual Property' < https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm > accessed 13 June 2019
[528] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration) para 6
[529] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision)
[530] Frederick M. Abbott and Jerome H. Reichmann, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 (4) Journal of International Economic Law 921, 929

such obligation and confined it to the exporting country. Moreover, the Decision encouraged member states to use the compulsory licence system to promote technology transfer in the pharmaceutical sector.[531] Furthermore, and contrary to the attempts by the US and EU to confine the diseases covered under the waiver to "grave public health problems" like HIV/AIDS, Malaria and Tuberculosis,[532] the Decision adopted the broad approach of the TRIPS which encompasses "any public health problems whether in developing or least-developed countries."[533]

Although such waivers could be a step forward to promote better accessibility to medicines, a lucid view of its administrative requirements shows that they required several intricate procedures for granting a compulsory licence. This renders utilizing the compulsory licensing system, under the waivers, onerous for both the exporting and importing countries.[534]

The dissertation demonstrated above some of these intricate procedures. It showed that the exporting and importing countries have to notify the TRIPS Council of their intention to issue a compulsory licence and that the notification should include several requirements. In addition, the exporting country has to grant a compulsory licence to export medicines, and the importing country is also obliged to issue a second compulsory licence if the medicine is still patented under its system.[535] Such notifications may waste a lot of time since they have to be approved by the TRIPS Council except in national or extreme emergency cases.[536] They may also draw the attention of patent holders and developed countries to impose pressure in order to impede the process.

Furthermore, the Decision required that the exported drugs have to be identified via specific labelling and marketing to guarantee that they will be exported and used in the destination stated in the license. It also required precise determination of the quantity of medicines that shall be

[531] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision) paras 2, 3, 7
[532] Frederick M. Abbott and Jerome H. Reichmann, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 (4) Journal of International Economic Law 921, 936-937
[533] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision) para 1(a)
[534] UN Millennium Project, *Prescription for Healthy Development: Increasing Access to Medicines* (Earthscan London 2005) 6 < https://www.taylorfrancis.com/books/9781849773553> accessed 20 November 2019
[535] Katri Paas, 'Compulsory licensing under the TRIPs Agreement: A Cruel Taunt for Developing Countries?' (2009) 31(12) European Intellectual Property Review 609, 613. **See also**, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision) para 2
[536] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision) para 1(b)

exported. Any change in this quantity would invalidate the whole process. This clarifies the inflexibility of the decision which is based on "drug-by-drug, country-by-country and case-by-case decision-making process." It ignores the fact that it is often harsh to identify quantities of medicines needed and specific marketing and labelling systems for them when there is a health crisis. Generic manufacturers might be discouraged from using the system due to such onerous requirements.[537]

Carlos Correa noted that the required information and notifications in addition to the obligation to adopt measures to avoid the diversion of generic versions of drugs to other countries would seem more suitable for the export of weapons or dangerous materials. It is not suitable for products that address public health needs.[538] The decision was described by the WTO as a proof that it is capable of handling humanitarian concerns and making medicines for HIV/AIDS, tuberculosis and other epidemics accessible to the most vulnerable.[539] However, the procedural burden imposed on countries willing to utilize the compulsory licensing system raised significant criticism.

Public health advocates, NGOs and many developing countries received the 30 August Decision with muted reception. It is a common view among scholars that the Decision is considered a defeat for developing countries due to the uncertainty it created regarding the usage of the compulsory licensing system for exporting medicines to eligible countries.[540] The TRIPS amendment, subsequently, did not alleviate the situation since it follows the same wording of the 30 August Decision and did not offer anything new as explained above.

Verma, the former director of the Indian Society of International Law, emphasized that the Decision created more hurdles than solutions to paragraph 6 of the Doha Declaration. She described the Decision as "saddled with many administrative pre-requisites, which will hamper the very purpose of paragraph 6." These measures will not only delay the manufacture and supply of generic medicines but will also increase the costs of drugs. As such, the Decision turns

[537] Katri Paas, 'Compulsory licensing under the TRIPs Agreement: A Cruel Taunt for Developing Countries?' (2009) 31(12) European Intellectual Property Review 609, 613-614
[538] Carlos M. Correa, 'Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?' (January 2019) South Center Policy Brief No 57, 3 < https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf> accessed 12 April 2020
[539] 'WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines' (WTO News Items, 23 January 2017) < https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm> accessed 29 April 2020
[540] Brook K. Baker, 'Arthritic Flexibilities: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (2004) 14(3) Indiana International and Comparative Law Review 613, 633-635, 655

to be "a temporary solution which is difficult to operate. It is considered not faithful to the Doha Declaration."[541]

Cohen-Kohler noted that the generic manufacturers are required to negotiate a voluntary license with multiple patent holders. The process of negotiations is lengthy, complex and expensive. The licence, if granted, is limited to two years subject to one-year renewal and "the quantity of the license is limited to that which was originally applied for by the country." The heavy front-end investment needed for generic manufacturers to produce generic medicines and the insufficient economic compensation give them little incentives to engage in compulsory licence processes.[542]

Further, a report issued by Médecins Sans Frontières organization emphasized the intricacy, time-consuming and burdensome procedures for the exportation of medicines which is opposite to the expected simple, fast, and automatic mechanism needed to respond to public health emergencies. The report noted that "the decision flies in the face of the practical reality of managing a health programme, where flexibility and rapidity of response to ever-changing circumstances are vital. It ignores the fact that economies of scale are needed to attract interest from producers. Without the pull of a viable market for drugs, generic manufacturers will not seek to produce for export."[543]

The Commission on Intellectual Property Rights enumerated several reasons that made developing countries disuse the system of compulsory licences. These reasons include; the complex administrative and legal procedures needed to utilize the system, the fear from sanctions that might be threatened, either bilaterally or multilaterally if they use the system, and the obligation to use the system predominantly for the domestic market.[544]

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[541] S. K. Verma, 'TRIPS Agreement and Access to medicines' (Kansai University Publications, 2016) 90-91 < https://www.kansai-u.ac.jp/ILS/publication/asset/nomos/29/nomos29-06.pdf> accessed 1 May 2020

[542] Jillian C. Cohen-Kohler et al, 'Canada's Implementation of the Paragraph 6 Decision: Is it Sustainable Public Policy?' (2007) 3(12) Globalization and health Journal < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2180169/> accessed 1 May 2020

[543] Médecins Sans Frontières, 'Neither Expeditious nor a Solution: The WTO August 30th Decision is Unworkable' (XVI International AIDS Conference, Toronto, August 2006) 5 < https://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_NeitherExpeditiousNorSolution_WTO_ENG_2006.pdf > accessed 15 August 2019

[544] Commission on Intellectual Property Rights, 'Report of the Commission on Integrating Intellectual Property Rights and Development Policy' (Commission on Intellectual Property Rights, September 2002) 42 < http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf > accessed 1 May 2019. **See also**, Graham Dutfield and Uma Suthersanen, *Global Intellectual Property Law* (Edward Elgar Publishing Limited UK 2008) 322. **See also**, Bryan C. Mercurio, 'TRIPS, Patents and Access to Life-Saving Drugs in the Developing World' (2004) 8(2) Marquette Intellectual Property Law Review 211, 231-232

This was further augmented by the view of generic pharmaceutical companies. They were sceptical regarding the effectiveness of the compulsory licensing system under the 30 August Decision in improving accessibility to medicines. For example, the Director General of the European Generic Medicine Association (EGA) declared that the Decision is "complicated, unworkable and unable to deliver any significant improvement in access to medicines."[545] Similarly, the representative of the Indian company Cipla, a multinational pharmaceutical company primarily specialized in generic medicines, observed that the system of compulsory licensing in the Decision is ineffective and cumbersome. He declared that Cipla would not use the Decision in its current state to produce generic medicines.[546]

Consequently, countries like Canada, Mexico, China and India had limited compulsory licence provisions in their national laws.[547] The Rwandan compulsory licence in 2007 emphasizes the complexities and the bureaucratic cumbersome process required to use the compulsory licensing system. Rwanda notified the TRIPS Council of its intention to use paragraph 6 of the Doha Declaration to import generic HIV/AIDS medication called Apo-TriAvir from the Canadian pharmaceutical company Apotex.[548] The company was authorized by the Canadian government to produce the Apo-TriAvir after the failure of negotiations between Rwanda and the patent holder of the original medicine to obtain a contractual licence. The generic alternative Apo-TriAvir would cost approximately 0.20 USD per pill compared to the original medicine that cost 6 USD per pill.[549] Similarly, Apotex had to apply for a compulsory licence to export Apo-TriAvir to Rwanda. This was followed by Canada's notification to the TRIPS Council of such authorization.[550]

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[545] Hafiz Aziz ur Rehman, 'WTO, Compulsory Export Licenses and Indian Patent Law' (2011) 1 Nordic Journal of Commercial Law 1, 13

[546] Carlos M. Correa, 'Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?' (January 2019) South Centre Policy Brief No 57, 4 < https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf> accessed 12 April 2020

[547] Michael Halewood, 'Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law' (1997) 35(2) Osgoode Hall Law Journal 243, 245

[548] WTO TRIPS Council, 'Notification Under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (19 July 2007) WTO Doc IP/N/9/RWA/1

[549] Vitor Palmela Fidalgo, 'Article 31bis of TRIPS: How Can African Countries Benefit from This Amendment' (Lexology, 9 June 2017) < https://www.lexology.com/library/detail.aspx?g=df73ba15-2a55-4337-86ed-756d2ba67e8b> accessed 29 March 2020

[550] WTO TRIPS Council, 'Notification Under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (8 October 2007) WTO Doc IP/N/10/CAN/1

Nevertheless, the system could be utilized as a room for manoeuvre. Governments can utilize it to put pressure on patent holders to reduce the prices of medicines, otherwise they would grant such licences to generic manufacturers. Yet, developing countries need to have the capacity to resist both the legal actions from pharmaceutical firms and the political pressure from their respective governments.[551]

An example of the ability of compulsory licences to strengthen the bargaining position of countries is the Brazilian threat to issue compulsory licences to obtain less expensive antiretroviral (hereinafter referred as ARV) medicines. The Brazilian President justified compulsory licences threat by stating that he is not "willing to sacrifice the health of his country's citizens for the sake of world trade."[552]

Another example is the US threats to Bayer pharmaceutical corporation producing Cipro medicine that treats Anthrax virus. Bayer agreed to drop Cipro's price in the US market after the US threatened to issue a compulsory licence to an Indian firm producing a generic equivalent named Cipla.[553] The paradoxical change in the US situation as one of the supporters to patent protection expresses how compulsory licences could be a tool to impose pressure on pharmaceutical companies to decrease the prices of medicines in case of national emergencies.

Surprisingly, only 30 out of 54 African countries accepted the TRIPS amendment. However, the amendment provisions are specifically designed to meet the health needs of African countries.[554] According to an up to date study conducted by the UN Department of Economic and Social Affairs in 2021 regarding the least-developed countries worldwide, Africa dominated the list with a total number of 33 least-developed countries.[555] This shows that the

[551] Carlos M. Correa, 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (Cambridge University Press UK 2005) 227, 248-250.
[552] Notification of Mutually Agreed Solution, *Brazil - Measures Affecting Patent Protection* (19 July 2001) WTO Doc WT/DS199/4, G/L/454, IP/D/23/Add.1. **See also**, Laurence R. Helfer and Graeme W. Austin, *Human Rights and Intellectual property: Mapping the Global Interface* (Cambridge University Press 2011) 132
[553] Lody Petersen and Robert Pear, 'A Nation Challenged: CIPRO; Anthrax Fears Send Demand for a Drug Far Beyond Output' (The new York Times, 16 October 2001) < https://www.nytimes.com/2001/10/16/business/a-nation-challenged-cipro-anthrax-fears-send-demand-for-a-drug-far-beyond-output.html?auth=login-google> accessed 2 April 2020. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 16-17
[554] WTO, 'Intellectual Property: TRIPS and Public Health: Members and Dates of Acceptance' < https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 17 April 2020
[555] UN Department of Economic and Social Affairs, 'The Least Developed Country Category: 2021 Country Snapshots' (2021) 4 <https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/Snapshots2021.pdf> accessed 4 May 2021

least-developed countries had largely forgone using the compulsory licence system due to its inefficiency even after amendment of the TRIPS agreement.

Eventually, it is necessary to change the complicated process required for obtaining a compulsory licence because it is inconsistent with the national emergency or other circumstances of extreme urgency as provided in the TRIPS amendment. It is also necessary to waive the requirement that demands attempt to obtain a voluntary licence from the patentee before utilizing the compulsory licence system. The numerous notifications should be avoided or simplified as well.

### 2.6.3 Differential Pricing and Parallel Importation

Differential pricing is widely practiced by pharmaceutical companies as one of their marketing strategies.[556] According to the strategy, pharmaceutical firms manage to sell their products in developing countries at a lower price than the market price in developed states. This concept was adopted by the WHO based on the narrative that developing and poor states are not required to pay the costs of R&D and marketing of medicines.[557] Among the examples of differential pricing are setting the prices of patented drugs according to generic equivalents, offering discounts, and drug donation programs.[558]

The UN Millennium Project stated that pharmaceutical companies should offer medicines to low-income countries at their production cost with "no profit, no loss," while offering it to middle-income countries with slightly higher prices. One of the successful examples of that system is the "market segmentation strategy" for Coartem medicine that treats Malaria. Novartis, the company producing the medicine, agreed to sell it to public health systems in developing countries at a low price. Kenya was one of those countries which benefited from the differential pricing agreement.[559] Further, the WHO recognized the importance of differential pricing in ensuring the accessibility to essential medicines at affordable prices, specifically in

[556] UN Millennium Project, *Prescription for Healthy Development: Increasing Access to Medicines* (Earthscan London 2005) 67 < https://www.taylorfrancis.com/books/9781849773553> accessed 20 November 2019
[557] Ibid
[558] Commission on Intellectual Property Rights, 'Report of the Commission on Integrating Intellectual Property Rights and Development Policy' (Commission on Intellectual Property Rights, September 2002) 41 < http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf > accessed 1 May 2019
[559] UN Millennium Project, *Prescription for Healthy Development: Increasing Access to Medicines* (Earthscan London 2005) 68 <https://www.taylorfrancis.com/books/9781849773553 > accessed 20 November 2019. **See also**, UN Millennium Development Goal Gap Task Force, *Millennium Development Goal 8: Delivering on the Global Partnership for Achieving the Millennium Development Goals* (UN Publication 2008) 38 < https://www.un-ilibrary.org/content/books/9789210542982/read > accessed 3 May 2020

poor countries. It suggested that this system could help in reconciling the affordability of medicines to people, and providing incentives for future R&D.[560]

However, pharmaceutical companies argued that such schemes could be misused by reselling the low-priced medicine to another buyer at a higher price (parallel importation). Poggie claimed that this would create a disincentive to continue offering medicines to developing countries at a preferential price. He suggested that the whole system would be "unworkable unless the different categories of buyers can be prevented from knowing about, or from trading with, one another."[561]

The admissibility of parallel importation in each country influences the differential pricing strategy of the pharmaceutical industry.[562] Previously, the dissertation had demonstrated the relationship between parallel importation and exhaustion of patent rights. Adopting the national exhaustion regime allows the pharmaceutical producers to set different prices, where they apply higher prices in rich countries and lower prices in developing countries whose markets cannot bear the high prices. As such, national exhaustion regime allows more market segmentation since parallel importation is not allowed in this regime. On the contrary, adopting the international exhaustion of patent rights allows parallel importation of medicines because the patent right is exhausted once the product is first sold or marketed in any country. Importers would utilize such system to buy cheap medicines from a country and resell them at a higher price in another. This explains why pharmaceutical companies are dissatisfied with the international exhaustion regime since parallel importation undercuts their ability to engage in price discrimination across national boundaries and severely reduces their profit levels. Consequently, they would abandon or relax offering medicines to developing countries at differential prices resulting in an increase in the prices of essential medicines in developing countries.[563] In fact, the national exhaustion tends to favour the inventor interest (private

[560] WTO, 'Report of Joint Workshop Convened by the WHO and WTO on Differential Pricing and Finance of Essential Drug' (Norwegian Ministry of Foreign Affairs 2001) 10 < https://apps.who.int/iris/bitstream/handle/10665/66919/a73725.pdf;jsessionid=F1D621F73B4A1AC92FD530343331CC0F?sequence=1 > accessed 28 August 2019

[561] Thomas Pogge, 'Human Rights and Global Health' (2005) 36 Meta philosophy LLC and Blackwell Publishing Ltd 182, 187

[562] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 231

[563] Bryan C. Mercurio, 'TRIPS, Patents and Access to Life-Saving Drugs in the Developing World' (2004) 8(2) Marquette Intellectual Property Law Review 211, 223, 245. **See also**, Mark Halle, 'The Exhaustion of Intellectual Property Rights: Should Countries Favour Consumers or Private Interests?' (The International Institute for Sustainable Development, June 2007) < https://www.iisd.org/system/files/publications/com_exhaustion.pdf?q=sites/default/files/publications/com_exhaustion.pdf > accessed 20 January 2021

interest), while the international exhaustion tends to favour the consumer interest (public interest).

The right to access to medicine supports the international exhaustion regime. Developing countries adopting the international exhaustion system will benefit from the low prices of medicines in foreign markets via parallel importation. Other countries that do not allow this system would opt for negotiations with pharmaceutical companies, with unguaranteed outcomes, regarding the differential pricing scheme.[564] The differential pricing strategy ensures that the prices of medicines are as low as possible for developing countries while maintaining its high prices in developed countries, thus it does not jeopardise R&D incentives. Nevertheless, even when pharmaceutical companies adopt the differential pricing strategy in developing countries, the prices of medicines are still unaffordable for them.[565]

The adoption of the international exhaustion regime was supported by the High Commissioner of Human rights, as well as the recommendation of the UK Commission on Intellectual Property Rights. Both stated that "since TRIPS allowed states to design their own exhaustion of rights regimes, developing countries should not eliminate a potential source of low-cost imports and should aim to facilitate parallel imports in their legislation."[566]

A group of commentators argued that the TRIPS does not allow the international exhaustion because article 28 (1)(a) of the TRIPS granted patent owners the exclusive rights to prevent third parties not having their consent from acts of importing.[567] This argument was rebutted by most scholars because the word "importing" mentioned in article 28 refers in its footnote to article 6 stating that "nothing in the TRIPS agreement shall be used to address the issue of intellectual property rights exhaustion."[568] Thus, a clear reading of article 28 with article 6

[564] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 234
[565] Vitor Palmela Fidalgo, 'Article 31bis of TRIPS: How Can African Countries Benefit from This Amendment' (Lexology, 9 June 2017) < https://www.lexology.com/library/detail.aspx?g=df73ba15-2a55-4337-86ed-756d2ba67e8b> accessed 29 March 2020
[566] Commission on Intellectual Property Rights, 'Report of the Commission on Integrating Intellectual Property Rights and Development Policy' (Commission on Intellectual Property Rights, September 2002) 42 < http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf > accessed 1 May 2019. **See also**, UN Sub-Commission on the Promotion and Protection of Human Rights, 'Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights' (27 June 2001) UN Doc E/CN.4/Sub.2/2001/13, para 66
[567] Laurence R. Helfer and Graeme W. Austin, *Human Rights and Intellectual property: Mapping the Global Interface* (Cambridge University Press 2011) 121
[568] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 6, footnote 6 of art 28

confirms that the TRIPS agreement did not prohibit international exhaustion, and accordingly parallel importation, but rather, it gave states complete discretion to adopt the exhaustion system that suits their need.[569]

Importantly, the Doha Declaration emphasized the freedom of each state to establish its own regime for exhaustion of IP rights. This confirms that parallel importation does not constitute any violation to the TRIPS agreement. Consequently, nearly all developing countries allowed international exhaustion of patent rights to retain flexibility to obtain patented medicines at the lowest price through parallel importation.[570] The patent legislations in developing countries rarely restrict parallel importation and have often managed to legalize it. For example, the Patent Acts in Indonesia, Argentina and Thailand clearly stated that importation of patented products shall not be deemed to be an infringement of the patent rights.[571] On the contrary, only few developed countries, like Japan and Switzerland, have adopted the international exhaustion regime.[572]

### 2.7. Conclusion

Pharmaceutical Patents are an instrumental framework meant to provide protection for medicines to retrieve the high costs of R&D and to incentivize inventors for future production. This rationale is largely supported by the history of patents showing that states have tried to tailor patent systems to suit their developmental agendas. States perceived patents at first as natural rights in ideas and a legal tool to achieve social objectives. They realized the existence of the notion of public domain after the proliferation of the argument that public access to inventions accelerate the progress of enlightenment in the society. After the industrial revolution and technological development, economic incentives arguments were used to justify the patent system as a tool for promoting economic and technological development, facilitating the transfer

[569] Marco M. Slotboom, 'The Exhaustion of Intellectual Property Rights: Different Approaches in EC and WTO' (2003) 6(3) World Intellectual Property Journal 421, 433

[570] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN(01)/DEC/W/2 (Doha Declaration) para 5(d). **See also**, Elizabeth Siew-Kuan Ng, 'Global Health and Development: Patents and Public Interest' in Thomas Pogge, Matthew Rimmer, and Kim Rubenstein (eds), *Incentives for Global Public Health* (Cambridge University Press 2010) 101, 118. **See also**, Bryan C. Mercurio, 'TRIPS, Patents and Access to Life-Saving Drugs in the Developing World' (2004) 8(2) Marquette Intellectual Property Law Review 211, 245-246

[571] Nick Gallus, 'The Mystery of Pharmaceutical Parallel Trade and Developing Countries' (2004) 7(2) World Intellectual Property journal 169, 176

[572] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 233

of technology and incentivizing R&D. This stimulated the universal recognition of the value of inventions and the exclusive rights of inventors to their work. States were free to enact patent legislations, with different scopes and levels of protection, that suit their level of industrial development.

Until the second half of the 20th century, states were not granting pharmaceutical patents to inventors. They argued that medicines are basic needs for human beings and necessary for public health, thus they should not be appropriated by any exclusive rights similar to tangible objects. However, with the advent of the WTO and the adoption of the TRIPS agreement, all WTO countries were obliged to grant patents for all inventions without discrimination. As such, pharmaceuticals, whether products or processes, became a subject matter for patents with possible exemptions to protect public order or morality including human health protection.

The TRIPS agreement attempted to harmonize intellectual property legislations, *inter alia*, patents. However, it did not oblige member states to adopt harmonized national laws. Instead, it imposed minimum standards for pharmaceutical protection leaving each WTO member state free to provide more extensive protection of intellectual property. It obliged all states to grant patent protection to pharmaceuticals, whether products or processes, for at least 20 years as a minimum standard if they satisfied certain patentability requirements. It also provided transitional periods to developing countries to fulfill their obligations in the pharmaceutical field.

Moreover, the TRIPS provides several ex-ante and ex-post flexibilities. The first are stipulated under article 27 of the TRIPS, where the TRIPS requires that the inventions eligible for patenting have to be new, involve an inventive step, and capable of industrial application. However, the TRIPS agreement does not provide a definition to these patentability criteria leaving each state to opt for the policy that best suits its level of development and scientific and technological capacity. From the perspective of accessibility to medicines, the dissertation argues that developing countries should adopt and apply a high threshold of novelty and inventive step. Adopting an absolute novelty criterion allows developing countries to prevent patenting of medicines that already exist in the public domain. Thus, patents shall be granted only to new or novel drugs that are unknown anywhere in the world, rather than providing protection to pharmaceutical inventions that are known in other countries and thus, in fact, are part of the prior art. Furthermore, strategic patenting or the “evergreening” practice that is often utilized by pharmaceutical companies have substantially impaired the ability of developing

countries to provide their population with affordable medicines. Pharmaceutical companies resort to such practices making minor or insignificant modifications to existing medicines and applying for patents with the aim to extending the breadth and duration of their medicines patent protection on which has expired or is close to expiration. This leads to the strengthening of their monopoly position by delaying or blocking the market entry of cheaper generics which enable them to continue charging high prices for their drugs. Accordingly, developing countries should adopt a high threshold of inventive step in order to prevent the negative effects of strategic patenting and to provide better accessibility to affordable medicines by facilitating generics competition. As Olga Gurgula argues, this contradicts the goal of the patent system aiming at incentivizing innovation since it reduces the originators' incentives to innovate and harms the follow-on innovation of generic companies.[573]

The other flexibilities in the TRIPS (ex-post flexibilities), namely the exceptions to patent rights in article 30, the compulsory licences in article 31 and the parallel importation in article 6, allow states to take measures, under specific conditions, that limit the exclusive rights of patentees after granting the patent rights. These flexibilities can be used in a way that protect public health, *inter alia*, accessibility to medicines for all people.

Any interpretation of the TRIPS provisions has to take into consideration public health interests particularly, accessibility to medicines. This obligation emanates from the Doha Declaration and the GATT/WTO jurisprudence which require interpreting the TRIPS provisions according to the VCLT. The GATT/WTO jurisprudence emphasizes that the TRIPS agreement should be interpreted in light of its objectives and principles that support the right to protect public health.

This is further supported by the findings reached when analysing the philosophical justifications for patent protection. The dissertation argued that it is crucial to combine the moral arguments that promote public accessibility to inventions with the economic incentives arguments which induce investment in R&D and promote technological innovation. Such perception is crucial when drafting patent legislations and policy frameworks in pharmaceuticals. It allows invoking human rights considerations to balance the right of patent owners with the human rights to health, otherwise, states would be violating their TRIPS obligations.

Theoretically, the TRIPS agreement tried to strike a balance between granting patent rights and protecting public health. It offered several solutions to developing countries with public health

[573] Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?' (2020) 51 International Review of Intellectual Property and Competition Law 1062, 1082

emergencies or with insufficient or no manufacturing capacities in pharmaceutical industry to access medicines at affordable prices. However, practically they produced different outcomes. The flexibilities were implemented and interpreted in a manner serving only the interests of the patent holders without considering the objectives and principles of the agreement. Countries were reluctant to use the flexibilities fearing trade retaliations or WTO dispute settlement proceedings with legal uncertainty. Also, the flexibilities were not adequately implemented due to drafting of the agreement in a way filled with maneuverers for the interests of developed countries. The agreement did not reflect the different norms and standards of developing countries in relation to the pharmaceutical sector. Thus, it impeded the accessibility to medicine for all people in developing countries.

While the Doha Declaration can be viewed as a forward step in achieving the balance between pharmaceutical patents under the TRIPS agreement and public health, the 30 August Decision watered down the wording of the Doha Declaration due to the intricate, cumbersome, and time-consuming procedures required by the Decision to grant compulsory licences. The TRIPS amendment followed the same wording of the 30 August Decision. It did not facilitate the usage of the compulsory licensing flexibility in the TRIPS which is crucial for the accessibility to medicines for WTO members with insufficient or no manufacturing capacity. Both the Decision and the TRIPS amendment failed to allow health concerns to prevail over the TRIPS obligations. Consequently, developing countries would prefer to negotiate for differential pricing with pharmaceutical companies or parallel imports, in case they adopt the international exhaustion of patent rights, rather than using the TRIPS flexibilities. The situation was worsened after the adoption of FTAs which led to more hiking of medicine pricing and more delay and impediments to the production of generics.

It could be argued that the shift of the patent system from a legal tool to achieve social objectives to a legal tool to protect economic incentives had transferred patents into a monopolized system. In pharmaceutical patents, such monopoly rights often restrict the accessibility to essential medicines in developing countries, i.e., interfering with a valuable resource that constitutes an integral component of the right to health.

Since the promotion of public health is considered one of the objectives and principles of the TRIPS, it is inevitable to rebalance the patentees' rights (economic objectives) with the public right to access essential medicines (social/moral objectives) by evaluating the role of human rights law within the WTO regime. This requires first to explore, in chapter 3, the human rights

framework for access to medicines and the nature of the obligations imposed on states to protect such rights.

## Chapter 3: The Human Rights Framework for Access to Medicines

### 3.1 Introduction

Developing countries suffer the most from the inequality in distribution and difficulty in accessing medicines. Over 5 billion people worldwide, constituting three-quarters of the world population lack access to essential medicines, according to a report issued by the UN in 2015. Almost forty thousand people die daily due to insufficient supply of essential medicines; most of them being children under five years old.[1]

After the adoption of the TRIPS Agreement in 1994, the debate around pharmaceutical patents was coined in a human rights framework. The UN General Assembly, the UN Committee on Economic, Social and Cultural Rights (hereinafter referred as CESCR), the Commission on Human Rights, the High Commissioner for Human Rights, and the WHO frequently contend that TRIPS Agreement has a negative impact on the accessibility to medicines. They demonstrated that all people have a legal right to access medicines as an indispensable component of the right to health. Pharmaceutical patents authorized inventors to set the prices of medicines at a high level rendering them unaffordable for many people, especially in developing countries. They asserted that such price surge constitutes an infringement of the right to access to medicines, which cannot be justified by any reason even under the argument of necessity of patents in spurring R&D.[2]

The UN Special Rapporteur on the Right to Health pointed out in his submission to the UN General Assembly in 2009 that "the framework of the right to health makes it clear that

[1] Margaret Chan, *Ten Years in Public Health 2007-2017* (WHO Publications 2017) 14 < https://apps.who.int/iris/bitstream/handle/10665/255355/9789241512442-eng.pdf?sequence=1 > accessed 8 February 2021. **See also**, Thomas Pogge, 'Montreal Statement on the Human Right to Essential Medicines' (2007) 16(1) Cambridge Quarterly of Healthcare Ethics 97, 104. **See also**, UN Millennium Project, *Prescription for Healthy Development: Increasing Access to Medicines* (Earthscan London 2005) 2 < https://www.taylorfrancis.com/books/9781849773553 > accessed 20 November 2019. **See also**, Hans V. Hogerzeil and Zafar Mirza, 'The World Medicines Situation 2011: Access to Essential Medicines as Part of the Right To Health' (WHO, 2011) WHO Doc WHO/EMP/MIE/2011.2.10, 1 < http://digicollection.org/hss/documents/s18772en/s18772en.pdf> accessed 17 October 2019. **See also**, UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, para 5. **See also,** 'Over 5 Billion People Worldwide Lacking Access to Essential Medicines, Says UN Report' (UN News, 3 March 2015) < https://news.un.org/en/story/2015/03/492482-over-5-billion-people-worldwide-lacking-access-essential-medicines-says-un> accessed 21 November 2020

[2] UN Human Rights Council, 'Resolution 6/29: Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (14 December 2007) UN Doc A/HRC/RES/6/29, Para 4(i). **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 76-78

medicines must be available, accessible, acceptable, and of good quality, to reach ailing populations without discrimination throughout the world. As has been evident, TRIPS has had an adverse impact on the price and availability of medicines, creating difficulty for countries to comply with their obligations to respect, protect and fulfil the right to health."[3]

Human right to health is a fundamental human right closely related to and dependent upon the realization of other human rights, *inter alia*, the right to life, human dignity, and non-discrimination. Those human rights and others constitute integral components of the right to health[4] since all human rights are universal, indivisible, interrelated, and interdependent.[5] Thus, states have to promote and protect all human rights in a fair and equal manner regardless of their political, economic or cultural systems.[6]

Most states have acceded to or ratified at least one of the regional or international human rights treaties, hence they are obliged to promote and protect all human rights in a fair and equal manner. However, not all countries exert enough efforts in fulfilling their human right to health obligations, including the accessibility to medicines.[7]

This chapter will address the human rights framework for access to medicines as an indispensable component of the right to health. First, it is necessary to shed light on the international human rights framework in general, showing its prominent instruments and the categories of human rights. Then, the chapter will address the right to health showing the international instruments and regional charters recognizing it and obliging states to protect it. This is followed by exploring the justiciability of the human right to health, then demonstrating the legal characters bound by it to show that states do not hold the sole responsibility for ensuring accessibility to medicines. Pharmaceutical companies also bear the responsibility. The

[3] Human Rights Council, 'Report of the Special Rapporteur Anand Groover on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights Including the Right to Development' (31 March 2009) UN Doc A/HRC/11/12, Para 94

[4] UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, paras 1,3. **See also,** Eibe Riedel, 'The Human Right to Health: Conceptual Foundations' in Andrew Clapham and Mary Robinson (eds), *Realizing the Right to Health: Swiss Human Rights Book,* Vol 3 (Ruffer and Rub Zurich 2009) 21. **See also**, Barbara Wilson, 'Social Determinants of Health from a Rights-Based Approach' in Andrew Clapham and Mary Robinson (eds), *Realizing the Right to Health: Swiss Human Rights Book*, Vol 3 (Ruffer and Rub Zurich 2009) 60

[5] Vienna Declaration and Programme of Action (12 July 1993) UN Doc A/CONF.157/23, para 5

[6] Ibid

[7] Hans V. Hogerzeil and Zafar Mirza, 'The World Medicines Situation 2011: Access to Essential Medicines as Part of the Right to Health' (WHO, 2011) 6 <http://digicollection.org/hss/documents/s18772en/s18772en.pdf> accessed 2 September 2019

chapter further demonstrates the right to access to medicines showing its elements, the international instruments that recognize it and the national court rulings which address it as a legally binding norm. This is followed by exploration of the nature of the right to access to medicines in public international law, namely, treaties and customary international law. It will be argued that the right to access to life-saving medicines as an element of the right to life in the ICCPR reaches the status of *jus cogens* norms. Then, the right to access to medicines as customary international law will be examined to identify the kinds of medicines that are placed under that category of international law. Eventually, the chapter will illustrate the challenges facing developing countries in their pursuit to improve access to medicines for their citizens.

### 3.2 International Human Rights Framework

Human rights are the basic rights and fundamental freedoms inherent to all human beings. They are equally applicable to all people regardless of their nationality, gender, colour, religion, ethnic origin or any other status. All people have moral claims against states by virtue of their humanity regardless of the legal regime in each state. Human rights are twofold: economic, social and cultural rights (hereinafter referred as ESCRs) category, like the right to health, education, and an adequate standard of living; civil and political rights (hereinafter referred as CPRs) category, like the right to life, liberty, freedom of expression, and property rights. The difference between the two categories is that the former group of rights demands action from the state to use its resources, including financial resources, to achieve such rights. Thus, they are called positive rights. Meanwhile, the latter group of rights is meant to protect individuals from government interference. They do not require state intervention to enjoy them, i.e., the state does not have to take any actions or to pledge its financial resources in accomplishing its duty. That is why they are called negative rights.[8]

The first international instrument that recognized human rights in general was the UN Charter 1945. One of the purposes of the UN Organization stated in its Charter is to achieve international co-operation in solving international problems of any character, *inter alia*, economic, social and

[8] 'Universal Declaration of Human Rights: The Foundation of International Human Rights Law' (UN) < https://www.un.org/en/about-us/udhr/foundation-of-international-human-rights-law> accessed 1 October 2020. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 89. **See also**, Ilias Trispiotis, 'Socio-Economic Rights: Legally Enforceable or Just Aspirational?' (2010) 8 Opticon 1826 UCL Journal 2 < http://www.ucl.ac.uk/opticon1826/archive/issue8/articles/Article_Laws_-_Ilias__Social_equality__Publish_.pdf > accessed 28 September 2019

cultural issues, and to promote and encourage respect for human rights and fundamental freedoms of all people without any kind of distinction.[9] To fulfil such purposes, the Charter required that states should pledge themselves to take joint and separate actions in cooperation with the UN organization to promote universal respect for, and observance of all human rights to all people without any kind of discrimination.[10]

Additionally, the Charter bestowed competency to the UN General Assembly and to the Economic and Social Council in human rights matters and required the Council to set up commissions for the promotion of human rights.[11] One of these commissions, namely the Commission on Human Rights, was responsible for drafting the UDHR which was unanimously adopted by the UN General Assembly in 1948 against the backdrop of the atrocious and violence of the Second World War.[12]

The UDHR is considered a codification of all human rights. The international legal system is full of international and regional agreements referring to the human rights stipulated in this declaration. As a General Assembly resolution, the UDHR is not binding as it is not a treaty but merely a recommendation to states to recognize human rights. Nevertheless, some scholars, arguably, opine that the declaration enjoys significant legal status reaching the status of customary international law because its norms and principles contribute to the formation of *opinio juris*. They supported their argument by pointing to the role played by the UDHR as a framework for expanding and recreating boundaries of human rights and the continuous referral to its provisions by academics and law practitioners when addressing universal rights.[13] At the end of this chapter, when analysing the nature of the right to medicine in public international law, the dissertation will explore whether the human rights in the UDHR constitute customary international law, or otherwise.

[9] Charter of the United Nations (adopted 26 June 1945, entered into force 24 October 1945) 1 UNTS XVI preamble, art 1(3)
[10] Ibid, arts 55, 56
[11] Ibid, arts 13(1)(b), 62, 68
[12] Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR). **See also**, 'History of the Universal Declaration of Human Right' (UN) <https://www.un.org/en/about-us/udhr/history-of-the-declaration> accessed 15 September 2020
[13] George P. Smith, 'Human Rights and Bioethics: Formulating a Universal Right to Health, Health Care or Health Protection?' (2005) 38(5) Vanderbilt Journal of Transnational Law 1295, 1300. **See also**, Vojin Dimitrijevic, 'Customary law as an Instrument for the Protection of human Rights' (2006) ISPI Working Paper-7, 8-10 < https://www.ispionline.it/sites/default/files/pubblicazioni/wp_7_2006_0.pdf > accessed 17 September 2019

The UN continued to aim for a legal binding document for human rights despite the difference in perspectives between socialist states and western liberal ones regarding which category of rights was worth protection. The former realized the ESCRs stemming from socialist ideas and opined that such rights have to be protected beside the CPRs in a comprehensive human rights document. Meanwhile, the latter preferred only the CPRs arguing that they are substantial for protecting the person from undue interference by the state. If both categories had to be protected, they insisted on adopting each category in a separate human rights document. Accordingly, two Covenants were drafted, the ICCPR and the ICESCR.[14] Since the entry into force of both Covenants, many human rights instruments have evolved. However, the UDHR together with the two Covenants are considered the pillars of universal human rights protection within the UN, named as the 'International Bill of Rights.'[15]

It is worth noting that 171 states are parties to the ICESCR as of May 2021, thus reflecting global consensus on the recognition of the human rights standards that apply to the ESCRs. Since it is considered an international human rights treaty, the ICESCR is a legally binding instrument, where the ratifying states have the responsibility to implement and maintain the human rights guaranteed therein.[16] The CESCR is considered the primary body responsible for monitoring, interpreting and implementing the human rights stipulated in the ICESCR. The Committee, which consists of independent experts, issues General Comments which are not legally binding (soft law) on states parties to the Covenant. However, they provide an authoritative interpretation of states obligations under the ICESCR. Such interpretation clarifies

[14] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 81, 82. **See also**, International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR). **See also**, International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171 (ICCPR)

[15] UN Commission on Human Rights, 'Resolution 2004/69: Status of the International Covenants on Human Rights' (21 April 2004) UN Doc E/CN.4/RES/2004/69, preamble

[16] UN Committee on Economic, Social and Cultural Rights, General Comment No 3: The Nature of States Parties' Obligations (Article 2, Paragraph 1 of the Covenant)' (14 December 1990) UN Doc E/1991/23. **See also**, 'Section 5: Background Information on the ICESCR' (ESCR-Network) < https://www.escr-net.org/resources/section-5-background-information-icescr#:~:text=Since%20the%20ICESCR%20is%20an,the%20standards%20contained%20in%20it > accessed 13 March 2020. For status of ratifications, see 'International Covenant on Economic, Social and Cultural Rights' (UN Treaty Collection, 12 May 2021) < https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-3&chapter=4&clang=_en> accessed 12 May 2021

the scope and content of each human right and delineates the obligations of states towards each of them.[17]

### 3.3 Human Right to Health

Health is one of the fundamental human rights indispensable for all human beings to live their life in dignity and to exercise other human rights.[18] The human right to health is an inclusive right which is recognized in several international and regional instruments. Nevertheless, its full enjoyment in practice still lacks global recognition especially in developing countries. It is systematically violated because the ESCRs in general are usually considered less important and not justiciable in comparison to the CPRs.[19]

The first international instrument to recognize the right to health was the WHO Constitution which entered into force on 7 April 1948 as a specialized agency of the UN.[20] It stipulated that "health is one of the fundamental rights of every human being which surpasses the absence of disease or infirmity to include a state of complete physical, mental and social well-being without any distinction based on race, religion, political belief and economic or social condition."[21]

The UDHR came after the WHO Constitution to recognize the right to health. It stated that "everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including … medical care."[22]

The most comprehensive and significant binding instrument recognizing the right to health is the ICESCR. It provided that "states parties to the Covenant recognize the right of everyone to

[17] 'Section 5: Background Information on the ICESCR' (ESCR-Network) < https://www.escr-net.org/resources/section-5-background-information-icescr#:~:text=Since%20the%20ICESCR%20is%20an,the%20standards%20contained%20in%20it > accessed 13 March 2020. **See also**, Yousuf A. Vawda and Brook K. Baker, 'Achieving Social Justice in the Human Rights/Intellectual Property Debate: Realizing the Goal of Access to Medicines' (2013) 13 African Human Rights Law Journal 55, 61-62. **See also**, Christian Tomuschat, *Human Rights: Between Idealism and Realism* (2nd edn, Oxford University Press New York 2008) 190-191

[18] UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, para 1

[19] Ibid, para 5. **See also**, Eibe Riedel, 'The Human Right to Health: Conceptual Foundations' in Andrew Clapham et al (eds), *Realizing the Right to Health: Swiss Human Rights Book*, Vol 3 (Ruffer and Rub 2012) 17 < https://saudeglobaldotorg1.files.wordpress.com/2014/06/01_453_riedel.pdf > accessed 2 September 2019

[20] Charter of the United Nations (adopted 26 June 1945, entered into force 24 October 1945) 1 UNTS XVI, art 57. **See also**, 'Global Health History: Origin and Development of Health Cooperation' (WHO) < http://www.who.int/global_health_histories/background/en/ > accessed 20 September 2019

[21] UN General Assembly, 'Entry into Force of the Constitution of the World Health Organization' (17 November 1947) UN Doc A/RES/131, preamble.

[22] Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR), art 25 (1)

the enjoyment of the highest attainable standard of physical and mental health." It obliged states to achieve the full realization of the right to health by pursuing a number of steps, *inter alia*, "the prevention, treatment and control of epidemic, endemic, occupational and other diseases" and creating suitable "medical service and medical attention in the event of sickness."[23]

The ICESCR also obliged each state party to the Covenant to take steps "to the maximum of its available resources, with a view to achieving progressively, the full realization of the rights recognized in the Covenant by all appropriate means, including particularly the adoption of legislative measures."[24] The drafters of the Covenant intentionally narrowed down the scope of health protection to become "highest attainable standard of health" instead of "a living standard adequate for health." They recognized that states cannot provide health protection against all causes of illness or guarantee that all people would enjoy good health. Instead, states have to promote conditions that lead to a healthy life, like food, housing and medicine. Wordings of "available resources" and "achieving progressively" confirm such meaning.[25]

Moreover, the right to health has been reiterated in the Alma-Ata Declaration on Primary Health Care in 1978 which stated that health is "a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector."[26]

Another prominent international instrument recognizing the right to health is the General Comment No. 14 of the CESCR which unequivocally showed that health is a fundamental human right indispensable for the exercise of other human rights and inevitable to living a life in dignity.[27] The General Comment noted that medicines, among other health services, should be available, accessible, acceptable, and of good quality in which they are scientifically and medically appropriate.[28] The General Comment added that the right to health imposes three

[23] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR), art 12 (1), (2)(c)(d)
[24] Ibid, art 2 (1). **See also**, UN Committee on Economic, Social and Cultural Rights, 'General Comment No 3: The Nature of States Parties' Obligations (Article 2, Paragraph 1 of the Covenant)' (14 December 1990) UN Doc E/1991/23
[25] UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, paras 4, 9
[26] Declaration of Alma-Ata International Conference on Primary Health Care (6–12 September 1978) para 1
[27] UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, para 1
[28] Ibid, para 12

types of obligations on states. A negative obligation to respect and positive obligations to protect and to fulfil. To respect requires states to refrain from interfering, either directly or indirectly, with the enjoyment of the right to health. To protect obliges states to take measures that prevent third parties from interfering with the right to health guarantees, namely, the availability, accessibility, acceptability, and quality of medicines. Finally, to fulfil requires states to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health.[29]

Such obligations are not confined to the domestic context, but rather, states parties to the ICESCR should ensure that the right to health is given due attention in international treaties and that such treaties do not adversely impact upon the right to health. Also, they should prevent third parties from violating the right to health in other countries in accordance with articles 55 and 56 of the UN Charter and the applicable international law.[30]

These obligations were further confirmed by several reports of the UN Special Rapporteur on the right to health.[31] In one of his reports, the Special Rapporteur stressed on the legal obligation of all states parties to the ICESCR "not to interfere with the rights conferred under the UDHR and the ICESCR, including the right to health."[32] He echoed the obligation of states, mentioned in both instruments, not to engage in any activity or to perform any act that destructs or limits the human rights recognized in them.[33]

Furthermore, the right to health has been proclaimed by the Commission on Human Rights which reaffirmed the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and recognized their right to access health care without any kind of

[29] Ibid, para 33
[30] Ibid, paras 38-39
[31] UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Addendum Mission to the World Trade Organization' (1 March 2004) UN Doc E/CN.4/2004/49/Add.1. **See also**, UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (11 February 2005) UN Doc E/CN.4/2005/51. **See also**, Human Rights Council, 'Report of the Special Rapporteur Anand Groover on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights Including the Right to Development' (31 March 2009) UN Doc A/HRC/11/12
[32] Human Rights Council, 'Report of the Special Rapporteur Anand Groover on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights Including The Right To Development' (31 March 2009) UN Doc A/HRC/11/12, para 11
[33] Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR) art 30. **See also**, International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR), art 5

discrimination. It encouraged the WHO and the Sub-Commission on Prevention of Discrimination and Protection of Minorities to continue its action in that regard and to examine the possibility of including other kinds of discrimination against sick or disabled persons in the study on discrimination against persons suffering from HIV/AIDS.[34]

Moreover, the right to health is recognized in many international conventions, *inter alia*, the Convention on the Elimination of All Forms of Discrimination against Women of 1979 which stated that states parties shall take appropriate measures to eliminate discrimination against women regarding the right to protection of health and health care services;[35] the International Convention on the Elimination of All Forms of Racial Discrimination of 1965 which stipulated that states parties shall undertake to prohibit and eliminate all forms of racial discrimination in the enjoyment of several human rights, *inter alia*, the right to public health and medical care;[36] the Convention on the Rights of the Child of 1989 which stipulated that states parties recognize the right of the child to the enjoyment of the highest attainable standard of health and shall strive to ensure that no child is deprived of such right, and that they undertake to promote and encourage international co-operation with a view to achieving progressively the full realization of such right, particularly the needs of developing countries.[37]

Finally, the right to health is recognized in several regional charters. The European Social Charter stipulated that states parties shall take appropriate measures, either directly or in co-operation with public or private organization, to ensure the effective exercise of the right to health and to prevent as far as possible, epidemic, endemic and other diseases.[38] Also, the African Charter on Human and Peoples' Rights of 1981 (Banjul Charter) recognized the right of everyone to enjoy the best attainable state of physical and mental health and stated that states parties shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.[39] Furthermore, the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights

[34] UN Commission on Human Rights, 'Report on Non-Discrimination in the Field of Health' (2 March 1989) UN Doc E/CN.4/RES/1989/11
[35] Convention on the Elimination of All Forms of Discrimination Against Women (adopted 18 December 1979, entered into force 3 September 1981) 1249 UNTS 13 (CEDAW) arts 11(1)(f), 12
[36] International Convention on the Elimination of All Forms of Racial Discrimination (adopted 21 December 1965, entered into force 4 January 1969) 660 UNTS 195 (CERD) art 5(e)(iv)
[37] Convention on the Rights of the Child (adopted 20 November 1989, entered into force 2 September 1990) 1577 UNTS 3 (UNCRC) art 24
[38] Council of Europe, European Social Charter (Revised) (adopted 3 May 1996, entered into force 1 July 1999) ETS 163 art 11
[39] African Charter on Human and Peoples' Rights (adopted 27 June 1981, entered into force 21 October 1986) OAU Doc CAB/LEG/67/3 rev 5, 21 ILM 58, 1520 UNTS 217 (Banjul Charter) art 16

of 1988 (Protocol of San Salvador) defined the right to health of everyone as the enjoyment of the highest level of physical, mental and social well-being. It stipulated that states should adopt several measures to recognize such a right, *inter alia*, the availability of primary health care to all individuals subject to states' jurisdiction, the satisfaction of health needs of high-risk groups and poor people, and the prevention and treatment of endemic, occupational and other diseases.[40]

Accordingly, it is important to address the justiciability of the right to health in the following section.

### 3.4 Justiciability of the Human Right to Health

Some jurists argued that the ESCRs are not justiciable and thus not important because states with limited financial resources are not able to fulfil the needs of such rights. Such states even rely on the wording of the Covenant itself, like "achieving progressively," and their national courts may be reluctant to adjudicate on cases dealing with such rights due to their significant effect on the states' economy. Adversely, the CPRs are justiciable because they could be implemented immediately since they do not affect the economy of states.[41]

This classification was rebutted because several human rights documents, *inter alia*, the Maastricht Guidelines on Violations of Economic, Social and Cultural Rights and the Vienna Declaration and Programme of Action 1993 emphasized that all human rights are interrelated, interdependent and indivisible. Therefore, each human right may contain positive and negative component.[42] For example, the right to education, one of the ESCRs, although classified as a positive right due to the duty imposed on the states to establish schools, requires that the state protects the freedom to teach which is a negative right. Also, the right to vote, one of the CPRs,

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[40] Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (adopted 17 November 1988, entered into force 16 November 1999) OAS Treaty Series No 69 (Protocol of San Salvador) art 10

[41] Ilias Trispiotis, 'Socio-Economic Rights: Legally Enforceable or Just Aspirational?' (2010) 8 Opticon 1826 Journal (UCL) 1 < http://www.ucl.ac.uk/opticon1826/archive/issue8/articles/Article_Laws_-_Ilias__Social_equality__Publish_.pdf > accessed 28 September 2019. **See also**, Audrey Chapman and Sage Russell, *Core Obligations: Building a Framework for Economic, Social and Cultural* (Intersentia Oxford 2002) 5

[42] Ida Elisabeth Koch, 'Social Rights as Components in the Civil Right to Personal Liberty: Another Possible Step forward in the Integrated Human Rights Approach?' (2002) 20(1) Netherlands Quarterly of Human rights 29, 32. **See also**, International Commission of Jurists, 'Maastricht Guidelines on Violations of Economic, Social and Cultural Rights' (26 January 1997) para 4 < http://hrlibrary.umn.edu/instree/Maastrichtguidelines_.html> accessed 13 October 2019. The Maastricht Guidelines is reissued in UN Doc E/C.12/2000/13 by the CESCR. **See also**, Vienna Declaration and Programme of Action (12 July 1993) UN Doc A/CONF.157/23, para 5

obliges states to ensure that every individual practices his right without any interference, i.e., a negative right, yet it includes obligations on the state to establish constituent assemblies which is a positive right.[43] Therefore, no right is considered only positive or only negative, where one category is worth protection more than the other. All human rights in both Covenants are of the same value and states cannot escape their obligations to equally protect them on the grounds of financial constraints.

The ICESCR is a legally binding instrument on the states that ratified it, however, they are not obliged to fully and immediately implement the rights enshrined in the Covenant including the right to health.[44] Instead, they are obliged to take steps to the maximum of their available resources with a view to achieve progressively the implementation of such rights.[45] This interpretation is affirmed by the wording of the ICESCR in addition to the VCLT stating that states have to interpret the Covenant in good faith and in light of the objective of realizing the rights enshrined in it.[46] As remarked by the Special Rapporteur on the Right to Health, Paul Hunt, the drafters of the ICESCR meant to insert the phrase "progressive realization of the right" due to recognizing that "comprehensive and integrated health care system cannot be constructed overnight."[47]

The progressive realization of the right to health in the ICESCR is limited only to the full implementation of the right, not the minimum core obligation of states which has to be achieved immediately to the maximum of the available resources in each state. The General Comment number 3 emphasized this notion when it stated that the human rights obligations stipulated in the ICESCR have to be read as establishing minimum core obligations, otherwise the Covenant would be largely deprived of its *raison d' être*. Nevertheless, there may be conditions beyond the control of states, where they fail to meet even the minimum core obligations, for example, natural catastrophes. However, any state attributing its failure to meet this minimum core obligations to the lack of available resources, has to "demonstrate that every effort has been

[43] E.W. Vierdag, 'The Legal Nature of the Rights Granted by the International Covenant on Economic, Social and Cultural Rights' (1978) 9 Netherlands Yearbook of International Law 69, 82, 86
[44] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 91
[45] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 2(1)
[46] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 31(1)
[47] Human Rights Council, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Promotion and Protection of all Human Rights, Civil, political, Economic, Social and Cultural Rights' (31 January 2008) UN Doc A/HRC/7/11, para 46

made to use all resources that are at its disposition in an effort to satisfy, as a matter of priority, those minimum obligations."[48]

The Vienna Declaration and Programme of Action adopted by the UN World Conference on Human Rights emphasized that the promotion and protection of human rights is a matter of priority for the international community and the first responsibility of governments.[49] Accordingly, it could be argued that the General Comment number 3, in line with the ICESCR, prioritize human rights over all other considerations when interpreting the meaning of the phrase "to the maximum of its available resources." Thus, governments should gather all the needed resources for the satisfaction of the minimum core obligations even though it would infringe the satisfaction of other rights in return.

Furthermore, the ICESCR obliged member states to adopt legislative measures that guarantee that all the human rights enunciated in it, including the right to health, shall be exercised without any kind of discrimination.[50] According to the principle of non-discrimination, any violation to the human right to health can be brought before the judiciary. The General Comment 14 emphasized the adoption of framework laws that operationalize the right to health, establish national mechanisms to monitor the implementation of national health strategies, and incorporate international instruments recognizing the right to health.[51]

Although the UN human rights framework is successful in creating and developing human rights norms, it is not effective regarding the provision of effective enforcement mechanisms. An encouraging step in that regard is the Optional Protocol to the ICESCR, entered into force on 5 May 2013, which allows individuals or group of individuals to file a complaint directly before the CESCR whenever they claim to be victims of a violation of any of the ESCRs by any state party. As of May 2021, 46 states have signed the Protocol, of which only 26 states have ratified or acceded to it.[52]

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[48] UN Committee on Economic, Social and Cultural Rights, 'General Comment No 3: The Nature of States Parties' Obligations (Article 2, Paragraph 1 of the Covenant)' (14 December 1990) UN Doc E/1991/23, para 10
[49] Vienna Declaration and Programme of Action (12 July 1993) UN Doc A/CONF.157/23, preamble, para 1
[50] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 2(2)
[51] UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, para 56
[52] UN General Assembly, 'Resolution 63/117: Optional Protocol to the International Covenant on Economic, Social and Cultural Rights' (5 March 2009) UN Doc A/RES/63/117. For status of ratifications and date of entry into force, see 'Optional Protocol to the International Covenant on Economic, Social and Cultural Rights' (UN Treaty Collection, 12 May 2021)

Reaffirming the justiciability of the right to health, the ICJ stated in an advisory opinion regarding the legal consequences of building a wall in Palestine that the ICESCR is applicable and relevant in assessing the legality of the act done by Israel. The ICJ stated that such act violates the provisions of the ICESCR, *inter alia*, the right to health.[53] Also, the African Commission on Human and Peoples' Rights stated in the case of *Social and Economic Rights Action Centre v. Nigeria* that the latter had violated the right to health because it did not require a study about the environmental impacts on health before allowing oil research in a city called Ogoniland.[54]

Several national courts have also applied the right to health in national verdicts, thus confirming the principle of the justiciability of the ESCRs in general and affirming the binding obligation on states to protect, respect and fulfil the right to health. These cases shall be demonstrated later in this chapter when addressing the right to access to medicines.

### 3.5 Legal Characters Bound by the Human Right to Health

Traditionally, human rights were envisaged as putting limits on state power and not binding on private parties. Article 2 stated in both Covenants that only states are bound by their provisions without any obligations imposed on private parties.[55] In the right to health, states are the sole addressee. The ICESCR stipulated that "states parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[56] However, this does not imply that human rights do not have any effect on the private sector. The human rights norms can be interpreted as the responsibility of the state to protect its individuals from any violation to their rights whether from the state itself or from any private

<https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3-a&chapter=4&clang=_en> accessed 12 May 2021

[53] *Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory* (Advisory Opinion) [2004] ICJ Rep 136, paras 112, 130

[54] *Social and Economic Rights Action Centre and the Centre for Economic and Social Rights v Nigeria*, Communication No 155/1996 (African Commission Decision, 27 May 2002) Case Ref ACHPR/COMM/A044/1, para 53

[55] Eckart Klein, 'The Duty to Protect and to Ensure Human Rights under the International Covenant on Civil and political Rights' in Eckart Klein (ed), *The Duty to protect and to Ensure Human Rights* (BWV Berliner-Wissenschaft 2000) 296, 297.

[56] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 12(1)

party. This is the approach adopted by the human rights law although not commonly applied on the national level.[57]

The WTO, administering the TRIPS Agreement, is considered an artificial person who can sign treaties and abide by its obligations, yet it did not sign any human rights agreement and its provisions are silent regarding human rights law. Thus, it is bound only by the general standards of human rights law. However, if the latter contradicts any of the WTO law, only the norms having *jus cogens* status shall bind the WTO.[58]

Also, pharmaceutical companies, as a non-state actor, have human rights responsibilities regarding the right to health. The Former UN Special Rapporteur on the right to health indicated that pharmaceutical companies have the duty to take all steps that would ensure the accessibility to medicines for all people who are in need "within a viable business model." If a new drug is placed in the market at higher prices, pharmaceutical companies have a range of mechanisms to make the drug accessible to people who cannot afford those prices, *inter alia*, differential pricing between states which the dissertation illustrated in chapter 2. The Special Rapporteur emphasized that pharmaceutical patents have a societal responsibility to ensure that such mechanisms are taken expeditiously and effectively. If a company neglected these responsibilities, the Special Rapporteur contended, it may be in breach of its responsibilities under the right to health.[59]

The human rights law required states to ensure that the pharmaceutical companies do not abuse the right to health. As per the preamble of the UDHR, every organ in the society shall strive to promote the respect of all human rights enshrined in the declaration. In clarifying the meaning of "every organ in the society," Louis Henkin explained that the phrase encompasses all companies and commercial entities within the territory of a state.[60] Thus, companies are among the characters addressed by the provisions of the UDHR. States are responsible for preventing any abuse from companies regarding all human rights including human right to health. However, due to globalization, the transnational corporations and multinational companies became more independent of the state control. Many developing countries are unwilling to fulfil their duty in

[57] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 98-99
[58] Ibid, 100-102
[59] Paul Hunt and Rajat Khosla, 'Are Drug Companies Living Up to Their Human Rights Responsibilities? The Perspective of the Former United Nations Special Rapporteur (2002-2008)' (2010) 7(9) PLOS Medicine Journal < https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000330> accessed 19 October 2019
[60] Louis Henkin, 'The Universal Declaration at 50 and the Challenges of Global Markets' (1999) 25(1) Brooklyn Journal of International Law 17, 25

protecting people from human rights abuses related to such entities. This is either due to fear of impeding foreign investments, or cooperating with such companies in human rights abuses and sharing the various companies' resources.[61]

The human rights responsibility of pharmaceutical companies is further identified by virtue of article 30 of the UDHR and the preambles of both Covenants. The UDHR prohibited any state, group, or person from engaging in any activity or performing any act aimed at the destruction of any of the rights and freedoms stated in the declaration.[62] The preamble of both Covenants used the word "individual" to refer to any natural or artificial person having a duty towards the community to strive for promotion and observance of the rights recognized in the Covenants.[63]

Although it is arguable that the preamble of an international instrument creates legal obligations, there is no doubt that its text addresses both the states and the private sector. The preamble can be used to interpret the meaning of any document's provisions because it contains the objects and purposes of such document. According to the VCLT, the objects and purposes should be taken into consideration when interpreting any treaty provisions. As such, any interpretation shall have to consider the preamble of both Covenants calling on businesses to respect human rights in the same way states are required to.[64]

Examples of initiatives attempting to create standards for companies to respect human rights as a principle include, the UN Global Compact and the OECD Guidelines for Multinational Enterprises. The first was established by the UN in 2000. It sets voluntary standards for the commercial sector including ten principles. The first 2 principles call upon businesses "to support and respect the protection of internationally proclaimed human rights and to make sure that they are not complicit in human rights abuses."[65]

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[61] Steven R. Ratner, 'Corporations and Human Rights: A Theory of Legal Responsibility' (2001) 111 Yale Law Journal 443, 462-463

[62] Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR) art 30

[63] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) preamble. **See also**, International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171 (ICCPR) preamble

[64] International Council on Human Rights, *Beyond Voluntarism: Human Rights and the Developing International Legal Obligations of Companies* (International Council on Human Rights Policy Switzerland 2002) 61 < https://reliefweb.int/sites/reliefweb.int/files/resources/F7FA1F4A174F76AF8525741F006839D4-ICHRP_Beyond%20Voluntarism.pdf> accessed 19 December 2019. **See also**, Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 31(1)

[65] 'The Ten Principles of the UN Global Compact' (UN Global Compact) < https://www.unglobalcompact.org/what-is-gc/mission/principles> accessed 19 December 2019

The second initiative was first adopted in 1976 by the Organization for Economic Co-operation and Development (OECD) and has been updated several times till 2011. It represents the only multilaterally agreed recommendations and code of business conduct addressed by governments to multinational companies. The OECD Guidelines are internationally recognized standards that are consistent with the applicable national laws. In addition to the principles and standards enshrined in the previous guidelines, the 2011 edition included a new chapter for human rights depending on the UN Framework and Guiding Principles on Business and Human Rights to "Protect, Respect and Remedy."[66]

The UN Human Rights Council submitted the UN "Protect, Respect and Remedy" framework in 2008, where it was unanimously approved. The framework comprises three core principles which delineate: the duty of states to protect against human rights abuse related to companies, the responsibility of companies to respect human rights by ensuring that there is no harm to human rights as a base-line responsibility, and the need for ensuring greater accessibility by victims to effective remedies, either judicial or non-judicial.[67]

To operationalize and promote the framework, the UN Secretary-General's Special Representative for Business and Human Rights, John Ruggie, issued the "Guiding Principles on Business and Human Rights: Implementing the United Nations 'Protect, Respect and Remedy' Framework" which was endorsed by the Human Rights Council in 2011.[68]

Moreover, the General Comment No. 14 of the CESCR stressed on the responsibility of pharmaceutical companies regarding the realization of the right to health. The General Comment emphasized that not only states parties to the ICESCR are accountable for compliance

[66] Organization for Economic Cooperation and Development (OECD), *OECD Guidelines for Multinational Enterprise* (2011 edn, OECD Publishing) 3, 4, 31-34

[67] Human Rights Council, 'Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, John Ruggie: Protect, Respect and Remedy: A Framework for Business and Human Rights' (7 April 2008) UN Doc A/HRC/8/5. **See also**, 'Special Representative of the Secretary-General on Human Rights and Transnational Corporations and Other Business Enterprises' (Office of the UN High Commissioner for Human Rights, 2011) < https://www.ohchr.org/EN/Issues/Business/Pages/SRSGTransCorpIndex.aspx> accessed 19 December 2019.

[68] Human Rights Council, 'Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, John Ruggie: Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework' (21 March 2011) UN Doc A/HRC/17/31. **See also**, Human Rights Council, 'Resolution 8/7: Mandate of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and other Business Enterprises' (18 June 2008) UN Doc A/HRC/RES/8/7. **See also**, Human Rights Council, 'Resolution 17/4: Human Rights and Transnational Corporations and Other Business Enterprises' (6 July 2011) UN Doc A/HRC/RES/17/4

with human rights provisions of the ICESCR, but also all members of the society including local communities, inter-governmental organizations, and private business sector.[69]

Furthermore, the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health submitted a report containing the human rights guidelines for pharmaceutical companies in relation to access to medicines. The guidelines set out the responsibilities of pharmaceutical companies to develop high-quality medicines accessible and affordable for people in need. They urged pharmaceutical companies to adopt a human rights policy that recognizes human rights, particularly the right to health. This can be achieved by integrating human rights into the companies' strategies, projects, and programs, and by refraining from any conduct that may constitute a violation to states obligations under human rights law. The Special Rapporteur highlighted in the guidelines the role of pharmaceutical companies in contributing to R&D for neglected diseases, either by providing in-house R&D or supporting external R&D for such diseases. He also drew attention to the issue of hiking prices of patented medicines stating that pharmaceutical companies should respect the right of states to fully use the flexibilities in the TRIPS agreement to promote accessibility to medicines, including the use of compulsory licensing and parallel importation. Pharmaceutical companies are committed not to lobby for a demand of stringent standards of patent protection other than those required by the TRIPS. They are also required to respect the Doha Declaration in order to promote access to medicines and the 30 August 2003 Decision to facilitate the issuance of compulsory licenses. The guidelines further recommended that companies should issue non-exclusive voluntary licenses to increase access to medicines in developing and less-developed countries. Finally, the guidelines stated that pharmaceutical companies should refrain from utilizing certain mechanisms in patent systems of developing and less-developed countries to patent incremental or trivial improvements on existing medicines.[70]

The aforementioned reports, frameworks, guidelines and international norms bearing upon the human right to health responsibility of the pharmaceutical companies infer that there is an international recognition regarding the duty of such companies to respect and promote human right to health. Nevertheless, patent-holding pharmaceutical companies argue that states hold the primary responsibility for ensuring accessibility to medicines. Their duty is confined to

[69] UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, para 42
[70] UN General Assembly, 'The Right to Health: Note by the Secretary-General in the Sixty-Third Session of the General Assembly' (11 August 2008) UN Doc A/63/263, paras 45, 47 and the Annex attached titled 'Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines' paras 1, 2, 4, 23, 26-32

research, develop and manufacture medicines treating various kinds of diseases, which they do in a profitable way to recoup their expenditures on R&D programs. If any pharmaceutical company perceives a moral obligation to do more whenever possible to help to alleviate health problems of poor people, such action is of a voluntary nature and should not become an obligation.[71]

It seems that patent-holding pharmaceutical companies perceive TRIPS flexibilities as a method that reduce their economic interests. Thus, they might be unwilling to acknowledge their responsibilities to respect the right of states to use such flexibilities for public health purposes. However, the evolving mechanisms and guidelines, issued by the UN Human Rights Council and other UN bodies, governing the responsibilities of pharmaceutical companies shall provide an effective specified content of the human rights responsibilities of patent-holding pharmaceutical companies.

### 3.6 The Right to Access to Medicines

Medicines play an important role in curing and preventing diseases. Thus, ensuring accessibility to medicines is considered a necessary component in enjoying the right to health. Essential medicines can be defined as those medicines that "satisfy the priority health care needs of the population and are intended to be available at all times in adequate amounts with assured quality and with an affordable price to all individuals."[72]

It is worth noting that access to medicines, in the human rights context, refers only to the essential medicines enumerated in the WHO Action Programme on Essential Drugs.[73] The WHO Action Programme provides a regularly updated model list of essential medicines that "satisfy the priority health care needs of the population." It is selected according to different criteria, *inter alia*, comparative cost to ensure the affordability and availability of the medicines

[71] Klaus M. Leisinger, 'Corporate Responsibilities for Access to Medicines' (2009) 85 Journal of Business Ethics 3, 7

[72] 'Essential Medicines' (WHO) < http://www.who.int/topics/essential_medicines/en/ > accessed 19 October 2019

[73] UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, para 12(a). **See also**, UN General Assembly, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (13 September 2006) UN Doc A/61/338, para 58

in the list to all people.[74] As such, 'Life-Style' drugs are excluded from the concept of the right to access to medicines.

Although each state is free to determine its list of essential medicines according to its national policy and cost of medicines, there is a minimum obligation on each state to take into consideration the WHO model list of essential medicines and to immediately take necessary steps to ensure the accessibility to the medicines in that model list at any time in adequate amounts.[75] States are also required to progressively realize the access to non-essential medicines. They are not required to perform an impossible duty to provide non-essential medicines for everyone immediately, but to take steps to the maximum of their available resources in this regard because the right to health is not a utopian notion.[76]

As such, any state argument justifying non-compliance of their obligations regarding essential medicines due to lack of, or insufficient financial resources would be easily rebutted. This is due to the normative supremacy of the minimum core obligation of states, where they cannot justify non-compliance with such obligations under any circumstances, i.e., such core obligations are non-derogable.[77]

The accessibility to essential medicines was recognized as an essential part of the right to health starting from the Alma-Ata Declaration on Primary Healthcare in 1978. The declaration prescribed that primary health care includes, among others, providing essential drugs, and called upon all governments to formulate national policies to promote and sustain primary health care for their citizens.[78]

This was confirmed by the General Comment No. 14 of the CESCR stating that the availability of essential medicines constitutes an essential element of the right to health. States have a core obligation to provide essential medicines to their people as from time to time defined under the

[74] 'Essential Medicines and Health Products' (WHO) < https://www.who.int/medicines/services/essmedicines_def/en/ > accessed 19 October 2019
[75] UN Committee on Economic, Social and Cultural Rights, 'General Comment No 3: The Nature of States Parties' Obligations (Article 2, Paragraph 1 of the Covenant)' (14 December 1990) UN Doc E/1991/23, para 10. **See also**, UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, paras 43(d), 47
[76] UN General Assembly, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (13 September 2006) UN Doc A/61/338, paras 57, 58
[77] UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, para 47
[78] Declaration of Alma-Ata International Conference on Primary Health Care (6–12 September 1978) paras 6(3), 7

WHO Action Programme on Essential Drugs. This obligation is not the sole responsibility of governments, but rather, intergovernmental organizations, NGOs and private business sector should work with governments to fulfil the obligation.[79] However, the General Comment did not specify the exact responsibilities of such non-state actors.

Although the right to access to medicines is not explicitly mentioned as an independent human right, it is well recognized in various international instruments and numerous national cases that the right is derived from the human right to health. The World Health Assembly resolution in 2001 provided that the progressive realization of the right to health should include access to medicines of good quality, appropriate usage and rational selection. To secure access to medicines, the WHO sets three critical factors: affordable prices, sustainable financing and reliable health and supply systems. [80]

Likewise, the UN Human Rights Council and the office of the High Commissioner for Human Rights reaffirmed in several resolutions that all states have to consider the fact that access to medicines is a fundamental element in the realization of the right to health for everyone. States should adopt public health insurance policies that would guarantee the availability, accessibility and affordability of pharmaceutical products. Moreover, states should avoid implementing any legislation or abide by any obligation when acceding to an international agreement, that would deny or limit the accessibility for all people to pharmaceutical medicines. The Human Rights Council also expressed its concerns about the effect of patents on raising the prices of medicines and called on all states to make sure that patents enforcement does not restrict the legitimate access to medicines.[81]

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[79] UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, paras 12(a), 17, 43(d). **See also**, Suerie Moon, 'Respecting the right to access to medicines: Implications of the UN Guiding Principles on Business and Human Rights for the pharmaceutical industry' (2013) 15(1) Health and Human Rights Journal 32, 33

[80] World Health Assembly, 'Resolution 54.11: WHO Medicines Strategy' (21 May 2001) WHA 54.11, preamble

[81] UN Human Rights Council, 'Resolution 6/29: Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (14 December 2007) UN Doc A/HRC/RES/6/29, Para 4(i). **See also**, UN Commission on Human Rights, 'Resolution 2003/29: Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria' (22 April 2003) UN Doc E/CN.4/RES/2003/29, Paras 1, 4. **See also**, 'Access to Medicines - A Fundamental Element of the Right to Health' (Office of the UN High Commissioner of Human Rights) < http://www.ohchr.org/EN/Issues/Development/Pages/AccessToMedicines.aspx > accessed 11 September 2019. **See also**, UN Human Rights Council, 'Access to Medicine in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (12 October 2009) UN Doc. A/HRC/RES/12/24, paras 1-6

Further, the reports of the UN Special Rapporteur on the Human Right to Health recognized the right to access to medicines as an indispensable part of the right to health. The reports stated that the right to health is an inclusive right with a broad concept that can be broken down to several specific entitlements, *inter alia*, the right to access to medicines. The reports considered medicines as one of the features of contemporary trade and obliged states to do all they reasonably could to ensure the availability, accessibility, and acceptability of medicines in good quality.[82]

a- The availability means that states provide adequate supply of medicines in their territory by all possible means including the usage of the TRIPS flexibilities, such as compulsory licenses and parallel imports whenever appropriate.[83] The availability of medicines also refers to the international cooperation between states to develop new medicines that address the priority health needs of people especially in developing countries. More efforts in pharmaceutical R&D should be directed to promote the production of new medicines for tropical and neglected diseases in developing countries.[84]

b- The accessibility means that all people can access medicines without any kind of discrimination, *inter alia*, sex, race, social origin, financial status, or the place of living whether an urban or rural area. States have to use the flexibilities enshrined in the TRIPS agreement to promote accessibility to medicines.[85]

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[82] UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Addendum Mission to the World Trade Organization' (1 March 2004) UN Doc E/CN.4/2004/49/Add.1, paras 18, 19, 34. **See also,** Human Rights Council, 'Report of the Special Rapporteur Anand Groover on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights Including The Right To Development ' (31 March 2009) UN Doc A/HRC/11/12, paras 10, 11, footnote 20.

[83] UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Addendum Mission to the World Trade Organization' (1 March 2004) UN Doc E/CN.4/2004/49/Add.1, para 35. **See also**, UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (11 February 2005) UN Doc E/CN.4/2005/51, para 46 (a)

[84] UN General Assembly, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (13 September 2006) UN Doc A/61/338, para 47. **See also**, UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Addendum Mission to Uganda' (19 January 2006) UN Doc E/CN.4/2006/48/Add.2, paras 4-9, 62, 65

[85] UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Addendum Mission to the World Trade Organization' (1 March 2004) UN Doc E/CN.4/2004/49/Add.1, paras 36, 37. **See also**, UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the

c- The acceptability means that medicines must be respectful of medical ethics and culturally and traditionally appropriate. For example, patients with mental illness should have the right to medications that suit their cultural background. Also, treatment drugs should be provided and revised regularly by professional staff.[86]

d- Medicines must be of good quality, including scientifically and medically appropriate. They should not be counterfeited, contaminated, or rejected from a developed state due to, for example, exceeding their expiry date.[87]

States have a duty to respect, protect and fulfil the right to access to medicines as a component of the right to health. The duty of states to respect the right to access to medicines means to ensure that its medicines policy does not discriminate against women, ethnic minorities, or other disadvantaged groups.[88] The duty to protect is achieved when states adopt appropriate legislations or measures that guarantee equal access to medicines provided by third parties, and control the marketing of medicines provided by such parties. It also entails ensuring that the privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of medicines.[89] Thus, the adoption of a stringent patent system that allows pharmaceutical companies to impose high prices on medicines rendering them inaccessible could constitute a violation of the duty to protect the right to access to medicines. Finally, the duty of states to fulfil the right requires that states provide people living in poverty with essential medicines if they do not have access to them.[90]

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Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (11 February 2005) UN Doc E/CN.4/2005/51, para 46 (b)

[86] UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (11 February 2005) UN Doc E/CN.4/2005/51, para 46 (c)

[87] UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Addendum Mission to the World Trade Organization' (1 March 2004) UN Doc E/CN.4/2004/49/Add.1, para 38. **See also,** UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (11 February 2005) UN Doc E/CN.4/2005/51, para 46 (d)

[88] UN General Assembly, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (13 September 2006) UN Doc A/61/338, para 59

[89] Ibid. **See also**, UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, para 35

[90] UN General Assembly, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (13 September 2006) UN Doc A/61/338, para 59

Several UN reports have highlighted that the TRIPS agreement has a negative impact on the accessibility to medicines. Those reports urged states to make sure that their IP laws, regulations and procedures do not create barriers to the accessibility to medicines or impede the usage of the TRIPS flexibilities whenever there is a public health concern. The reports also accentuated the need to revise trade-related agreements by including TRIPS flexibilities to help countries fulfil their obligations to protect, promote and fulfil the right to health. The reports suggested a few solutions to reduce the effect of the TRIPS on the accessibility to medicines. These include, *inter alia*, limiting the number of patents granted to pharmaceuticals by setting a high patentability threshold to ensure that patents are granted only to genuine inventions in the pharmaceutical field, and adopting an international exhaustion regime which allows parallel importation of medicines.[91]

Recognizing the tension between pharmaceutical patents and accessibility to medicines, the former UN Secretary-General Ban Ki-moon established the UN High-Level Panel on Access to Medicines in 2015 with a mandate to address such tension. The report of the panel concluded that "market-based models, which incentivize innovation, often lead to insufficient investment in R&D for diseases that predominantly affect the poor." The report found that the prices charged by some patent holders often place severe burdens on national health systems rendering medicines inaccessible for many people in both, wealthy and resource-constrained countries. Among several recommendations, the report encouraged states to reinforce the usage of compulsory licenses and other TRIPS flexibilities as a fundamental part of the TRIPS agreement, not as an exception.[92]

Several national courts' rulings also acknowledged that the right to access to medicines forms an essential part of the right to health. A prominent case in this context is the South African case regarding accessibility to an ARV drug named "Nevirapine." In this case, a program designed by the Ministry of Health in South Africa was challenged by civil society associations because it imposed restrictions on the accessibility and availability of the "Nevirapine drug." The

[91] Human Rights Council, 'Report of the Special Rapporteur Anand Groover on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights Including The Right To Development ' (31 March 2009) UN Doc A/HRC/11/12, paras 5, 15, 16, 35, 45. **See also**, UN Human Rights Council, 'Access to Medicine in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (12 October 2009) UN Doc. A/HRC/RES/12/24, para 6. **See also**, Graham Dutfield and Uma Suthersanen, *Global Intellectual Property Law* (Edward Elgar Publishing Limited UK 2008) 320

[92] UN Secretary-General's High-Level Panel on Access to Medicines, 'Report on Promoting Innovation and Access to Health Technologies' (September 2016) 9, 16 < http://www.unsgaccessmeds.org/final-report> accessed 12 December 2019

Constitutional Court in South Africa held that the government is responsible for making the drug accessible and available to prevent transmission of HIV/AIDS from a mother to her child and ordered the government to remove any obstacles that may deny access to that medicine.[93]

In contrast, the Constitutional Court of South Africa did not find any violation to the right to health in the *Soobramoney* case. The appellant, Soobramoney, suffered from chronic renal failure and required regular renal dialysis treatment. Due to the limited number of renal dialysis machines, the Ministry of Health had established specific emergency policy regarding the usage of such machines and the appellant did not meet the necessary criteria for eligibility. He challenged the policy arguing that it violated the South African Constitution which guarantees the right of everyone to have access to health care services. While acknowledging the right, the court stated that the obligation of the government to guarantee the right was dependent upon the availability of resources. As such, the government had the right to determine how to allocate those limited resources. The appellant's medical condition was not an emergency condition that called for immediate remedial treatment.[94] This case shows that states are required to adopt a comprehensive approach to the realization of the right to health. They should address the larger needs of the society rather than focusing on specific needs of a group of people within the society.

In another case, mentioned in chapter two, the High Court of Madras in India rejected the writ petitions filed by Novartis pharmaceutical company in 2006. Novartis claimed that section 3(d) of the Indian Patent Act, amended in 2005, is inconsistent with article 27 of the TRIPS and unconstitutional because it confers uncontrolled discretion to the patent controller in determining the meaning of "enhancement of the known efficacy" when considering patent applications.[95] That section stipulates that the changes made to a previous medicine must result in the enhancement of the efficacy of the medicine in order to be granted a patent.[96] In this case, the Madras Patent Office refused to grant Novartis a patent for its new versions of a cancer drug named "Glivec" due to lack of novelty and inventive step. Although it did not have jurisdiction to decide whether a national law is violating an international agreement, the court opined that the TRIPS principles allow states to adopt measures, when formulating their laws, to protect

[93] *Minister of Health et al v Treatment Action Campaign et al*, Constitutional Court of South Africa, [2002] ZACC 15; 2002 (5) SA 721; 2002 (10) BCLR 1033 (5 July 2002)
[94] *Soobramoney v Minister of Health* (Kwazulu-Natal), Constitutional Court of South Africa, (CCT32/97) [1997] ZACC 17; 1998 (1) SA 765 (CC); 1997 (12) BCLR 1696 (27 November 1997)
[95] *Novartis v Union of India*, High Court of Madras, (2007) 4 MLJ 1153
[96] Indian Patents (Amendment) Act No 15 of 2005, sec 3(d)

public health. It added that India had a constitutional duty to ensure accessibility to affordable medicines to its citizens. Therefore, the decision of the Indian Patent Office was justified based on the objectives of the Indian Patent Act which prevent "ever-greening" and allow generic medicines to be available in the market.[97]

Noticeably, if Novartis had won the case, the generic industry in India would have been affected, thus impeding the availability of cheap medicines, either in India or other developing countries that import Indian generic medicines. The case also shows that there must be consistency between states' legislations and the human rights principles without prejudice to the TRIPS provisions. It also highlights the role of judges in safeguarding the public health of people when interpreting domestic legislations.

Furthermore, in the case of *Mariela Viceconte v. Ministry of Health and Social Welfare* concerning the availability of a vaccine named "Candid-1" used to treat an endemic disease, the Argentinian Federal Court issued a ruling that ordered the government to produce "Candid-1" vaccine and make it available to all people.[98]

Moreover, the Supreme Court of Venezuela ruled against the government and ordered it to ensure that all citizens infected with HIV/AIDS have full access to ARV Drugs. The court acknowledged that the government had allocated insufficient health budget to fulfil its duty to assist HIV/AIDS patients. It stated that the principle of progressive realization of the right to health does not legitimize the failure of the government on the grounds of lack of financial resources without proving that it has taken all steps available to fulfil its duty.[99]

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[97] *Novartis v Union of India*, High Court of Madras, (2007) 4 MLJ 1153. **See also**, Sarah Joseph, *Blame it on the WTO* (Oxford university Press UK 2013) 227. **See also**, Manzoor Elahi, 'Case Analysis on *Novartis A.G. v Union of India*, 2007' (Academia Platform) < https://www.academia.edu/3060975/Case_Analysis_on_Novartis_A.G_Vs._Union_of_India_2007> accessed 8 November 2019

[98] *Mariela Viceconte v Ministry of Health and Social Welfare*, Federal Administrative Court of Appeal of Argentina, Case No 31.777/96 (2 June 1998). English translation of the case is provided by Global Health and Human Rights Database website < https://www.globalhealthrights.org/wp-content/uploads/2014/01/ENGLISH-Viceconte-Argentina-1998-English-2.pdf> accessed 14 November 2019

[99] *Cruz del Valle Bermúdez et al v Ministerio de Sanidad y Asistencia Social*, Supreme Court of Venezuela, Case No 15.789 Decision No 916 (1999). English translation of the case is provided by Global Health and Human Rights Database website < https://www.globalhealthrights.org/wp-content/uploads/2013/08/Ruling-5-April-1999-venezuela.pdf > accessed 14 November 2019. **See also**, UNAIDS, *Courting Rights: Case Studies in Litigating the Human Rights of People Living with HIV* (Canadian HIV/AIDS Legal Network and UNAIDS 2006) 64-68 < https://data.unaids.org/pub/report/2006/jc1189-courtingrights_en.pdf > accessed 10 May 2020

Finally, the Constitutional Court of Ecuador issued a ruling stating that the Ministry of Health decision to cut-off the supply of ARV treatment from patients infected with HIV/AIDS constitutes a violation of the right to health.[100]

### 3.7 The Nature of the Right to Access to Medicines in Public International Law

The statute of the ICJ enumerated the main sources of public international law as follows: "international conventions, whether general or particular, establishing rules expressly recognized by the contesting states," "international custom as evidence of a general practice accepted as law," and "the general principles of law recognized by civilized nations."[101] The latter shall be applied whenever treaties and custom do not provide any rules to be applied on the disputed matter.

Due to the vagueness of the general principles and the notion that they mostly stem from the private law branch, it is far from settled that human rights are within their ambit.[102] As such, the dissertation in this section shall scrutinize the nature of the right to access to medicines according to the international conventions and international custom.

#### 3.7.1 International Conventions

The dissertation demonstrated several treaties referring to the human right to health and accessibility to medicines. In the following sub-sections, the dissertation shall scrutinize the nature of the right to access to medicines focusing on the International Bill of Rights (ICCPR, ICESCR, UDHR).

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[100] *Edgar Carpio Castro Jofre Mendoza et al v Ministry of Health*, Constitutional Court of Ecuador, Case No 749-2003-RA (2004). The case is summarized in Paul Hunt et al, 'Neglected Diseases: A Human Rights Analysis' (2007) Special Topics in Social, Economic and Behavioural Research Report Series No 6, 34 < https://www.who.int/tdr/publications/documents/seb_topic6.pdf?ua=1> accessed 8 November 2019

[101] Statute of the International Court of Justice (adopted 26 June 1945, entered into force 24 October 1945) 3 Bevans 1179, 59 Stat 1031, TS 993 (ICJ) art 38/1(a)(b)(c)

[102] Marcelo Kohen and Bérénice Schramm, 'General Principles of Law' (Oxford Bibliographies, 27 March 2019) < https://www.oxfordbibliographies.com/view/document/obo-9780199796953/obo-9780199796953-0063.xml?rskey=8M0OfB&result=1&q=Marcelo+Kohen+and+B%C3%A9r%C3%A9nice+Schramm#firstMatch> accessed 12 November 2019

#### 3.7.1.1 The Right to Access to Life-Saving Medicines as an Element of the Right to Life in the ICCPR

The ICCPR is considered one of the potent human right conventions and a part of the International Bill of Rights. It obliges states parties to respect the CPRs of individuals, including the right to life, and to implement and maintain the human rights guaranteed therein.

The VCLT stated that a treaty is binding upon its parties.[103] It does not create either rights or obligations for a third state without its consent, a principle known as *pacta tertiis nec nocent nec prosunt*.[104] Thus, the ICCPR binds only its member states. As of May 2021, 173 states are parties to the Covenant and 19 states are not.[105]

Contrary to the principle of *pacta tertiis nec nocent nec prosunt*, the ICCPR contains few rules that are binding on all states even those that are not parties to the Covenant. Such rules are hierarchically superior to other rules of public international law because they play an important role in maintaining international peace and security, protecting peoples, and promoting the fundamental values of the international community as a whole. They are known as *jus cogens* norms, i.e., peremptory norms that are recognized and accepted by all international community as norms from which no derogation is permitted. For a rule to be identified as a *jus cogens* norm, it must have acceptance and recognition by a very large majority of states. It is not required to be accepted by all states. However, once it is deemed to be a *jus cogens* norm, it becomes binding on all states including those which expressly refused to acknowledge it. *Jus cogens* norms do not have an exhaustive list. They include, *inter alia*, the prohibition of genocide, slavery, torture, and the human right to life.[106]

Consequently, the right to life in the ICCPR, as a *jus cogens* norm, represents an exception to the *pacta tertiis* principle. The right to life is the supreme human right, fundamental in any

[103] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 26
[104] Ibid, art 34. **See also**, Robert Jennings and Arthur Watt (eds), *Oppenheim's International Law*, Vol 1 Pt 3 (9th edn, Pearson Higher Education 1992) 1260
[105] For status of ratifications, see 'International Covenant on Civil and Political Rights' (UN Treaty Collection, 12 May 2021) < https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-4&chapter=4&clang=_en> accessed 12 May 2021
[106] Ibrahim Seif Menshawy, 'Unilateral Acts and Premptory Norms (*Jus Cogens*) in the International Law Commission's Work' (2019) 4(3) Review of Economics and Political Science 182, 183-186. **See also**, UN General Assembly, 'Report of the International Law Commission on the Work of its Seventy-First Session' (2019) UN Doc A/74/10, 142-147. **See also**, Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 53

society, and indispensable for the enjoyment of all other human rights.[107] The ICCPR emphasized that everyone has an inherent right to life which is protected by law.[108] As such, all states even those not parties to the ICCPR, are obliged to protect the right to life. They cannot derogate from this obligation even in matters of "public emergency which threatens the life of the nation,"[109] or due to other treaty obligations. The VCLT stated that any treaty is void if, at the time of its conclusion, it conflicts with a *jus cogens* norm.[110]

Since the right to life is inherent to all human beings, i.e., a natural right, it cannot be narrowly interpreted. To be effective, a broader reading of the right to life is inevitable to encompass the basic conditions of life and the necessary components for survival of human beings, even if that part of the right to life coexists, to some extent, with the ESCRs. Therefore, the protection of the right to life requires that states should adopt positive measures, not only their negative obligation of non-intervention to allow people to enjoy the right. In this regard, the Human Rights Committee considered that states "should take all possible measures … to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics."[111] Consequently, the right to access to essential medicines needed for survival (life-saving medicines) is an indispensable component of the right to life.[112]

This broad interpretation deeming access to life-saving medicines a part of the right to life is observable with respect to the jurisprudence of the right to life provided by several international and regional human rights bodies.

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[107] UN General Assembly, 'Report of the Economic and Social Council on the Protection of Human Rights in Chile' (4 November 1982) UN Doc A/37/564, para 22. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 115-116. **See also**, Alicia Ely Yamin, 'Not Just a Tragedy: Access to Medications as a Right Under International Law' (2003) 21(2) Boston University International Law Journal 325, 330-331. **See also**, UN Human Rights Committee, 'General Comment No 6: Right to Life (Article 6 of the ICCPR)' (30 April 1982) UN Doc HRI/GEN/1/Rev.1, para 1

[108] International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171 (ICCPR) art 6(1). **See also,** Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR) art 3

[109] UN Human Rights Committee, 'General Comment No 6: Right to Life (Article 6 of the ICCPR)' (30 April 1982) UN Doc HRI/GEN/1/Rev.1, para 1

[110] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 53

[111] UN Human Rights Committee, 'General Comment No 6: Right to Life (Article 6 of the ICCPR)' (30 April 1982) UN Doc HRI/GEN/1/Rev.1, para 5. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 116. **See also**, Bertrand G. Ramcharan, 'The Right to Life' (1983) 30(3) Netherlands International Law Review 297, 305

[112] Alicia Ely Yamin, 'Not Just a Tragedy: Access to Medications as a Right Under International Law' (2003) 21(2) Boston University International Law Journal 325, 330-331

In *Association of Parents v. United Kingdom* case regarding a vaccination scheme designed to eliminate an infectious disease, the former European Commission of Human Rights stated that the right to life, as stipulated in article 2 of the European Convention on Human Rights, imposes on states, in addition to a negative obligation, a positive obligation to take preventive operational measures to protect people whose life is at risk. The Commission confirmed that the appropriate steps to safeguard life include the provision of adequate and appropriate medical care.[113] The Commission reiterated this view in the case of *Tavares v. France*, where the applicant alleged that the doctors' delay in providing medical care to his wife, who suffered medical complications after delivering their child, constituted a breach of state's obligation to provide prompt medical care. The Commission upheld the domestic court's decision stating that the death was a result of a series of exceptional circumstances which did not constitute a breach of state's obligation regarding the right to life. However, it affirmed that providing adequate medical care is a component of the right to life.[114]

Further, the Convention on the Rights of the Child provided that "states parties recognize that every child has the inherent right to life" and that they should "ensure to the maximum extent possible the survival and development of the child."[115] The Committee on the Rights of the Child, which monitor and report on the implementation of the Convention, recommended that every state party should seek technical assistance from, among others, UNAIDS in order to establish an effective national medical program capable of providing better accessibility to HIV/AIDS drugs. States' efforts to minimize the impact of HIV/AIDS on children, which causes the death of their parents and others, and affects their survival, emanate from their responsibility to protect the right to life.[116]

Similarly, the Inter-American Court of Human Rights in *Morales v. Guatemala* case interpreted article 4 of the American Convention on Human Rights, addressing the right to life, in a broad sense. The court underscored the *jus cogens* nature of the right to life which requires not only that no person shall be deprived of his life arbitrarily (negative obligation) but also states have positive obligation to take all necessary measures to protect and preserve the right to life. The court clarified that the right to life has to be examined in relation to states obligation under the

[113] *Association of Parents v United Kingdom* App No 7154/75 (ECHR, 12 July 1978) 31
[114] *Antonio Conceiçao Tavares v France* App No 16593/90 (ECHR, 12 September 1991)
[115] Convention on the Rights of the Child (adopted 20 November 1989, entered into force 2 September 1990) 1577 UNTS 3 (UNCRC) art 6
[116] UN Committee on the Rights of the Child, 'Concluding Observations of the Committee on the Rights of the Child: Côte d'Ivoire' (9 July 2001) UN Doc CRC/C/15/Add.155, para 43

Convention, to respect and guarantee the full exercise of all human rights.[117] This view conceptualizes the right to life as a right which belongs to both categories of rights, thus asserting the indivisibility and interrelation of all human rights.

National courts are also embracing the broad interpretation of the right to life, invoking it when a particular medicine is potentially a life-saving one. The Indian Supreme Court in *Samity v. State of West Bengal* case affirmed the obligation of the government, by virtue of the Indian constitution, to protect the right to life of every person. The court held that the failure of a governmental hospital to provide effective and timely medical treatment to a patient in dire need of such treatment violates the right to life guaranteed by the constitution.[118]

In another case, the Indian Supreme Court provided that the right to life has to be interpreted broadly to include the right to live in dignity and all human rights that go along with it, including health.[119] Likewise, the Supreme Court of Venezuela stated that the failure of the social security institute to provide ARV drugs on a regular basis destroys the immune system of patients which may lead to their death. This constitutes a violation of the right to life protected under the Venezuelan Constitution.[120] Also, the Constitutional Court of Colombia held that the denial of ARV medicines under the governmental medical insurance system of the country is considered a violation to the right to life safeguarded by the constitution.[121] Finally, the Constitutional Chamber of the Supreme Court of Justice of Costa Rica decided that the right to health is a part

[117] American Convention on Human Rights (adopted 22 November 1969, entered into force 18 July 1978) OAS Treaty Series No 36, 1144 UNTS 123 (Pact of San Jose, Costa Rica). **See also**, *Case of the "Street Children" (Villagran-Morales et al) v Guatemala*, Merits, IACHR Series C No 63 (19 November 1999) para 139

[118] *Paschim Banga Khet Mazdoor Samity v State of West Bengal,* Supreme Court of India, 1996 SCC (4); 37 JT 1996 (6) 43 (6 May 1996) para 9

[119] *Francis Coralie Mullin v Union Territory of Delhi*, Supreme Court of India, 1981 AIR 746; 1981 SCR (2) 516 (13 January 1981) paras 6, 7

[120] *Glenda Lopez et al v Instituto Venezolano de Seguros Sociales,* Supreme Court of Venezuela, Constitutional Chamber, Case No 00-1343 (6 April 2001). English translation of the case is provided by Global Health and Human Rights Database website < https://www.globalhealthrights.org/wp-content/uploads/2013/08/Lopez-v.-IVSS-English-Translation.pdf > accessed 2 December 2019. **See also**, Alicia Ely Yamin, 'Not Just a Tragedy: Access to Medications as a Right Under International Law' (2003) 21(2) Boston University International Law Journal 325, 335

[121] *Sandra Clemencia Perez Calderon et al v Ministry of Health*, Constitutional Court of Colombia, Case SU-225/1998 (20 May 1998). English translation of the case is provided by Global Health and Human Rights Database website < https://www.globalhealthrights.org/wp-content/uploads/2013/09/CC-1998-Perez-Calderon-v.-Ministry-of-Health-Case-SU-225-98.pdf > accessed 2 December 2019. **See also**, Alicia Ely Yamin, 'Not Just a Tragedy: Access to Medications as a Right Under International Law' (2003) 21(2) Boston University International Law Journal 325, 335

of the right to life. The state is obliged to provide HIV/AIDS medicines to all patients based on its obligation to protect the right to life.[122]

National courts emphasized that the right to life not only includes accessibility to access to HIV/AIDS medicines, but also of other diseases that pose serious risk to human life, like cancer, pandemics and tuberculosis. For example, in Argentina, the Supreme Court issued a protective writ that forced the Ministry of Health to provide a particular anti-cancer medicine necessary for the survival of an old woman suffering from colon cancer.[123]

Anthony Paul in his article "The Right to Food Exists via Customary International Law" argued that the right to food is a matter of *jus cogens* because adequate food is necessary to the fulfilment of the right to life.[124] Similarly, it could be strongly argued that the right to access to life-saving medicines as a component of the right to life reaches the status of *jus cogens* because the right to life is considered a *jus cogens* norm. Additionally, health is necessary for the fulfilment of other human rights, including the right to life since all human rights are interrelated and interconnected. This would give the right to health greater force and allow it to trump any treaty provision that might conflict with it.

However, the traditional view contradicts such broad reading of the right to life, arguing that it is limited to imposing an obligation on states to protect people from murder and to prohibit states from arbitrarily depriving any person of life. According to this narrow reading of the text of article 6 of the ICCPR, the right to life does not guarantee an appropriate standard of medical care. The traditional view supported this argument by stating that article 6 of the ICCPR protects the right to life and not the life *per se*.[125]

Several scholars criticized such a narrow view because it creates an artificial unclear distinction between the right to life and life. Such distinction does not support restricting the right to life to acts of killing people. They emphasized that the general wording of article 6(1) of the ICCPR stating that "every human being has the inherent right to life" constitutes a compelling reason

[122] The case is cited in Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 118
[123] Alicia Ely Yamin, 'Not Just a Tragedy: Access to Medications as a Right Under International Law' (2003) 21(2) Boston University International Law Journal 325, 336
[124] Anthony Paul Kearns, 'The Right to Food Exists Via Customary International Law' (1998) 22 Suffolk Transitional Law Review 223, 255-256
[125] Yoram Dinstein, 'The Right to Life, Physical Integrity and Liberty' in Louis Henkin (ed), *The International Bill of Rights: The Covenant on Civil and Political Rights* (Columbia University Press New York 1981) 114, 115. **See also**, Franciszek Przetacznik, 'The Right to Life as a Basic Human Right' (1976) 9 Human Rights Journal 585, 586-587

to include within its ambit the right of everyone to access life-saving medicines. They opined that there is no plausible reason for considering the latter right less significant than the insufficient panel legislations on murder. The right to life has to be effective enough, as required by the ICCPR, to encompass all the components necessary for survival, *inter alia*, saving the life of people in dire need of certain medicines. However, they noted that the scope of medicines related to the right to life are only life-saving medicines which is a narrower scope than the one related to access to medicines under the right to health.[126]

In essence, access to life-saving medicines is deemed to be an element of the right to life stated in the ICCPR. Since the right to life is considered a *jus cogens* norm, then it could be strongly argued that the right to access to life-saving medicines, as a life-saving tool, reaches the status of *jus cogens* norm as well. As such, all states, whether members to the ICCPR or not, are obliged to guarantee the accessibility to such medicines for all people as a part of their obligation to safeguard the right to life.

Consequently, any interpretation to any treaty addressing pharmaceutical patents has to be compatible with the right to access to life-saving medicines, otherwise the interpretation would be considered violating a *jus cogens* norm.[127]

#### 3.7.1.2 The Right to Access to Essential Medicines as an Element of the Right to Health in the ICESCR

Being part of the International Bill of rights, the ICESCR obliges its states parties to respect, protect and fulfil the right to access to essential medicines as a component of the right to health as indicated above.

The dissertation explained above that the ICESCR is legally binding on its states' members. They are obliged, as such, to take necessary steps to ensure the accessibility to essential medicines which are defined from time to time by the WHO Action Programme on Essential Drugs. Those obligations are emphasized by the General Comment 14, the UN Human Rights Council, the Office of the High Commissioner for Human Rights, and by various reports of the UN Special Rapporteur on the Human Right to Health.

[126] Bertrand G. Ramcharan, 'The Right to Life' (1983) 30(3) Netherlands International Law Review 297, 305. **See also**, Alicia Ely Yamin, 'Not Just a Tragedy: Access to Medications as a Right Under International Law' (2003) 21(2) Boston University International Law Journal 325, 330-331

[127] Valentina Vadi, *Public Health in International Investment Law and Arbitration* (Routledge London 2013) 86

### 3.7.1.3 The Right to Access to Medicines as an Element of the Right to Health in the UDHR

Article 25 of the UDHR stipulated that "everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including … medical care." Such provision is echoed in article 12 of the ICESCR which provides that "states recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and obliged states to take steps to achieve the full realization of the right to health including "the prevention, treatment and control of epidemic, endemic, occupational and other diseases." The right to health in the UDHR and the ICESCR has been elaborated in subsequent human rights treaties and several national constitutions as previously demonstrated.

It is technically inaccurate to consider the UDHR as a Convention. It is merely a resolution of the UN General Assembly containing basic principles of human rights and freedoms which serve as a common standard of achievement for all peoples and all states. The UDHR is considered to be the foundation of international human rights law because it inspired a rich body of legally binding regional and international human rights agreements.[128] At the time of its adoption in1948, it was unanimously agreed that the UDHR is "a manifesto with primarily moral authority."[129] This was confirmed by the statement of Eleanor Roosevelt, the chair of the UN Commission on Human Rights during the drafting of the declaration, who stated that the declaration is not an international agreement, nor does it impose any binding legal obligations on states.[130]

However, some scholars argue that the UDHR reaches the position of a treaty law since its provisions together with the two Covenants are considered an interpretation of the human rights provisions in the UN Charter. If this argument is accepted, then the UDHR provisions would be binding on all UN member states. This argument was rebutted because the UN General

[128] 'Universal Declaration of Human Rights: The Foundation of International Human Rights Law' (UN) < https://www.un.org/en/about-us/udhr/foundation-of-international-human-rights-law> accessed 1 October 2020. **See also**, 'Universal Declaration of Human Rights' (UN) < https://www.un.org/en/about-us/universal-declaration-of-human-rights> accessed 1 October 2020

[129] UN, *Human Rights: The International Bill of Human Rights, 40th Anniversary of the Universal Declaration of Human Rights 1948-1988* (UN Department of Public Information Publication 1988) 1 < https://searchlibrary.ohchr.org/record/10494?ln=en> accessed 26 May 2021

[130] Hurst Hannum, 'The UDHR in National and International Law' (1998) 3(2) Health and Human Rights Journal 144, 147

Assembly does not have the power to issue binding interpretations of the Charter. The UDHR is merely a recommendation of the UN General Assembly, therefore it is not binding.[131]

There was a Belgium proposal to confer such power to the General Assembly, but it was explicitly rejected.[132] Therefore, the right to access to medicines under the UDHR provisions cannot be justified as a binding obligation on all states. It is strongly doubtful that the UDHR acquires the status of an international treaty. The following part shall examine, among other issues, whether the UDHR provisions constitute customary international law or otherwise.

### 3.7.2 Customary International Law

#### 3.7.2.1 Identification of Customary International Law Rules

The ICJ statute provides that a norm is considered customary international law if there is "evidence of a general practice accepted as law."[133] Contrary to the international treaties which are *pacta tertiis nec nocent nec prosunt*, customary international law binds all states. Determining a rule of customary international law requires establishing the existence of two constituent elements. "A general practice, and acceptance of that practice as law (*opinio juris*)."[134] The first is an objective element which requires that the practice must be sufficiently widespread and representative and must exhibit consistency.[135] In the wording of the ICJ in the *North Sea Continental Shelf* cases, the practice must be a "settled practice." It must be "both extensive and virtually uniform."[136] The second element (*opinio juris*) is a subjective element which refers to the requirement, as mentioned by the ICJ in the *North Sea Continental Shelf* cases, that the general practice must be undertaken "in such a way, as to be evidence of a belief that this practice is rendered obligatory by the existence of a rule of law requiring it."[137] The

[131] Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR) arts 10-14. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 120

[132] Bruno Simma et al (eds), *The Charter of the United Nations: A Commentary*, vol 1 (2nd edn, Oxford University Press 2002) art 10, para 46

[133] Statute of the International Court of Justice (adopted 26 June 1945, entered into force 24 October 1945) 3 Bevans 1179, 59 Stat 1031, TS 993 (ICJ) art 38(1)(b)

[134] UN General Assembly, 'Report of the International Law Commission on the Work of its Seventieth Session' (2018) UN Doc A/73/10, 124-125

[135] Ibid, 129, 135, 136

[136] *North Sea Continental Shelf Case (Federal Republic of Germany v Denmark; Federal Republic of Germany v The Netherlands)* (Judgment) [1969] ICJ Rep 3, paras 74, 77

[137] Ibid, para 77. **See also,** UN General Assembly, 'Report of the International Law Commission on the Work of its Seventieth Session' (2018) UN Doc A/73/10, 138-139

acts of states that constitute general practice and the relationship between that practice and *opinio juris* is a subject of continuous debate between scholars.[138]

Concisely, neither the length of the period, nor the number of states involved in the general practice are important when considering the formation of a new rule of customary international law. An indispensable requirement, as stated by the ICJ, would be that "within the period in question, short though it might be, state practice, including that of states whose interests are specially affected, should have been both extensive and virtually uniform in the sense of the provision invoked."[139]

The requirement of uniformity in state practice does not require that the practice is identical with the norm in question. Similarity or consistency with the norm in question is sufficient. This was illustrated in the *Nicaragua* case when the ICJ stated that "it is sufficient that the conduct of states should, in general, be consistent with customary rules."[140]

The ILC, the ICJ, and Sir Ian Brownlie enumerated a wide variety of examples of state practice that could constitute customary international law. Among the examples mentioned are: international and national courts decisions; the adoption and incorporation of international law or human rights law principles in national constitutions and legislations; the opinions of official legal advisers, governments participations and comments when preparing drafts of the ILC and drafts of treaties; diplomatic correspondences; governmental statements recognizing human rights principles in international law and referring to such principles in international forums; and finally, the frequent affirmation of states that they adhere to human rights even if only in principle.[141]

In the same vein, the ICJ stated that *opinio juris* plays a crucial role in differentiating between legal obligations and acts which are "motivated only by considerations of courtesy, convenience

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[138] Anthea Elizabeth Roberts, 'Traditional and Modern Approaches to Customary International Law: A Reconciliation' (2001) 95(4) American Journal of International Law 757, 757-791

[139] *North Sea Continental Shelf Case (Federal Republic of Germany v Denmark; Federal Republic of Germany v The Netherlands)* (Judgment) [1969] ICJ Rep 3, para 43

[140] *Military and Paramilitary Activities in and against Nicaragua (Nicaragua v United States of America)* (Judgment) [1986] ICJ Rep 14, para 186

[141] *North Sea Continental Shelf Case (Federal Republic of Germany v Denmark; Federal Republic of Germany v The Netherlands)* (Judgment) [1969] ICJ Rep 3. **See also**, *Fisheries Jurisdiction Case (United Kingdom of Great Britain and Northern Ireland v Iceland)* (Merits) [1974] ICJ Rep 3. **See also**, *Military and Paramilitary Activities in and against Nicaragua (Nicaragua v United States of America)* (Judgment) [1986] ICJ Rep 14. **See also**, UN General Assembly, 'Yearbook of the International Law Commission 1950 Vol II: Documents of the Second Session Including the Report of the Commission to the General Assembly' (1957) UN Doc A/CN. 4/SER.A/1950/Add. 1, 368-372. **See also**, Ian Brownlie, *Principles of Public International Law* (6th edn, Oxford University Press 2003) 4-11

or traditions." So, the practice should be performed by states as a legal duty.[142] This does not mean that the *opinio juris* has to exist separately from state practice. Sometimes, the state practice may include within itself, legal conviction demonstrating that "certain conduct is permitted, required or forbidden by international law."[143]

#### 3.7.2.2 State Practice in Accessibility to Medicines

State practice supports the customary nature of the right to access to medicines. However, this is confined only to medicines in the context of pandemics, like HIV/AIDS, Malaria and Tuberculosis. It is doubtful that access to medicines in general is considered customary law due to insufficient state practice in this regard. There are several UN and WHO resolutions regarding the accessibility to medicines in the context of pandemics. Such resolutions show the consistency and spread needed for the existence of a general practice in this regard.

In 2001, the UN General Assembly adopted a resolution titled the "Declaration of Commitment on HIV/AIDS." In this resolution, states affirmed that access to medicines in the context of pandemics represents a fundamental element to achieve progressively the full realization of the right to health. They announced that they are committed to exert all possible efforts to "provide progressively, and in a sustainable manner, the highest attainable standard of treatment for HIV/AIDS, including the prevention and treatment of opportunistic infections."[144] Notably, states are not obliged to ensure the full realization of accessibility to medicines in the context of pandemics immediately, but to undertake steps towards fulfilling their commitments in this regard.[145]

Similarly, in 2003, the UN General Assembly adopted another resolution that reiterated the states commitment under the 2001 resolution. However, it extended the scope of medicines to include Malaria and Tuberculosis along with HIV/AIDS. It called upon states to develop and implement national policies and strategies, in accordance with the applicable international law, to progressively realize the accessibility to comprehensive treatment for all individuals infected

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[142] *North Sea Continental Shelf Case (Federal Republic of Germany v Denmark; Federal Republic of Germany v The Netherlands)* (Judgment) [1969] ICJ Rep 3, para 44

[143] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 137

[144] UN General Assembly, 'Resolution S-26/2: Declaration of Commitment on HIV/AIDS' (2 August 2001) UN Doc A/RES/S-26/2, paras 15, 55

[145] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 2(1)

and affected by pandemics. It requested states to promote the availability, accessibility and affordability of pharmaceutical products, of good quality, used to treat pandemics or the most common opportunistic infections that accompany them. It also urged states to refrain from pursuing measures that would deny or limit equal access to pharmaceuticals treating HIV/AIDS and other pandemics, and to adopt appropriate legislations and measures to safeguard the accessibility to such medicines.[146]

In 2006, the UN General Assembly adopted another resolution committing states to improve their legislations and regulatory policies in order to enhance the accessibility to affordable HIV/AIDS medicines of good quality. Also, states committed themselves to move towards the "goal of universal access to comprehensive prevention programmes, treatment, care and support by 2010."[147] States' commitment regarding HIV/AIDS medicines was further confirmed by virtue of the UN General Assembly resolution in 2011.[148]

Moreover, the Millennium Development Goals addressed the commitment of states to promote accessibility to medicines in the context of pandemics and to set goals to combat HIV/AIDS and other pandemic diseases. Such goals were derived from the Millennium Declaration that was adopted by the UN General Assembly in 2000 and was widely accepted by states.[149] States are frequently confirming their commitments to the millennium goals in various UN international meetings.

The Commission on Human Rights also adopted several resolutions that recognize the right to access to medicines in the context of pandemics. These resolutions reiterated the necessity of enacting legislations and implementing national policies that would progressively realize and promote the availability, accessibility and affordability of pharmaceutical products of good quality needed for treating pandemics. The resolutions call upon states to apply their human right to health obligations, namely to respect, protect and fulfil, and to ensure better accessibility to such medicines.[150]

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[146] UN General Assembly, 'Resolution 58/179: Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria' (17 March 2004) UN Doc A/RES/58/179, paras 4, 6, 7

[147] UN General Assembly, 'Resolution 60/262: Political Declaration on HIV/AIDS' (15 June 2006) UN Doc A/RES/60/262, paras 42, 49

[148] UN General Assembly, 'Resolution 65/277: Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV and AIDS' (8 July 2011) UN Doc A/RES/65/277

[149] UN General Assembly, 'Resolution 55/2: United Nations Millennium Declaration' (18 September 2000) UN Doc A/RES/55/2. **See also**, UN Millennium Development Goal, 'Goal 6: Combat HIV/AIDS, Malaria and other Diseases' (UN, 2015) < https://www.un.org/millenniumgoals/aids.shtml> accessed 27 November 2019

[150] UN Commission on Human Rights, 'Resolution 2001/33: Access to Medication in the Context of Pandemics Such as HIV/AIDS' (23 April 2001) UN Doc E/CN.4/RES/2001/33. **See also**, UN Commission on Human

Within the WHO, states adopted several resolutions recognizing the "Declaration of Commitment on HIV/AIDS" that was adopted by the UN General Assembly in 2001. By virtue of such resolutions, states undertake to adopt and implement appropriate strategies to ensure the accessibility to pandemics medication to all people.[151]

All these resolutions were unanimously adopted by UN members with the exception of the US which voted against the General Assembly 2003 resolution.[152] Notably, one state refusal to an international resolution does not change the fact that the resolutions represent an embodiment of state practice which contribute to the formation of customary international law.

The resolutions are sufficient to satisfy the requirements of a settled state practice regarding safeguarding accessibility to medicines in the context of pandemics. The Secretary-General report in 2017 issued within the context of implementation of the "Declaration of Commitment on HIV/AIDS" showed that states are acting to progressively fulfil their commitments mentioned in the resolutions. The report mentioned that the global commitment and financial responsibility yielded success in AIDS response towards the 2030 Agenda for sustainable development, targeting to end the AIDS epidemic by 2030. According to the report, states' response to provide accessibility to pandemics medication led to reducing AIDS-related deaths and contributed to reducing new HIV infections. Responding to various resolutions and declarations calling for safeguarding accessibility to AIDS medication made an "important

Rights, 'Resolution 2002/32: Access to Medication in the Context of Pandemics Such as HIV/AIDS' (22 April 2002) UN Doc E/CN.4/RES/2002/32. **See also**, UN Commission on Human Rights, 'Resolution 2003/29: Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria' (22 April 2003) UN Doc E/CN.4/RES/2003/29. **See also**, UN Commission on Human Rights, 'Resolution 2004/26: Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria' (16 April 2004) UN Doc E/CN.4/RES/2004/26. **See also**, UN Commission on Human Rights, 'Resolution 2005/23: Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria' (15 April 2005) UN Doc E/CN.4/RES/2005/23. **See also**, UN Commission on Human Rights, 'Report of the Secretary-General on Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria' (3 December 2004) UN Doc E/CN.4/2005/38

[151] UN General Assembly, 'Resolution S-26/2: Declaration of Commitment on HIV/AIDS' (2 August 2001) UN Doc A/RES/S-26/2. **See also**, World Health Assembly, 'Resolution 53.14: Global Strategy for the Prevention and Control of Non-Communicable Diseases' (22 March 2000) WHA 53.14. **See also**, World Health Assembly, 'Resolution 56.30: Global Health-Sector Strategy for HIV/AIDS' (28 May 2003) WHA 56.30. **See also**, World Health Assembly, 'Resolution 57.14: Scaling Up Treatment and Care Within a Coordinated and Comprehensive Response to HIV/AIDS' (22 May 2004) WHA 57.14. **See also**, World Health Assembly, 'Resolution 59.24: Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action' (27 May 2006) WHA 59.24. **See also,** World Health Assembly, 'Resolution 61.21: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property' (24 May 2008) WHA 61.21

[152] UN General Assembly, '77th Plenary Meeting' (22 December 2003) UN Doc A/58/PV.77, 20

contribution to the demographic dividend of Africa, its recent economic growth, and the emerging vision of Africa as a continent of hope, promise and vast potential."[153]

State practice constitutes only one element of customary international law. For an international act to become a customary law, the state practice should be accompanied by *opinio juris*, i.e., evidence that states are recognizing such practice as obligatory.

#### 3.7.2.3 Does the State Practice in Accessibility to Medicines Represent Opinio Juris?

The ICJ stated that it cannot take into account moral principles unless they are sufficiently expressed in a legal form.[154] In an advisory opinion regarding the legal consequences of building a wall in Palestine, the court mentioned that the right to health within the context of the ICESCR is a legal norm binding on all states.[155]

National constitutions and courts' decisions are considered strong evidence supporting the *opinio juris* requirement. The dissertation has demonstrated above, several Constitutional and Supreme Courts' rulings from South Africa, Ecuador, India, Venezuela, Colombia, Costa Rica, and Argentina. The rulings showed the responsibility of governments to make ARV drugs, including HIV/AIDS medication, fully accessible and available to all citizens. The courts obliged governments to remove all obstacles that may deny access to such medicines. The obligations emanate from the constitutional duties of states to protect both the right to life and the right to health. Failing to perform such obligations constitutes a violation to the constitution, thus, they are legally binding on all states.

Other court rulings stipulated that access to essential medicines treating pandemics is an integral part of the fulfilment of the right to health. A systematic search conducted by Hans Hogerzeil and others in 2006 showed that 59 court cases from 12 low and middle-income countries enforced accessibility to essential medicines. The courts based their rulings on the constitutional provisions obliging states to respect, protect and fulfil the right to health, in addition to the human rights treaties obliging them to act the same. In 49 cases, the court judgment linked the right to health with the right to life. 24 cases were related to the right to access HIV/AIDS

[153] UN General Assembly, 'Report of the Secretary-General on Reinvigorating the AIDS Response to Catalyse Sustainable Development and United Nations Reform' (7 April 2017) UN Doc A/71/864
[154] S*outh West Africa Cases (Ethiopia v South Africa; Liberia v South Africa)* (Second Phase Judgment) [1966] ICJ Rep 6, 34
[155] *Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory* (Advisory Opinion) [2004] ICJ Rep 136, paras 112, 130

medicines and other life-saving drugs like the ones used to treat leukaemia and liver transplantation.[156]

Further, other research conducted in 2016 showed that 22 constitutions worldwide obliged governments to respect, protect and fulfil accessibility and availability of medicines of good quality. The research showed that governments' commitments to essential medicines are increasingly included in states' constitutions since 2008. The recently adopted constitutions include not only the obligation of states to respect, protect and fulfil the right to access to essential medicines, but also to protect medicines from international trade barriers and IPRs.[157]

Moreover, many provisions in the international resolutions demonstrated above represent a legal obligation on states to ensure better accessibility to pharmaceutical products needed for treating pandemics. Also, the binding nature of the ICESCR imposes a legal duty on states to achieve the full realization of such right in cases of pandemics and epidemics.[158]

This infers that state practice to ensure and provide accessibility to pharmaceuticals in the context of pandemics is based on a legal obligation under the right to health in order to satisfy the *opinio juris* requirement. State practice and *opinio juris* support the view that the right to access to medicines in the context of pandemics is emerging as a rule of customary international law. States perform such practice with a belief that it is a legal duty. The numerous international resolutions and declarations adopted by states, in addition to the various court rulings and national constitutions support this finding. Accessibility to COVID-19 medicines and vaccines could also be regarded as customary international law since the COVID-19 is a global pandemic. Notably, this view does not encompass accessibility to medicines in general as there is no sufficient state practice in this regard.

#### 3.7.2.4 Does the UDHR Constitute Customary International Law?

The dissertation showed previously that it is strongly doubtful that the UDHR acquires the status of an international treaty. The UDHR recognized the right to health in article 25(1). If the UDHR

[156] Hans V. Hogerzeil et al, 'Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable Through the Courts?' (2006) 368(9532) The Lancet Medical Journal 305, 305-311
[157] S. Katrina Perehudoff, Brigit Toebes, and Hans Hogerzeil, 'Essential Medicines in National Constitutions Progress Since 2008' (2016) 18(1) Health and Human Rights Journal 141, 145-149, 153
[158] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 12(2)(c)

provisions constitute customary law, it could be argued that the right to access to medicines, in general, enjoys the same nature.

With time, the UDHR acquired significant legal status to the extent that some scholars argued that many of its provisions became accepted as a source or evidence of customary international law.[159] Scholars drew several examples of state practice to justify this argument.

During the World Conference on Human Rights in Vienna 1993, Malta and Iceland noted that the UDHR is considered a part of the international customary law. They demanded all states to implement and enforce the principles and purposes of the UDHR as binding provisions. Other countries, like Denmark, Switzerland, and Australia, believed that many provisions of the UDHR have come to be accepted as norms that constitute binding customary international law. Furthermore, in the Third Committee of the UN General Assembly, Finland declared that it considers the rights and freedoms in the UDHR customary international law. Moreover, several South American Countries, like Uruguay, Mexico, and Chile, had declared on many occasions that the UDHR constitutes customary international law.[160]

Nevertheless, some states, *inter alia*, the US and Canada, even though they supported the goals and confirmed the significance of the declaration, refused to extend the status of customary international law to the UDHR.

Turning to the international bodies' practice, the International Law Association declared in 1994 that "many if not all of the rights elaborated in the UDHR are widely recognized as constituting rules of customary international law binding on all states."[161] The former Representative of the UN Commission on Human Rights, Galindo Pohl, confirmed that the rights and freedoms stipulated in the UDHR became international customary law through state practice and *opinio juris*. He opined that the provisions of the UDHR meet the robust standards of the approach adopted to determine the elements forming international customary law.[162]

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[159] Hurst Hannum, 'The UDHR in National and International Law' (1998) 3(2) Health and Human Rights Journal 144, 147-148

[160] Ibid, 148. **See also**, Hurst Hannum, 'The Status of the Universal Declaration of Human Rights in National and International Law' (1996) 25(1) Georgia Journal of International and Comparative Law 287, 326, 327, 330-332

[161] International Law Association, 'Report of the Sixty-Sixth Conference Held at Buenos Aires, Argentina' (14 to 20 August 1994) 526

[162] UN Commission on Human Rights, 'Report on the Human Rights Situation in the Islamic Republic of Iran by the Special Representative of the Commission, Mr. Reynaldo Galindo Pohi, Appointed Pursuant to Resolution 1986/41' (28 January 1987) UN Doc E/CN. 4/1987/23, paras 22-23

The UDHR also served as the foundation for the two binding international Covenants, the ICCPR and the ICESCR. Its principles were adopted and incorporated in many international treaties, like the International Convention on the Elimination of Discrimination Against Women and the UN Convention on the Rights of the Child.

Further the *obiter dictum* of the ICJ expressed in several cases that the basic human rights stipulated in the UDHR are considered customary international law. A prominent case which opened the door for the enforcement of several human rights as obligations *erga omnes* is the *Barcelona Traction* case.[163] In this case, the ICJ stated that the principles and rules concerning basic human rights are obligations *erga omnes*. Realizing the importance of such rights, the court suggested that states have a genuine legal interest in the universal respect and protection of "the basic rights of the human person."[164] In *South West Africa* case, the ICJ Vice-President Ammoun wrote in his separate opinion that the UDHR can bind states either because it constitutes a codification of customary law within the meaning of article 6 of the VCLT, or because it acquired the force of custom through general practice accepted as law as stipulated in article 38 (1)(b) of the ICJ statute.[165]

In the same vein, several national court decisions used some UDHR provisions as a source of standards for judicial decisions, thus reflecting the customary binding nature of these provisions. In the case of *Fernandez v. Wilkinson*, for example, the US District Court of Kansas cited in its decision the opinion of Richard Bilder, an international jurist, who suggested that "it may currently be argued that the UDHR standards, although initially only declaratory and non-binding, have by now, through wide acceptance and recitation by nations as having normative effect, become binding customary law. Whatever may be the weight of this argument, it is certainly true that the declaration is in practice frequently invoked as if it were legally binding, both by nations and by private individuals and groups."[166] The court added that many human rights stated in the UDHR are considered binding customary law because "they have acquired

[163] Evan J. Criddle, 'Standing for Human Rights Abroad' (2015) 100(2) Cornell Law Review 269, 283-284. **See also**, *Barcelona Traction, Light & Power Co (Belgium v Spain*) (Second Phase Judgment) [1970] ICJ Rep 3
[164] *Barcelona Traction, Light & Power Co (Belgium v Spain*) (Second Phase Judgment) [1970] ICJ Rep 3, paras 33-34
[165] *Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) Notwithstanding Security Council Resolution 276 (1970)* (Separate Opinion of Vice-President Ammoun(tr) ) [1971] ICJ Rep 16, 76
[166] *Rodriguez Fernandez v Wilkinson*, Trial Judgment, 505 F Supp 787 (D Kan 1980), ILDC 2019 (US 1980), 31st December 1980, United States; Kansas; District Court for the District of Kansa, para 796

the force of custom through a general practice accepted as law" within the meaning of article 38 (1)(b) of the statute of the ICJ.[167]

Furthermore, the UDHR had influenced national laws and migrated to national constitutions through constitutional drafting and interpretation. The South African constitution 1996, for example, is considered the most recent constitution that embedded the ESCRs in the UDHR in its statutes. Notably, South Africa was one of the countries that refused the inclusion of the economic and social rights in the UDHR upon its adoption in 1948.[168] Apart from the South African Constitution, it was estimated that since 1948, not less than 90 national constitutions were inspired by the fundamental rights of the UDHR.[169]

Moreover, the opinions of distinguished legal advisers and scholars have taken the position that the current status of the UDHR represents customary international law. John Humphrey, one of the principle drafters of the UDHR, emphasized that the declaration is now binding on all states, including the states that did not vote for it in 1948.[170] Similarly, Waldock concluded that the widespread recognition of the declaration principles renders it in the rank of customary international law.[171] Thornberry argued that "there is a strong evidence that the UDHR has become part of the customary international law and represents the most valid interpretation of human rights and freedoms which the members of the United Nations pledge to promote."[172]

Katharine Young viewed the UDHR status as customary international law because it constitutes the authoritative interpretation of the human rights obligations in the UN Charter which is understood in itself to be customary international law. She highlighted the continuous invocation of its provisions in treaties, states practices, national constitutions and legislations, and the decisions of both national and international courts. Accordingly, all states, even those that did not ratify one or both Covenants, are bound by the UDHR provisions as a matter of

[167] Ibid
[168] Constitution of the Republic of South Africa, 10 December 1996. **See also**, UN Commission on Human Rights, 'Comments from Governments on the Draft International Declaration on Human Rights, Draft International Covenant on Human Rights and the Question of Implementation' (27 April 1948) UN Doc E/CN.4/82/Add.4, 25
[169] Hurst Hannum, 'The UDHR in National and International Law' (1998) 3(2) Health and Human Rights Journal 144, 150
[170] John P. Humphrey, *No Distant Millennium: The International Law of Human Rights* (UNESCO 1989) 155
[171] Humphrey Waldock, 'Human Rights in Contemporary International Law and the Significance of the European Convention' (1965) 11 The British Institute of International and Comparative Law Quarterly Supplementary Publication 1, 15
[172] Patrick Thornberry, *International Law and the Rights of Minorities* (Oxford University Press New York 1991) 237-238

international law.[173] Similarly, Lung-Chu Chen considered that the "frequent invocation and application by officials, at all levels of government and in many communities around the world, have conferred on the UDHR those expectations characteristic of customary international law."[174]

The Human Right's Special Rapporteur on the situation in Iran, Galindo Pohl, asserted that the rights and freedoms set out in the UDHR have become international customary law through state practice and *opinio juris*. He stated that the UDHR provisions not only meet the classical doctrine of customary law but also the stringent requirements of the contemporary doctrine on the constitutive two elements of such law.[175]

Other scholars went even further arguing that some provisions of the UDHR not only constitute customary international law but also *jus cogens* norms because they achieved universal recognition.[176] A third group restricts the customary law nature on the CPRs in the declaration.[177]

The latter notion has been criticized since the two categories of rights enshrined in the UDHR are drafted in two Covenants, and each of them has been ratified by almost equal number of states.[178] Hence, the ESCRs should enjoy the same customary nature as the CPRs. Critics attributed such differentiation to the ideological polarization accompanying the cold war, where the international environment was considered the main obstacle to satisfying the test of state practice and *opinio juris*. But things changed after the end of the cold war in 1991. States formed

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[173] Katharine G. Young, 'Freedom, Want, and Economic and Social Rights: Frame and Law' (2009) 24(1) Maryland Journal of International Law 182, 198-199

[174] Lung-Chu Chen, 'Protection of Persons (Natural and Juridical)' (1989) 14 Yale Journal of International Law 542, 546-547

[175] UN Commission on Human Rights, 'Report on the Human Rights Situation in the Islamic Republic of Iran by the Special Representative of the Commission, Mr. Reynaldo Galindo Pohi, Appointed Pursuant to Resolution 1986/41' (28 January 1987) UN Doc E/CN. 4/1987/23, para 22

[176] Bertrand G. Ramcharan, 'The Legal Status of the International Bill of Human Rights' (1986) 55(4) Nordic Journal of International Law 366, 380. **See also**, David F. Klein, 'A Theory for the Application of the Customary International Law of Human Rights by Domestic Courts' (1988) 13(2) Yale Journal of International Law 332, 354 footnote 111

[177] John P. Humphrey, 'The Universal Declaration of Human Rights: Its History, Impact and Juridical Character' in Bertram G. Ramcharan (ed), *Human Rights: Thirty Years After the Universal Declaration* (Martinus Nijhoff Publishers 1979) 21, 29

[178] As of May 2021, the ICCPR has been ratified by 173 states and the ICESCR has been ratified by 171 states. For status of ratifications, see 'International Covenant on Economic, Social and Cultural Rights' (UN Treaty Collection, 12 May 2021) < https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-3&chapter=4&clang=_en> accessed 12 May 2021. **See also**, 'International Covenant on Civil and Political Rights' (UN Treaty Collection, 12 May 2021) < https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-4&chapter=4&clang=_en> accessed 12 May 2021

sufficient practice in many regions, including food and health crises, with the purpose of developing international custom.[179]

On the contrary, other scholars deny the customary nature of the UDHR arguing that there is no sufficient *opinio juris* from recognized international legal bodies supporting the customary nature of all the human rights in the declaration including the right to health. Scholars derived several opinions to justify their argument in this regard.

Antonio Cassese, a jurist specialized in public international law and the first President of the International Criminal Tribunal for the former Yugoslavia as well as the first President of the Special Tribunal for Lebanon, contended that the UDHR is not legally binding but possesses only moral and political force.[180] Van Hoof showed great concerns regarding conferring the customary nature on the human rights in the UDHR.[181] Alexandre Kiss, in the special issue of the UN Bulletin of Human Rights, asserted that the UDHR does not have a customary nature due to the acts of states which indicate that they do not accept such nature to be conferred on the declaration provisions.[182]

Bruno Simma and Philip Alston emphasized that the UDHR is a declaration, and since it is a soft law, it is not legally binding. They added that there is insufficient jurisprudence from the ICJ supporting the customary nature of all human rights stipulated in the UDHR. A list of human rights constituting part of customary law include the right of equality before the law, the right to non-discrimination, the right to fair trials and the right of defence. However, other human rights including the right to health, the right to freedom from hunger and the right to primary education are all excluded from that list. They referred to the domestic high courts in Switzerland, Germany, and the US which consider human rights as a part of the general principles of international law at times, and at others a part of *jus cogens*. The courts did not mention the customary international law in any of their decisions.[183]

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[179] Katharine G. Young, 'Freedom, Want, and Economic and Social Rights: Frame and Law' (2009) 24(1) Maryland Journal of International Law 182, 198-201**. See also**, Smita Narula, 'The Right to Food: Holding Global Actors Accountable Under International Law' (2006) 44(3) Columbia Journal of Transnational Law 691, 793

[180] Antonio Cassese, *International Law in a Divided World* (Oxford University Press 1986) 299

[181] G. Van Hoof, *Rethinking Sources International Law* (Springer Press 1985) 107-108

[182] Alexandre kiss, 'The Role of the Universal Declaration of Human Rights in the Development of International Law' in UN Centre of Human Rights, *Bulletin of Human Rights: Special Issue: Fortieth Anniversary of the Universal Declaration of Human Rights* (UN 1988) 47-48

[183] Bruno Simma and Philip Alston, 'The Sources of Human Rights law: Custom, Jus Cogens and General Principles' (1992) 12 Australian Yearbook of International Law 82, 94-97, 106

Ultimately, there is some evidence that part of the human rights mentioned in the UDHR could constitute customary international law. However, it is highly doubted that the declaration *in toto* is considered customary law as there is insufficient state practice and *opinio juris* to support this proposition. It is dubious to propose that access to medicines as a component of the right to health in the UDHR falls within the rights protected under customary international law.

### 3.8 Challenges Facing Developing Countries Regarding Accessibility to Medicines

The current international patent regime foreseeably aggravates the health problems in developing countries due to inflating the prices of medicines rendering them inaccessible and unavailable to many people. According to the Millennium Development Goals Gap Task Force, the cost of many essential medicines, particularly those for chronic diseases, remains prohibitive in many developing countries.[184]

The report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health demonstrated that there is a significant relationship between the state of health and poverty. 50 to 90 percent of essential medicines are paid by patients themselves in developing countries. The report showed that only one third of essential medicines needed are available for public sector rendering essential medicines inaccessible for about 2 billion people in developing countries. It was estimated that improving the accessibility to essential medicines could save the lives of 10 million people per year, among them 4 million in Africa and Southeast Asia. The report elaborated that such challenges escalated after applying the new Indian patent law in 2005 responding to its TRIPS obligations. India, as illustrated by the report, was considered the main supplier of essential generic medicines for developing countries with about 67 percent of such medicines being manufactured and exported to developing countries.[185]

In other reports, the special Rapporteur warned of the exploitation of pharmaceutical patents by patentees as a tool to increase the price of medicines which reduce the economic accessibility

[184] UN Millennium Development Goal Gap Task Force, *Millennium Development Goal 8: The Global Partnership for Development: Making Rhetoric a Reality* (UN Publication 2012) 64 < https://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2012/mdg8report2012_engw.pdf> accessed 17 January 2021

[185] Human Rights Council, 'Report of the Special Rapporteur Anand Groover on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights Including the Right to Development' (31 March 2009) UN Doc A/HRC/11/12, paras 13, 14, 21, 29 footnote 34

to essential medicines. He illustrated that the TRIPS Agreement includes some flexibilities to address the issue, such as allowing WTO members to authorize third parties to locally work the patent without the authorization of the patent holder (compulsory licences as stated in article 31 of the TRIPS). This supports producing and selling generics at a lower price than patented medicines, thus ensuring accessibility to essential medicines. The Special Rapporteur listed several constraints that hamper the usage of the compulsory licensing system. Such constraints include supplying the domestic market only of the state that issued the compulsory license, the payment of reasonable fees to the patent holder, and the usage of the system by WTO members acquiring domestic pharmaceutical manufacturing capacity. Other developing countries with little or no manufacturing capacity might not be able to benefit from this system. For these reasons, the Special Rapporteur welcomed the 30 August Decision as it allowed generic producers to utilize the compulsory license flexibility to export drugs to developing countries with no or little drug manufacturing capacity. The Special Rapporteur noted that the conclusion of the 30 August Decision emanated from the human rights responsibility of developed states to engage in international assistance and cooperation in relation to the right to health. Nevertheless, the Decision did not achieve its goals due to its intricate and cumbersome procedures for granting compulsory licences.[186]

The Special Rapporteur emphasized what the dissertation illustrated in chapter 2. He clarified that even though there are other flexibilities in the TRIPS agreement, such as the experimental non-commercial usage, the regulatory review, and the parallel importation, developing countries are exposed to political and economic pressure from developed countries and multinational pharmaceutical companies whenever they try to utilize the flexibilities to address public health concerns.[187]

[186] Ibid, para 38. **See also**, UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Addendum Mission to the World Trade Organization' (1 March 2004) UN Doc E/CN.4/2004/49/Add.1, para 43. **See also**, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision). **See also**, Brook K. Baker, 'Arthritic Flexibilities: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (2004) 14(3) Indiana International and Comparative Law Review 613, 633-635, 655. **See also**, Peter Drahos, 'Four Lessons for Developing Countries from Trade Negotiations over Access to Medicines' (2007) 28(1) Liverpool Law Review 11, 14

[187] Human Rights Council, 'Report of the Special Rapporteur Anand Groover on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights Including the Right to Development' (31 March 2009) UN Doc A/HRC/11/12, paras 56-60

Other constraints facing developing countries in their pursuit to improve accessibility to essential medicines include natural disasters, armed conflicts, poverty, population problems, and ineffective health policies.[188] The UK government added to these challenges, the lack of sufficient incentives for developing new medicines in developing countries. It stated that there is a "mismatch between pharmaceutical needs in developing countries and the current nature of the global pharmaceutical market."[189]

Furthermore, the quality of medicines moving from developed countries to developing ones are considered one of the problems in the enjoyment of the right to access to medicines. In some cases, medicines that are refused in developed countries for being unsafe or beyond expiry dates are counterfeited in developing countries, then recycled and sold in their market. Many developing countries do not have a well-established regulatory system to check drugs safety and quality due to lack of financial and technical capabilities. Thus, the Special Rapporteur stressed the importance of ensuring that medicines have to be of a good quality, where the recycling of medicines is unacceptable.[190]

The accessibility to essential medicines can be improved in developing countries through strengthening partnerships between the public sector, civil society, and the pharmaceutical companies. The inadequate financing and low budget in the public sector can be surmounted via special financial support programs and differential pricing schemes with private sectors. For example, the financial support that Kenya received from the Global Fund to Fight AIDS, Tuberculosis, and Malaria in 2006 increased the accessibility to medicines that cure these diseases. There is also the agreement signed between Kenya and Novartis pharmaceutical company regarding differential pricing, where Novartis accepted to provide medicines to the public sector in Kenya below the market price.[191]

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[188] 'Over 5 Billion People Worldwide Lacking Access to Essential Medicines, Says UN Report' (UN News, 3 March 2015) < https://news.un.org/en/story/2015/03/492482-over-5-billion-people-worldwide-lacking-access-essential-medicines-says-un> accessed 21 November 2020

[189] UN Millennium Project, P*rescription for Healthy Development: Increasing Access to Medicines* (Earthscan London 2005) 4 < https://www.taylorfrancis.com/books/9781849773553 > accessed 20 November 2019

[190] Human Rights Council, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Promotion and Protection of all Human Rights, Civil, political, Economic, Social and Cultural Rights' (31 January 2008) UN Doc A/HRC/7/11, para 54

[191] UN Millennium Development Goal Gap Task Force, *Millennium Development Goal 8: Delivering on the Global Partnership for Achieving the Millennium Development Goals* (UN Publication 2008) 35, 38 < https://www.un-ilibrary.org/content/books/9789210542982/read > accessed 3 May 2020

These challenges envisage that the interests of developed countries and pharmaceutical industry are often in conflict with the attempts of developing countries to provide better accessibility to medicines for their citizens. The UN Sub-Commission on the Promotion and Protection of Human Rights emphasized this conflict when it declared that "the implementation of the TRIPS agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including … the right to health." The Sub-Commission noted that there are apparent conflicts between the IPRs system in the TRIPS and human rights law.[192]

### 3.9 Conclusion

In this chapter, the dissertation attempted to provide a clear picture of the right to access to medicines as an indispensable component of the human right to health. It addressed several sources of international law that acknowledged the right to access to medicines and obliged states to respect, protect and fulfil that right. States have a minimum core obligation to guarantee the accessibility, availability, and acceptability of essential medicines, as identified from time to time under the WHO Action Programme on Essential Drugs, with sufficient quantity and good quality throughout its territory. This obligation has to be achieved immediately to the maximum of the available resources in each state.

States are also required to progressively realize the accessibility to non-essential medicines. The realization is limited to the full implementation of the right, not to the minimum core obligation. States are not required to perform an impossible duty to provide non-essential medicines for everyone immediately because the right to health is not a utopian notion.

As such, states cannot justify their non-compliance, regarding essential medicines, on the lack of or insufficient financial resources. They can meet their obligations in this regard by adopting effective health insurance policies that assist people to obtain medicines or by financing a comprehensive system for health care that guarantees accessibility to medicines for all people without any kind of discrimination. The duty to respect and promote human right to health lies with not only states, but also patent-holding pharmaceutical companies, as non-state actors.

[192] UN Sub-Commission on the Promotion and Protection of Human Rights, 'Resolution 2000/7 on Intellectual Property Rights and Human Rights' (17 August 2000) UN Doc E/CN.4/Sub.2/RES/2000/7, para 2. **See also**, UN Sub-Commission on the Promotion and Protection of Human Rights, 'Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights' (27 June 2001) UN Doc E/CN.4/Sub.2/2001/13, para 2

They should carry out human rights due diligence regarding access to medicines and co-operate with states to enhance R&D for neglected diseases.

The dissertation also addressed the debate about the justiciability of the human right to health. Contrary to the argument stating that the right to health, as a positive right, is not worth protection like CPRs, the dissertation showed that all human rights either in the ICESCR or the ICCPR have the same value and binding force. States cannot escape from their obligations in offering protection to any of them on the grounds of financial constraints. They have to ensure that the right to health is given due consideration when interpreting and implementing international agreements. Thus, WTO members should interpret and apply the TRIPS agreement in a manner consistent with their obligations under the right to health by making full use of the TRIPS flexibilities.

Although states have a legal obligation to protect the right to access to medicines, the scope of such protection differs according to the sources of international law.

The ICESCR protects the accessibility to essential medicines, defined by the WHO Action Programme on Essential Drugs, as an essential element of the right to health. According to the principle of *pacta tertiis nec nocent nec prosunt*, states that did not adopt the ICESCR cannot be obliged to protect such right without their consent.

On the other hand, the ICCPR protects the accessibility to life-saving medicines as an element of the right to life necessary for human survival. Since the right to life is considered a *jus cogens* norm in public international law, it could be strongly argued that its component (right to life-saving medicines) should reach the same status accordingly. Contrary to the principle of *pacta tertiis nec nocent nec prosunt*, the protection of life-saving medicines, as a *jus cogens* norm, is binding on all states whether they are parties to the ICCPR or not. They cannot derogate from their obligation to protect the right to access to life-saving medicines even in matters of public emergency. Consequently, any interpretation to any treaty addressing pharmaceutical patents has to be compatible with the right to access to life-saving medicines, otherwise the interpretation would be considered violating a *jus cogens* norm.

From the customary international law perspective, state practice and *opinio juris* supported protecting the right to access to medicines as customary international law. However, such protection is confined only to medicines in the context of pandemics like HIV/AIDS, Malaria and Tuberculosis. There is insufficient state practice to support the customary nature of access

to all medicines generally. The dissertation showed that it is highly doubtful to rely on the right to health under the UDHR to argue that the right to access to medicines in general is a customary international law. There is insufficient state practice and *opinio juris* to support that the rights and obligations *in toto* in the UDHR are customary international law. In addition, the UDHR is not a legally binding treaty, but rather, a manifesto with primarily moral authority as described by the United Nations.

Eventually, the dissertation illustrated the challenges facing developing countries in ensuring accessibility to medicine for their people. It showed the negative implications of the international patent system in hindering the attempts of governments to ensure better access to medicine. National court rulings in developing countries illustrated that the governments should be responsible for making essential medicines accessible and affordable to all people.

Having set out the international framework for the right to access to medicines in this chapter and that of the pharmaceutical patents in chapter 2, chapter 4 will explore whether both rights conflict or coexist.

## Chapter 4: Conflict or Coexistence between Pharmaceutical Patents & Access to Medicines

### 4.1 Introduction

The intellectual Property system and the human rights system have been addressed independently for a long time. Recently, there has been continuous expansion in both regimes. The IP system was linked to trade via the TRIPS agreement due to the increase of technological inventions and the dire need to protect and regulate the rights of inventors.[1] Meanwhile, the human rights system expanded with time and received more global recognition, especially the ESCRs which were not receiving the same form of recognition like the CPRs. The adoption of General Comments that delineate the scope of each human right and provide authoritative interpretation of the obligations under it, in addition to the various academic writings, led to the refinement of the obligations under human rights law.

This expansion was induced by emergence of community interests in international law. They transformed the international legal order from a law dealing with coexistence between sovereign states and seeking only the achievement of bilateral/reciprocal relations, into a law that also regulates co-operation between states to protect public goods and fulfil community interests. The expansion increased the number of international norms with diversified subject matters leading to potential conflicts between norms in international law,[2] a phenomenon known as the fragmentation of international law. This was emphasized by Jenks when he described the conflict of law-making treaties. He showed that such conflict "has to be accepted as being in certain circumstances, an inevitable incident of growth, and an essential part of the duty of international lawyers to encourage the adoption of procedures that minimize the occurrence of such conflict and to formulate principles for resolving such conflicts when it arises."[3]

The expansion of intellectual property and human rights regimes led to blurring of the demarcation between both regimes. It created dense policy spaces in which the previously unrelated norms in IP and human rights systems increasingly overlapped in inconsistent and

[1] Bona Muzaka, 'Developing Countries and the Struggle on the Access to Medicines Front: Victories Won and Lost' (2009) 30(7) Third World Quarterly 1343
[2] Santiago Villalpando, 'The Legal Dimension of the International Community: How Community Interests are Protected in International Law' (2010) 21(2) The European Journal of International Law 387, 388-389
[3] Clarence Wilfred Jenks, 'The Conflict of Law-Making Treaties' (1953) 30 British Yearbook of International Law 401, 405

incoherent ways.[4] In the last few years, it is said that the "two systems that were once strangers are now becoming increasingly intimate bedfellows."[5]

The aim of WTO law is to liberalize trade by eliminating all forms of trade barriers. While the WTO system may jeopardize human rights law in some cases, the human rights regime may impede the free flow of trade resulting in a potential conflict. From a human rights perspective, there has been increasing recognition of the impact of WTO rules on social matters which go beyond trade. However, the international trade community did not effectively take into consideration the role of human rights law within the WTO regime.[6]

It is only within the last two decades, that the international organizations, NGOs and legal academics have started to recognize the interference between IP rights and human rights. An example of such realization is the South African Medicines and Related Substances Control Amendment Act in 1997, previously discussed in chapter 2, which was one of the issues that received big attention in the international arena. Accordingly, two approaches appeared regarding the interference between pharmaceutical patents and the right to access to medicine. The first approach views them as being in fundamental conflict, where the first unjustifiably interferes with the latter; meanwhile, the second approach views them as coexistent.[7]

Some scholars argued that the pharmaceutical patent system in the TRIPS agreement and the right to health in the ICESCR are in fundamental conflict. They opined that the robust patent protection provided by the TRIPS undermines the right to health obligations in the ICESCR. They argued that the object and purpose of the two instruments contradict. The ICESCR addresses the fundamental and inalienable rights of all people which are timeless expression of their entitlements. It indicates that accessibility to medicines is a crucial element for the realization of the right to health. Meanwhile, the TRIPS agreement focuses on the protection of property rights and the elimination of any trade distortions that would interfere with that protection. It emphasized that accessibility is restricted to the conditions set by the patent holders due to the exclusive rights conferred to them under its provisions.[8] Unequivocally, there is a

[4] Laurence R. Helfer, 'Toward a Human Rights Framework for Intellectual Property' (2007) 40 University of California Davis Law Review 971, 980-982
[5] Laurence R. Helfer, 'Human Rights and Intellectual Property: Conflict or Coexistence?' (2003) 5(1) Minnesota Journal of Law, Science and Technology 47, 47-48
[6] James Harrison, *The Human Rights Impact of the World Trade Organization* (Hart publishing 2007) 36
[7] Peter K. Yu, 'Ten Common Questions about Intellectual Property and Human Rights' (2007) 23(4) Georgia State University Law Review 709, 709-710
[8] Hans Morten Haugen, 'Patent Rights and Human Rights: Exploring their Relationships' (2007) 10(2) World Intellectual Property Journal 97, 102. **See also**, Frantzeska Papadopoulou, 'TRIPS and Human Rights' in

contrast between fundamental rights which are entitlements belonging to all people by virtue of being human beings and property rights which can be relinquished by voluntary transactions.[9] To resolve this conflict, scholars opined that the normative primacy of human rights system has to be prioritized in situations of conflict with IP obligations.[10]

Other scholars disagreed and considered pharmaceutical patents in TRIPS and human rights to health in the ICESCR compatible. They argued that both systems are concerned with the same query. Both systems seek a suitable scope of monopoly rights that incentivize inventors to produce more drugs and encourage them to disclose their inventions, while at the same time ensuring that the consumers have adequate accessibility to the fruits of their labour. Therefore, they opined that a fair balance should be struck between incentives to produce and accessibility to scientific progress and its application.[11] They referred to the objectives and principles of the patent system in the TRIPS agreement which correspond with article 15 of the ICESCR, thus protecting the rights of producers, and at the same time the rights of users in enjoying the benefits of scientific progress and its applications. A reference was also made to the TRIPS flexibilities that could provide the necessary balance between accessibility and protection through the curve outs they contain.[12]

This chapter will explore the interference between patents protection and accessibility to medicines. It will seek an answer to the question whether the right to access to medicines conflicts or coexists with pharmaceutical patents. In the first case, what is the type of such conflict?

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Annette Kur and Marianne Levin (eds), *Intellectual property Rights in a Fair World Trade System. Proposals for Reform of TRIPS* (Edward Elgar UK 2011) 262, 270

[9] Martha C. Nussbaum, 'Capabilities and Human Rights' (1997) 66(2) Fordham Law Review 273.

[10] Philippe Cullet, 'Patents and Medicines: The Relationship between TRIPS and Human Rights to Health' (2003) 79(1) International Affairs 139, 157-159

[11] Laurence R. Helfer, 'Human Rights and Intellectual Property: Conflict or Coexistence?' (2003) 5(1) Minnesota Journal of Law, Science and Technology 47, 48-49. **See also**, Peter K. Yu, 'Reconceptualizing Intellectual property Interests in a Human Rights Framework' (2007) 40 University of California Davis Law Review 1039, 1077

[12] UN Sub-Commission on the Promotion and Protection of Human Rights, 'Report of the Secretary-General on Intellectual Property Rights and Human Rights' (14 June 2001) UN Doc E/CN.4/Sub.2/2001/12, 7-9 sec 2(b). **See also**, UN Sub-Commission on the Promotion and Protection of Human Rights, 'Report of the Secretary-General on Intellectual Property Rights and Human Rights. Addendum' (3 July 2001) UN Doc E/CN.4/Sub.2/2001/12/ Add.1, 13-15 sec II. **See also**, International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 15(1)(b)(c). **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) arts 7, 8

To address the questions, the chapter will first scrutinize the different justifications for the interference between pharmaceutical patents and accessibility to medicines. It will be argued that the patent system in TRIPS is unjustifiably interfering with the right to access to medicines, thus a conflict is recognized between both regimes. This conflict is an instance of a larger conflict between the WTO system and the human rights system. The chapter will then seek to scrutinize the type of conflict to delineate an appropriate method, if any, to resolve it.

Before delving to explore the concept of conflict of norms in public international law, it is necessary first to explicate the structure and the development of international law norms since the problem of regime conflict is rooted in that development. So, the chapter will address the traditional setting of international law as a law of co-existence without any normative hierarchy. Then, it will demonstrate the development that occurred to international law when the notions of community interests and co-operation were introduced to the concept of bilateral paradigm. In this context the chapter will analyse the UN obligations, the *erga omnes* obligations, and the *jus cogens* norms.

The chapter will then address the emergence of the fragmentation phenomenon due to the institutionalization of international legal system and its consequences on establishing a *de facto* hierarchy beside, and entirely independent of the normative hierarchy. The chapter will explore the nature of the WTO and human rights obligations and the effect of the normative hierarchy and the *de facto* hierarchy on the WTO and human rights regimes. The analysis of the fragmentation phenomenon will show that such *de facto* hierarchy is responsible for placing the human rights regime at a lower level than the WTO system, which undermines the role of human rights law within the WTO regime. This downgrade is not recognized under the normative hierarchy which generally places human rights norms at a higher position.

Finally, the chapter will examine the concept of conflict of norms in public international law showing both the strict and the broad definition of norms conflict. It will show that human right to health in the ICESCR and the pharmaceutical patents in TRIPS do not contain mutually exclusive obligations according to the strict definition of norms conflict. However, according to the broad definition, the factual hierarchy created by the WTO agreement is responsible for identifying two types of conflicts between both rights.

The chapter will argue that such conflicts are realized even before the need to interpret and analyse the TRIPS flexibilities. Assuming that they are effective, albeit not, as proved in chapter 2, the nature of the TRIPS flexibilities, as an obligation to utilize them rather than a right to

invoke them, constitutes a conflict *per se* between the patent system in TRIPS and the right to health under the definition of norms conflict in public international law.

The chapter will conclude by suggesting that the conflict between both regimes turned to be an objective question. The question aims to explore possible methods, if any, that could be utilized to overcome the factual hierarchy of the WTO system by applying human rights law within the WTO system.

### 4.2 Justifications for the Interference Between Pharmaceutical Patents and Human Right to Health

The following part shall examine several justifications for the pharmaceutical patents interference with the right to access to medicine. First, it shall address the justification related to the right of authors to benefit from the protection of the moral and material interests resulting from their scientific productions (article 15(1)(c) of the ICESCR), then the one related to the research incentives, and finally the justifications related to the transfer of technology and competition policy.

#### 4.2.1 Justification According to Article 15(1)(C) of the ICESCR

Several IP proponents and scholars justify pharmaceutical patents in developing countries according to the rights of authors to benefit from the protection of the moral and material interests resulting from their scientific productions which is stated in article 15(1)(c) of the ICESCR.[13] However, clearly examining the scope of protection in the article suffices to rebut this justification for several reasons. The most prominent ones are as follows:

First: Article 15(1)(c) of the ICESCR provides for the protection of the fundamental human rights and is not meant to protect patent rights as such. IPRs go beyond the moral and material

[13] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 15(1)(c). Same Statute is found also in article 27 (2) of the Universal Declaration of Human Rights (UDHR). **See also**, Jennifer Anna Sellin, 'Does One Size Fit All' Patents, the Right to Health and Access to Medicines' (2015) 62 Netherlands International Law Review 445, 462. **See also**, Joseph Millum, 'Are Pharmaceutical Patents Protected by Human Rights?' (2008) 34(11) Journal of Medical Ethics 3 < https://www.researchgate.net/publication/23441979_Are_Pharmaceutical_Patents_Protected_By_Human_Rights> accessed 5 December 2019

interests of authors and inventors, where they are, as described by Drahos, "instrumental rather than fundamental."[14]

This was affirmed by the CESCR in its General Comment number 17. It stated that there is a clear distinction between both rights due to the difference in their nature. Human rights in general are inherent to human persons, fundamental, inalienable, and timeless expressions of universal entitlements belonging to individuals or groups of individuals and communities. Its aim is the inherent dignity and worth of all people. Meanwhile, patent rights, like all IPRs, are of a temporary nature. They are limited in time and scope. They can be revoked, allocated, traded, licensed, amended, assigned to someone else or even fortified. States use patent rights as a tool to encourage creativity, provide incentives for innovators, and promote the dissemination of inventions for the benefit of the society as a whole. Further, the General Comment reaffirmed that what is protected in article 15(1)(c) is the personal link between the inventor and his invention from one side and between him and his material interest, necessary to enjoy adequate standard of living, from the other side. The Comment concluded that the article did not protect IPRs which is primarily directed to protect businesses and corporates' interests and investments.[15]

Second: The history of international human rights law and the wording of article 15(1)(c) is clearly directed to protect the interests, whether moral or material, of natural persons only in their qualifying inventions, i.e., the inventors' rights, ignoring pharmaceutical companies as legal entities. All human rights conventions when addressing various types of human rights restrict their enjoyment to human persons, barring legal persons, with the exception of specific rights like trade union rights.[16] This was confirmed by the General Comment number 17 which stated that the entitlements of the legal entities are not protected under human rights instruments because of their different nature to natural persons, who are the ones meant by the text of article 15. Since pharmaceutical patents are rarely owned by inventors, but by pharmaceutical

[14] Peter Drahos, 'The Universality of Intellectual Property Rights: Origins and Development' in WIPO (ed), *Intellectual Property and Human rights: A Panel Discussion to Commemorate the 50th Anniversary of the Proclamation of the Universal Declaration of Human Rights* (WIPO Geneva 1999) 13, 32

[15] UN Committee on Economic, Social and Cultural Rights (CESCR), 'General Comment No 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He or She is the Author (Article 15, paragraph 1(c) of the Covenant)' (12 January 2006) UN Doc E/C.12/GC/17, paras 1-3

[16] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 154-155. **See also**, Walter Kalin and Jorg Kunzli, *The Law of International Human Rights Protection* (2nd edn, Oxford University Press 2019) 114

corporates, they are not meant to be protected by virtue of the ICESCR wording.[17] This was emphasized by Holger Hestermeyer when he stated that "the ICESCR does not elevate modern day intellectual property lock, stock and barrel to human rights."[18]

Third: The protection of the moral and material interests of the author stated in article 15(1)(c) of the ICESCR is not relevant in the context of pharmaceutical patents protection. Article 15 mentions the authors of scientific, literary or artistic production which is related to writers and their right to protect their production, i.e., the article protects the copyrights of authors. It is highly doubted that the word "author" itself can encompass inventors since it is defined as writers. The moral interests of the authors, as such, could be exemplified by their right to have their names on their work. Their material interests are meant to ensure that the authors can reap the fruits of their labour in the form of adequate remuneration.[19] As such, it is doubtful that inventors could rely on such provision to seek protection for their inventions.

This proposition is buttressed by the fact that the ICESCR language is reflected in several copyright agreements, *inter alia*, the Berne Convention for the Protection of Literary and Artistic Works which confers protection on "every production in the literary, scientific and artistic domain." It is also reflected in the Universal Copyright Convention which conferred protection to the "rights of authors and other copyright proprietors in literary, scientific and artistic works."[20] Consequently, the protection addressed in article 15(1)(c) of the ICESCR is directed towards the human right of the author, not the interests of pharmaceutical companies.

The CESCR affirmed such opinion when it stated that the extension of IP protection to business inventions is outside the scope of human rights protection. The Committee emphasized that human rights are dedicated to assuring satisfactory standards of human welfare and well-being, while the IP system focusses on the protection of corporates investments. Therefore, "the scope of protection of the moral and material interests of the author stipulated under article 15 of the

[17] UN Committee on Economic, Social and Cultural Rights (CESCR), 'General Comment No 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He or She is the Author (Article 15, paragraph 1(c) of the Covenant)' (12 January 2006) UN Doc E/C.12/GC/17, para 7

[18] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 154

[19] Ibid, 155, 157

[20] Universal Copyright Convention (adopted 6 September 1952 and revised 24 July 1971 including Protocols 1 and 2) 13444 Vol 943 UNTS 178, art 1. **See also**, Berne Convention for the Protection of Literary and Artistic Works (adopted 9 September 1886, completed at Paris 4 May 1896, revised at Berlin 13 November 1908, completed at Berne 20 March 1914, revised at Rome 2 June 1928, revised at Brussels 26 June 1948, and revised at Stockholm 14 July 1967) 828 UNTS 221, arts 1, 2(1)

ICESCR "does not necessarily coincide with what is termed intellectual property rights under national legislation or international agreements."[21]

Fourth: The social value of pharmaceuticals is totally different from other industries since medicines are intended to improve the health of people and save their lives. Meanwhile, other industries are meant to improve the social welfare of people. As such, the patent monopoly system embodying the concepts of incentives and generating profits is often incompatible with the notion of increasing the accessibility to medicine as a human right.[22]

Finally, assuming, albeit weakly, that the word "author" in article 15(1)(c) encompasses inventors, the whole article 15 of the ICESCR attempted to strike a balance between the protection of the interest of the inventor and the public accessibility to the invention. This is indicated in paragraph 1(b) of the same article which provides for the right of everyone to enjoy the benefits of scientific progress, i.e., the right to access to inventions. It is also indicated in paragraph 2 of the article calling on states to balance between the moral and material rights of inventors and the public accessibility to inventions in a way which contribute to "the development and diffusion of science and culture."[23]

In striking such balance, the inventors' interests should not be unduly favoured and the public interests in enjoying broad accessibility to scientific inventions should be given due consideration. States parties to the ICESCR have a duty to ensure that their legal regimes achieve that balance and do not constitute any impediment to their ability to comply with their core obligations under the covenant, including the right to health. Accordingly, states parties to the ICESCR should prevent unreasonably high costs for access to essential medicines from undermining the right to health for all people. Also, they should prevent the use of scientific progress for purposes contrary to human rights and dignity. So, states are obliged to exclude inventions from patentability whenever their commercialization would jeopardize the full realization of the right to health.[24]

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[21] UN Committee on Economic, Social and Cultural Rights (CESCR), 'Statement of the Committee on the Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: Follow-Up to the Day of General Discussion on Article 15 (1) (c)' (14 December 2001) UN Doc E/C.12/2001/15, para 6

[22] Aidan Hollis, 'An Efficient Reward System for Pharmaceutical Innovation' (WHO, 6 October 2004) 1, 4 < http://www.who.int/intellectualproperty/news/Submission-Hollis6-Oct.pdf > accessed 13 December 2019

[23] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 15 (1)(b), (2)

[24] UN Committee on Economic, Social and Cultural Rights (CESCR), 'General Comment No 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific,

In essence, article 15(1)(c) of the ICESCR is not meant to justify pharmaceutical patents interference with the human right to access to medicines, even if it is assumed, albeit weakly, that the word "author" in the article encompasses inventors. Reading paragraph 15(1)(c) within the whole context of article 15 infers that it is meant to provide a balance between inventors' rights and public accessibility to inventions, and not to justify the interference between both rights. Eventually, it could be inferred that justifying pharmaceutical patents interference with the right to access to medicines according to article 15(1)(c) of the ICESCR is untenable.

### 4.2.2 Research Incentives Justification

The repeated justification for pharmaceutical patents in developing countries is providing incentives for future innovation and enabling companies to recoup the costs spent on R&D.[25] The industry claims that without the profits generated from patents, there would be no research-based companies. These companies are the foundation for the production of new medicines for new infectious diseases or improving the existing medicines for diseases that have grown drug resistance.[26] IP supporters opine that the incentive argument disfavours any derogation from patent law.

The Pharmaceutical industry also claimed that patents are not considered an obstacle to the accessibility to medicines in developing countries since the health care problems existed even before introducing the patents systems. Ineffective health systems in developing countries are primarily responsible for failing to provide people with medical treatment, when needed, resulting in millions of deaths.[27] They circulated a number of studies after the Doha Declaration to show that the real barriers to better access to medicines in Africa are related to their weak

Literary or Artistic Production of Which He or She is the Author (Article 15, paragraph 1(c) of the Covenant)' (12 January 2006) UN Doc E/C.12/GC/17, para 35

[25] Valbona Muzaka, *The Politics of Intellectual Property Rights and Access to Medicines* (Palgrave Macmillan UK 2011) 23

[26] UN Millennium Project, *Prescription for healthy development: Increasing access to medicines* (Earthscan London 2005) 137 < https://www.taylorfrancis.com/books/9781849773553> accessed 20 November 2019. **See also**, Harvey Bale, 'Patents, Patients and Developing Countries: Access, Innovation and the Political Dimensions of Trade Policy' in Brigitte Granville (ed), *The Economics of Essential Medicines* (Royal Institute of International Affairs 2002) 100, 102

[27] Amir Attaran and Lee Gillespie-White, 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa' (2001) 286(15) Journal of American Medical Association 1886, 1890-1891

economic capacities, inaccurate assignment of resources, ineffective health care systems, and poverty.[28]

This was affirmed by a statement of dissent from the representative of the research-based pharmaceutical industry responding to the report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. The statement declared that neither patent protection nor companies' pricing practices could be responsible for barring medicines to poor people.[29]

Although many human rights scholars had acknowledged the benefit of research-incentives to spur innovation, they criticized the pharmaceutical industry claims from several aspects.

The most prominent counter argument is that there is no specification of how much profit is considered a sufficient incentive. There are no economic studies that identify the twenty-year patent term, as stated in the TRIPS, as sufficient to recoup what has been spent. Some scholars suggested a longer duration but weaker patent system, while others claimed that the best economic revenue would be achieved when a short period is granted with a stringent patent system.[30] However, human rights scholars accepted the fact that poverty and lack of economic capacity in developing countries have a prominent influence on access to medicine, but they argued that patents exacerbated the situation. More expenditure was paid by people on expensive patented medicines, due to the unavailability of the generic alternatives, instead of spending on other essentials of life, like education, housing, and food. This leads to inadequate living conditions resulting in illness.[31] On the contrary, developed countries were not affected

[28] Valbona Muzaka, *The Politics of Intellectual Property Rights and Access to Medicines* (Palgrave Macmillan UK 2011) 82. **See also**, Graham Dutfield and Uma Suthersanen, *Global Intellectual property law* (Edward Elgar Publishing Limited UK 2008) 312-313. **See also**, Amir Attaran, 'How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?' (2004) 23(3) Journal of Health Affairs 155, 163-164 <http://content.healthaffairs.org/content/23/3/155.full > accessed 3 February 2020

[29] Stephen P. Marks, 'Access to Essential Medicines as a Component of the Right to Health' in Andrew Clapham and Mary Robinson (eds), *Realizing the Right to Health: Swiss Human Rights Book*, Vol 3 (Ruffer & Rub Zurich 2012) 82, 85. **See also**, UN Millennium Project, *Prescription for Healthy Development: Increasing Access to Medicines* (Earthscan London 2005) 136 < https://www.taylorfrancis.com/books/9781849773553 > accessed 20 November 2019

[30] Richard Gilbert and Carl Shapiro, 'Optimal Patent Length and Breadth' (1990) 21(1) Rand Journal of Economics 106, 111. **See also**, M. Rafiquzzaman, 'The Optimal Patent Term under Uncertainty' (1987) 5(2) International Journal of Industrial Organization 233, 234-234

[31] Commission on Intellectual Property Rights, 'Report of the Commission on Integrating Intellectual Property Rights and Development Policy' (Commission on Intellectual Property Rights, September 2002) 36 < http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf > accessed 1 May 2019

by the high prices of patented medicines due to their developed medical insurance systems that ensure sufficient accessibility to such medicines for people.[32]

Furthermore, human rights scholars argued that most of the incentives for R&D are directed towards "Profitable Diseases." Pharmaceutical industry directs its investments towards "Life-Style Drugs" for impotence, obesity and other non-life-threatening diseases neglecting the "Unprofitable Diseases" or the serious ones which mostly affect poor people. Shifting towards "Profitable Diseases," in addition to pricing medicines over the financial abilities of people in developing countries created what is called the "Global Drug Map."[33]

Moreover, they contended that the pharmaceutical industry directs a considerable amount of investment towards "Me-Too Drugs," also called "Copycat Drugs." These are new drugs but similar to the ones already existing, so they acquire novelty, but they lack the inventive step. Companies succeeded in one way or another, to get patent protection for such drugs, thus extending the patentability of medicines. These practices "divert R&D investments away from diseases with higher unmet needs," damage innovation, and limit generic medicines production.[34]

Additionally, human rights proponents argued that the R&D incentives are chiefly directed towards the treatment of diseases afflicting patients in the developed world. This is due to their profitable pharmaceutical market which allow them to recoup their investment. Diseases mainly affecting developing countries are neglected because the contribution of such countries to the pharmaceutical companies' profits is marginal.[35]

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[32] Ellen 't Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha' (2002) 3(1) Chicago Journal of International Law 27, 28-29

[33] Jurgen Drews, 'Drug Research: Between Ethical Demands and Economic Constraints' in Michael A. Santoro and Thomas M. Gorrie (eds), *Ethics and the Pharmaceutical Industry* (Cambridge University Press 2005) 21, 28. **See also**, Laurence R. Helfer and Graeme W. Austin, *Human Rights and Intellectual property: Mapping the Global Interface* (Cambridge University Press 2011) 92. **See also**, Merrill Goozner, *The $800 Million Pill: The Truth Behind the Cost of New Drugs* (California University Press 2004) 230, 233 < www.jstor.org/stable/10.1525/j.ctt1pnwb6 > accessed 30 November 2019

[34] Stephane Regnier, 'What is the Value of 'Me-Too' Drugs?' (2013) 16(4) Health Care Management Science Journal 300, 301 < http://link.springer.com/article/10.1007%2Fs10729-013-9225-3 > accessed 29 November 2019

[35] Amir Attaran and Lee Gillespie-White, 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?' (2001) 286(15) Journal of American Medical Association 1886, 1890. **See also**, Jennifer Anna Sellin, 'Does One Size Fit All' Patents, the Right to Health and Access to Medicines' (2015) 62 Netherlands International Law Review 445, 446-447. **See also**, Saeed Ahmadiani and Shekoufeh Nikfar, 'Challenges of Access to Medicine and the Responsibility of Pharmaceutical Companies: A Legal Perspective' (2016) 24(13) Daru Journal of pharmaceutical Sciences < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855755/> accessed 22 March 2021

This observation is buttressed by several reports from major pharmaceutical companies showing the insignificant role that the developing countries' markets are playing in the global pharmaceutical economy. Reports in 2019 showed that nearly 70 percent of the global market sales from pharmaceuticals is directed to North America and Europe, while nearly 10 percent is directed to Latin America, Middle East and African countries and the rest is directed to Asia-Pacific pharmaceuticals market.[36] Therefore, it is highly unlikely that the patent system in developing countries is necessary to maintain R&D expenditure due to its marginal contribution in global pharmaceutical market.[37]

Confirming those findings, several economists and experts in the field of IPRs and public health highly doubted the validity of pharmaceutical patents as a sole incentive for future innovation and a means to recoup the R&D expenditures. The WHO Commission on Macroeconomics and Health stated that "poor-country governments lack the means to subsidize R&D, and patent protection means little when there is no significant market at the end of the process. The result is that the R&D for diseases specific to poor countries, such as Malaria or other parasitic diseases, tends to be grossly underfinanced. The poor countries benefit from R&D mainly when the rich also suffer from the same diseases."[38]

Similarly, the WHO Commission on Intellectual Property Rights, Innovation and Public Health opined that "where the market has very limited purchasing power, as is the case for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to market."[39] Also, the Commission on Intellectual Property Rights concluded that "regardless the IP regime prevailing in developing countries, in reality there is little commercial incentive for the private sector to

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[36] 'The Pharmaceutical Industry in Figures' (European Federation of Pharmaceutical Industries and Associations, 2019) < https://www.efpia.eu/media/413006/the-pharmaceutical-industry-in-figures.pdf> accessed 25 February 2020. **See also**, 'Global Pharmaceuticals Industry Analysis and Trends 2023' (Report Linker, March 2019) < https://www.reportlinker.com/p05750669/Global-Pharmaceuticals-Industry-Analysis-and-Trends.html?utm_source=GNW> accessed 25 February 2020

[37] Carlos M. Correa, 'Some Assumptions on Patent Law and Pharmaceutical R&D' (June 2001) Quaker UN Office Geneva Occasional Paper 6, 5 < https://quno.org/sites/default/files/resources/PatentLaw-R-D.pdf > accessed 23 February 2020. **See also**, Jennifer Anna Sellin, 'Does One Size Fit All' Patents, the Right to Health and Access to Medicines' (2015) 62 Netherlands International Law Review 445, 446

[38] WHO Commission on Macroeconomics and Health, *Report on Macroeconomics and Health: Investing in Health for Economic Development*' (WHO Publications 2001) 77 < https://apps.who.int/iris/bitstream/handle/10665/42435/924154550X.pdf?sequence=1&isAllowed=y > accessed 17 January 2020

[39] Commission on Intellectual Property Rights, Innovation and Public Health, *Public health, Innovation and Intellectual Property Rights* (WHO Geneva 2006) 22 <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf > accessed 17 January 2020

undertake research of specific relevance to the majority of poor people living in low income countries. Accordingly, little of such work is done by private sector."[40]

In the same vein, the dissertation showed in chapter 3 that the UN Secretary-General's High-Level Panel on Access to Medicine addressed in its 2016 report the inadequate funding in R&D for epidemic diseases that mainly afflict people in developing countries. Due to the relatively low purchasing power in such countries, many pharmaceutical companies refrain from investing on such infectious diseases since they would not recoup their investment.[41]

A question can be raised in this context as to why pharmaceutical companies have lobbied for implementing a strong patent system in developing countries, when they have a marginal contribution in global pharmaceutical market. Most likely they wanted to prevent parallel importation of medicines, i.e., prevent the prices of medicines set for developing countries from being leaked to developed ones. Moreover, they may have feared that the low-priced generics could urge developed countries' governments to put pressure on them to reduce medicine prices, even with the awareness in such countries that profits are necessary for pharmaceutical R&D. That is why a restricted compulsory licensing system is their continuous demand.[42]

Ultimately, it could be deduced that the research incentives justification also failed to justify patents interference with the right to access to medicines in developing countries.

### 4.2.3 Other Justifications Related to the Transfer of Technology and Competition Policy

IP proponents argued that pharmaceutical patents would contribute in increasing the flow of technology transfer to developing countries which is one of the objectives and principles stated in TRIPS provisions.[43] However, India, Brazil, South Korea and other developing countries with manufacturing capacities have always expressed in international fora, that the implementation

[40] Commission on Intellectual Property Rights, 'Report of the Commission on Integrating Intellectual Property Rights and Development Policy' (Commission on Intellectual Property Rights, September 2002) 32 < http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 17 January 2020

[41] UN Secretary-General's High-Level Panel on Access to Medicines, 'Report on Promoting Innovation and Access to Health Technologies' (September 2016) 7 < http://www.unsgaccessmeds.org/final-report> accessed 26 October 2020

[42] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 165

[43] Carlos M. Correa, 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (Cambridge University Press UK 2005) 227. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) arts 7, 8 (2)

of the TRIPS agreement hinders the flow of technology that they were importing excessively, to produce generic medicines.[44]

Frederick Abbott was of the view that the TRIPS agreement does not restrict the right to health due to the competition principles stated in the agreement.[45] This proposition was criticized by human rights proponents arguing that it uses competition policy to analyse the interference, neglecting the fact that the goal of TRIPS in the WTO context is to promote international trade and provide for stringent intellectual property protection. Such protection often restricts competition by excluding generic medicines from the market causing an artificial inflation to medicine prices.[46]

This was asserted by the European Commission, when commenting on the European General Court decision in *AstraZeneca v. European Commission* case.[47] The European Commission affirmed the importance of patent protection for medicines. However, it stated that generic medicines have a substantial effect in keeping drugs prices down for the benefit of health care. It noted that generic products competition spurs pharmaceuticals innovation.[48] Also, the UN Special Rapporteur on the Right to Health stated that the exclusion of generics increases the prices of medicines which exclude poor people from having access to them.[49]

However, patent supporters noted that patents are not meant to be at any time an obstacle to generic competition. They argued that out of the essential medicines stated in the WHO model list, only very few are the patented ones (about 1.4%). As such, pharmaceutical patents do not impede market competition nor interfere with the accessibility to medicines.[50]

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[44] Carlos M. Correa, 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (Cambridge University Press UK 2005) 227, 227-228

[45] Frederick M. Abbott, 'The 'Rule of Reason' and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS' in Thomas Cottier, Joost. Pauwelyn and Elisabeth Bürgi (eds), *Human Rights and International Trade* (Oxford University Press 2003) 279, 300

[46] Sarah Joseph, *Blame it on the WTO* (Oxford University Press UK 2013) 217

[47] Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010] ECR II–2805

[48] European Commission, 'Competition: Commission Fines AstraZeneca €60 Million for Misusing Patent System to Delay Market Entry of Competing Generic Drugs' (15 June 2005) IP/05/737 < http://europa.eu/rapid/press-release_IP-05-737_en.htm > accessed 21 July 2019

[49] UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Addendum Mission to the World Trade Organization' (1 March 2004) UN Doc E/CN.4/2004/49/Add.1, Para 43

[50] Amir Attaran, 'How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?' (2004) 23(3) Journal of Health Affairs 155, 157-158 < http://content.healthaffairs.org/content/23/3/155.full > accessed 3 February 2020

Others argued that the TRIPS agreement did not take a consistent approach to human rights since they are only included as exceptions to the patent rights conferred to patentees. The agreement did not also clearly identify the responsibilities of the patentees towards human rights. Those scholars asserted that the TRIPS minimum standards are not appropriate for states with different levels of technological and industrial development. The TRIPS agreement's main concern is protecting IP in international trade, where its subject matter is IP rights, and does not deal with human rights.[51] Since human rights considerations in TRIPS are envisaged as exceptional, no justification would serve to release the tension or the interference between both regimes without providing further clarification of human rights considerations in the TRIPS agreement.

Ultimately, there is no compelling justification for patent interference with the right to access to medicine in developing countries. While pharmaceutical companies argue that without patents there would be no new medicines, human rights proponents rebutted all derived arguments to justify the interference between both systems. The conclusion reached is that patents artificially inflated the prices of medicines which hinder the accessibility to medicines in developing countries. Thus, pharmaceutical patents interfere with access to medicines in developing countries without any justification.

This unjustifiable interference leads to a conflict between states obligations in the TRIPS agreement regarding patent protection to medicines, and their obligations in the ICESCR regarding accessibility to medicines, i.e., a conflict between the WTO system and the human rights system. Affirming such conflict, the UN and WHO expressed their concerns regarding the TRIPS approach to patent protection as a "one size fits all."[52]

In the following section, the dissertation will address the structure and development of international law. It is necessary to explain this development before delving into the notion of conflict. The development caused fragmentation of international law, which is responsible for potential conflict of norms.

[51] Simon Walker, 'A Human Rights Approach to the WTO's TRIPS Agreement' in Frederick M. Abbott, Christine Kaufmann and Thomas Cottier (eds), *International Trade and Human Rights: Foundations and Conceptual Issues* (Michigan University Press 2006) 171, 173-174

[52] UN Millennium Project, *Prescription for Healthy Development: Increasing Access to Medicines* (Earthscan London 2005) 69 <https://www.taylorfrancis.com/books/9781849773553> accessed 20 November 2019

### 4.3 The Structure & Development of Norms in International Law

#### 4.3.1 The Structure of Norms in International Law

It is generally accepted that there is no *a priori* hierarchy of sources of international law like the one established in domestic law. A norm derived from one source of international law is not *a priori* of a higher rank or value to another norm derived from another source regardless of the organ that created the norm, or the procedure followed. There is no vertical hierarchical structure of norms to guide the relations between sovereign states because the international law norms exist on a horizontal plane of mutual equality.[53] This indicates that separate issues are regulated by separate international law instruments and such instruments rarely get embraced by the same states. Each international law instrument has its own structure of internal hierarchy, and all instruments have equal legal value whatever their sources. None of such instruments is subject to an overall executive or legislative structure since there is no single sovereign in international law.[54]

The enumeration of the traditional sources of international law stipulated in article 38(1) of the statute of the International Court of Justice is not meant to establish a definite *a priori* hierarchy. Article 38(1) categorized the sources of public international law into primary sources (treaties, international custom and general principles of law) and secondary sources (judicial decisions and the teachings of the most highly qualified publicists of the various nations). The draftsman intended only to set a logical sequence in which the rules would occur to the judge's mind. It was suggested in the draft of article 38 of the ICJ that the sources be listed in a specific order, but the suggestion was refused. Thus, the order in the article does not imply any legal hierarchy of sources.[55]

The lack of any inherent hierarchical order in international law emanates from its distinctive features making it different from domestic law. International law is decentralized. It has no

[53] Mario Prost, 'Hierarchy and the Sources of International Law: A Critique' (2017) 39 Houston Journal of International Law 285, 286-287. **See also**, Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 94. **See also**, Antonio Cassese, *International Law* (2nd edn, Oxford University Press 2005) 154. **See also**, Andreas Fischer-Lescano and Gunther Teubner, 'Regime-Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law' (2004) 25(4) Michigan Journal of International Law 999, 1002-1004, 1036-1038

[54] Ronnie R. Yearwood, *The Interaction between World Trade Organization (WTO) Law and External International Law: The Constrained Openness of WTO Law* (Routledge London 2012) 30

[55] Statute of the International Court of Justice (adopted 26 June 1945, entered into force 24 October 1945) 3 Bevans 1179, 59 Stat 1031, TS 993 (ICJ) art 38(1). **See also**, Antonio Cassese, *International Law* (2nd edn, Oxford University Press 2005) 198. **See also**, Ian Brownlie, *Principles of Public International Law* (6th edn, Oxford University Press 2003) 3. **See also**, Mario Prost, 'Hierarchy and the Sources of International Law: A Critique' (2017) 39 Houston Journal of International Law 285, 290

central legislator drafting its rules, nor a centrally organized effective system of sanctions, nor an executive authority with power to enforce the law. The creators and the main subjects of international law are the states themselves. They do not elect an international legislator to draft international law on their behalf, like individuals in domestic law who elect an independent legislator. Whenever they need to regulate a new subject, they conclude bilateral or multilateral treaties or consent to elevating a specific practice to become a customary international law. Since all international norms are derived from the consent or the will of states which have an equal influence in international law-making due to the principle of sovereign equality of states, all international instruments, whatever their source, are of the same legal value without any inherent hierarchy that makes one instrument superior to another.[56]

Moreover, due to the lack of a centralized legislator, international law does not have a centralized court system with general and compulsory jurisdiction. If such court existed, it could have created some order in the international law-making process. Although the ICJ is the principle judicial organ of the UN, its compulsory jurisdiction, as stated in its statute, is restricted to certain subject matters between the states that accepted its compulsory jurisdiction. The existing international tribunals or adjudicatory systems are either treaty-based, like the WTO dispute settlement system under the WTO Agreement and the International Tribunal (ITLOS) stated in the UN Convention for the Law of the Sea, or *ad-hoc* tribunals. The lack of a centralized court system creates a risk of conflict arising in the way of interpretation or enforcement of international law. A conflict between two norms may arise, for example, due to different interpretations by several adjudicators or tribunals.[57]

As a result of the lack of an inherent hierarchy in international law, treaty norms do not necessarily prevail over customary norms, and the latter do not necessarily prevail over general principles of law. Also, there is no hierarchy as per the international organization which created

[56] Mario Prost, 'Hierarchy and the Sources of International Law: A Critique' (2017) 39 Houston Journal of International Law 285, 286-287. **See also,** Joost Pauwelyn, 'The Role of Public International Law in the WTO: How Far Can We Go?' (2001) 95(3) The American Journal of International law 535, 535-536. **See also**, Clarence Wilfred Jenks, 'The Conflict of Law-Making Treaties' (1953) 30 British Yearbook of International Law 401, 403-405. **See also**, H. L. A. Hart, *The Concept of Law* (3rd edn, Oxford University Press 2012) 3-4, 214. **See also**, Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 13, 95

[57] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 16-17. **See also**, H. L. A. Hart, *The Concept of Law* (3rd edn, Oxford University Press 2012) 214. **See also**, Shane Spelliscy, 'The proliferation of International Tribunals: A Chink in the Armor' (2001) 40 Colombia Journal of Transnational Law 143. **See also**, Statute of the International Court of Justice (adopted 26 June 1945, entered into force 24 October 1945) 3 Bevans 1179, 59 Stat 1031, TS 993 (ICJ) art 36(2). **See also**, Charter of the United Nations (adopted 26 June 1945, entered into force 24 October 1945) 1 UNTS XVI art 92

the norm, whether WTO organization or a human rights body, except the hierarchy of norms which is created within the international organization itself. This hierarchy of norms is meant to delineate the rank of the acts of the organization and the rank of its internal laws and regulations. Therefore, norms conflict in international law cannot be simply resolved according to the sources from which the international norms originate.[58] All international norms are equal in status and value whatever their sources, since they are derived from states' consent. It is not similar to solving conflict of norms in domestic law, where there exists a hierarchical order according to the sources of national norms, whether a constitutional procedure, a legislation, or an administrative regulation.

### 4.3.2 The Development of International Law Norms

#### 4.3.2.1 International Law as a law of Co-existence

In the traditional setting of international law, international norms lacking any *a priori* hierarchical order were regarded as bilateral/reciprocal instruments. Bruno Simma strongly argued that most of the structure of international law is in a form "bequeathed by the bilateral mode."[59] Treaty norms are *pacta tertiis nec nocent nec prosunt*, i.e., they only bind the states that adopted them.[60] The enforcement system was also bilateral, where the injured state only has the right to renounce the claim, seek remedies, or withdraw from the agreement whenever it is violated. Not only bilateral agreements embody bilateral/reciprocal system, but also multilateral agreements, as they consist of a bundle of bilateral obligations which followed the rules of reciprocity.[61] A couple of exceptions to this reciprocal/bilateral system are customary international law and the general principles of law. They are not of a bilateral type, but rather, they are systems of international law which are binding on all states.

Due to the principle of state sovereignty, states did not intervene into the internal affairs of each other. Relations between states were relatively limited and based mainly on compromise and solidarity since there were no common goals for the international community that would demand

[58] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 95-96

[59] Benedict Kingsbury and Megan Donaldson, 'From Bilateralism to Publicness in International Law' (January 2011) New York University School of Law, Public Law Research Paper No 11-07, 79, 80-81 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1753063> accessed 18 December 2019

[60] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) arts 34-38

[61] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 183

co-operation. So, international law was achieving only individual objectives and was confined to resolving possible conflicts related to territorial jurisdictions, delineating states responsibilities, and the preservation of the personal interest of each state within its own territory.[62] This is clear from the limited subject matters that were governed by the international law which include among others; diplomatic relations, high seas, territorial sovereignty, the law on war and peace treaties, the protection of citizens in other states, in addition to the rules related to the state identity, recognition and succession.[63]

These previous issues were mainly regulated by bilateral agreements. The typical type of conflicts in the traditional setting of international law was conflicting obligations under two or more bilateral treaties. This type of conflict is referred to as AB/AC conflict, where a state A has an obligation with state B under a bilateral agreement and at the same time has another obligation, conflicting with the previous one with state C due to another bilateral agreement.[64]

As a result of the reciprocal/bilateral legal relations between states, the normative conflicts were resolved through a bilateral model. The equal value of international norms with no hierarchical order as explained above induced states to settle such conflicts by analogy to solving conflicts in domestic law and contract law. The only hierarchy that could appear is the one related to the content of the norm rather than its source. Such hierarchy is subject to the will of states if they consent to upheaving a specific international norm to a higher rank because it regulates a special subject matter. Notably, states regarded human rights, at that time, as norms outside the ambit of international law because they might interfere with the principle of state sovereignty.[65]

Accordingly, in the traditional setting of international law, if two or more norms stood on the same issue, they were interpreted, to the extent possible, to avoid conflict. Interpretation rules, for example, the textual or the contextual interpretation, were used to give rise to compatible obligations. If it was found that such norms point to incompatible obligations regarding the same issue and both are valid and applicable, then the conflict resolution principles were used to

[62] Santiago Villalpando, 'The Legal Dimension of the International Community: How Community Interests are Protected in International Law' (2010) 21(2) The European Journal of International Law 387, 390-391
[63] David J. Bederman et al, 'Subjects of International Law' (2003) 35 Studies in Transnational Legal Policy 61. **See also,** Robert Kolb, 'Introductory aspects of public international law' (Baripedia, 5 October 2018) < https://baripedia.org/wiki/Introductory_aspects_of_public_international_law#Classical_international_law> accessed 19 January 2020
[64] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 18
[65] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 184

resolve the issue. Examples of such conflict resolution principles are the *lex posterior derogat legi priori* principle and the *lex specialis derogat legi generali* principle which are stipulated in the VCLT. The dissertation shall demonstrate both principles in chapter 5 to examine whether or not they are relevant to actually resolve the conflict between the right to health and patent protection.

The following sub-section shall examine international law as a law of co-operation and community interests aiming for a normative hierarchy by introducing the *jus cogens* norms, the *erga omnes* obligations and the argument of superiority of UN Charter obligations.

#### 4.3.2.2 Towards Hierarchy: International Law as a Law of Co-operation and Community Interests

The intensification of social intercourse between states implied the transformation of international law structure from a law governing inter-state relations to a transnational network that provides a normative framework for all actors in the international legal community. While increasing their relations and cooperation with each other, states realized a category of interests that could not be fulfilled under the traditional setting of international law. As such, matters that only belonged to the domestic realms became matters of global concern.[66] As scholars have noted, international law has transformed itself and changed due to the power of globalization.[67]

International law came to regulate new fields of common interest to the global community rather than achieving reciprocal advantages. What was traditionally left for the state sovereign reign to regulate via domestic law became of interest to other states. Many international laws and regulations appeared in new areas, *inter alia*, health law, consumer law, labor law, trade law and antitrust law.[68] The internationalization of activities transferred the international law from a law of co-existence and reciprocity into a law of co-operation between states in order to

[66] Milena Sterio, 'The Evolution of International Law' (2008) 31(2) Boston Collage International and Comparative Law Review 213, 214. **See also**, Charles Leben, 'The Changing Structure of International Law Revisited' (1997) 8(3) European Journal of International Law 399, 401-402. The article revisits Wolfgang Friedmann book issued in 1964 under the name *The Changing Structure of International Law*

[67] Paul Schiff Berman, 'From International Law to Law and Globalization' (2005) 43 Columbia Journal of Transnational Law 485. **See also**, Philippe Sands, 'Turtles and Torturers: The Transformation of International Law' (2001) 33 New York University Journal of International Law and Politics 527

[68] Philippe Sands, 'Turtles and Torturers: The Transformation of International Law' (2001) 33 New York University Journal of International Law and Politics 527, 548-549. **See also**, Milena Sterio, 'The Evolution of International Law' (2008) 31(2) Boston Collage International and Comparative Law Review 213, 219

harmonize states' interests.[69] This change in international law structure was best described as "a shift in certain inter-state relations from an egotistic rationale to a sense of togetherness and the pursuit of goals that benefit the group as a whole."[70]

Further, international legal bodies, whether organizations, tribunals, institutions, or conferences, were created to facilitate co-operation and coordination among states in order to achieve their common interests. These bodies played a prominent role in international law. They created and administered new international law instruments thereby multiplying them. A few such bodies include an adjudicatory system to settle disputes arising under, and in connection with such instruments.[71]

Within the human rights context, human rights bodies moved away from the logic of reciprocity in treaty relations towards collective understanding. Human rights became a concern for the whole international community instead of a matter of domestic jurisdiction mainly related to the internal affairs of states. Specific human rights are recognized as universal and paramount, for which any state would have the right to interfere if the principles are violated. Notably, such principles were accompanied by the notion of universal jurisdiction.[72] This led to an increase in human rights instruments with diversified subjects in international law.

Within the trade context, a remarkable growth in international trade accompanied the second wave of globalization that started after the Second World War. National economies were integrated into a global economic system, leading to intertwining economic relations between states. States found that the recourse to internationalize economic policies was a good solution to prevent misplaced policies. Recognizing that working alone could not achieve important

[69] Philippe Sands, 'Turtles and Torturers: The Transformation of International Law' (2001) 33 New York University Journal of International Law and Politics 527, 537–538, 548. **See also,** Milena Sterio, 'The Evolution of International Law' (2008) 31(2) Boston Collage International and Comparative Law Review 213, 215

[70] Santiago Villalpando, 'The Legal Dimension of the International Community: How Community Interests are Protected in International Law' (2010) 21(2) The European Journal of International Law 387, 392

[71] Barry E. Carter, Allen S. Weiner and Duncan B. Hollis, *International Law* (5th edn, Aspin Publishers 2007) 11-13. **See also**, Jeffrey L. Dunoff, Steven R. Ratner and David Wippman, *International Law: Norms, Actors, Process: A Problem-Oriented Approach* (2nd edn, Aspin Publishers 2006) 28. **See also**, Philippe Sands, 'Turtles and Torturers: The Transformation of International Law' (2001) 33 New York University Journal of International Law and Politics 527, 553

[72] Milena Sterio, 'The Evolution of International Law' (2008) 31(2) Boston Collage International and Comparative Law Review 213, 222-226, 228. **See also**, Paul Schiff Berman, 'From International Law to Law and Globalization' (2005) 43 Columbia Journal of Transnational Law 485, 531. **See also**, Martti Koskenniemi and Päivi Leino, 'Fragmentation of International Law? Postmodern Anxieties' (2002) 15(3) Leiden Journal of International Law 553, 567

economic goals, states cooperated through a system of treaty institution including the GATT system and the WTO system.[73]

With time, the expansion of international instruments with diversified subjects rendered them widely separated from each other. With the lack of any *a priori* hierarchical order in international law and the lack of a centralized legislator, international norms in certain instances could react against each other, giving rise to potential conflicts. These factors were responsible for disintegration of the international legal order, a phenomenon known as the fragmentation of international law. Fragmentation could generate negative effects by exposing the conflicts and contradictions between various international rules and imposing mutually exclusive obligations on states. It also jeopardizes the credibility, reliability and consequently the authority of international law.[74]

Due to fragmentation, multiple sets of international primary rules may apply to a given situation giving rise to more conflicts that were previously resolved by domestic interpretation or by resorting to the *lex posterior or lex specialis* rules if interpretation did not resolve the conflict.[75] The phenomenon also affected the secondary rules of international law, known as rules of recognition, by creating special regimes and methods of enforcement. Each enforcement mechanism applied only its own rules and standards to disputes brought before it, except the ICJ. This caused problems when a state resorted to different mechanisms when attempting to solve the same issue. Also, a settlement reached by one mechanism could only resolve a dispute within that mechanism and not necessarily for the purpose of settling disputes within other mechanisms or for a universal system of disputes settlement.[76] This resulted in divergent solutions which undermined the tendency towards homogenous international law. It exposed the whole international law to more uncertainty as to the standards applied in each case.

The fragmentation phenomena attracted the attention of the ILC, which established a study group on the fragmentation of international law to address the difficulties arising from the

[73] Esteban Ortiz-Ospina and Diana Beltekian, 'Trade and Globalization' (Our World in Data, October 2018) < https://ourworldindata.org/trade-and-globalization#trade-from-a-historical-perspective> accessed 16 January 2020. **See also**, Peter Sutherland et al, 'Report of the WTO Consultative Board on the Future of the WTO: Addressing Institutional Challenges in the New Millennium' (2004) 29-30 < https://www.wto.org/english/thewto_e/10anniv_e/future_wto_e.pdf> accessed 16 January 2020

[74] Gerhard Hafner, 'Pros and Cons from Fragmentation of International Law' (2004) 25(4) Michigan Journal of International Law 849, 849-851, 854, 855

[75] Ibid, 856

[76] Ibid, 857-858

diversification and expansion of international law.[77] Also, ICJ Judges expressed their concerns to the UN General Assembly regarding the danger of fragmentation due to the expansion of international law and the serious uncertainty that it produced to both academics and legal practitioners. They also showed concerns about the proliferation of international tribunals which resulted in "giving rise to serious risk of conflicting jurisprudence since the same rule of law might be given different interpretations in different cases."[78]

However, fragmentation does not mean that the international law system has collapsed into chaos, but rather, it means that it is impossible for such system to cohere all the fragmented sub-systems considering that each sub-system maintains its own rule of law. Due to the lack of coherence resulting from fragmentation, an exponential increase in norms conflict in international law occurred not only between international norms part of different sub-systems, such as conflicts between WTO norms and human rights norms, but also conflict of norms within the same sub-system, for example, the conflicts between two norms of WTO law.[79] This is similar to domestic law when two legislators enact two contradictory laws.

The new multilateral treaties in various fields in addition to the new rules of customary law are not appropriately described according to the bilateral paradigm used before with bilateral treaties. The principles of *lex posterior* and *lex specialis* were not able to settle the conflict of norms between multilateral treaties. For instance, it is hard to apply the *lex specialis* principle, when different states parties accede to a multilateral treaty at different times rendering it the posterior treaty for one party and the earlier one for another. It is useful to clarify concisely, the motivation for this transformation in international law.

In contemporary international law, states realized the existence of specific public goods or values, like humanity and peace, and the necessity to protect them in their mutual relations. In contrast to individual interests, public goods are characterized by being non-excludable and non-rivalrous. Their benefits are indivisibly spread among the whole community. Thus, any attack on public goods affects the enjoyment of its benefits not only by certain individual members but

[77] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682
[78] Martti Koskenniemi and Päivi Leino, 'Fragmentation of International Law? Postmodern Anxieties' (2002) 15(3) Leiden Journal of International Law 553, 553-554
[79] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 17-19

also by the international community as a whole. Each member in the international community has an interest in protecting such public goods and thus, encouraging social cohesion.[80]

Consequently, since they are characterized by being global, public goods cannot be protected by fragmented norms, otherwise it could be preserved for the benefit of a group of states only. As such, the notion of community interests (public goods) came to challenge the concept of bilateral paradigm producing two areas of law. The first is governed by individual interests, while the second area is governed by community interests, and mainly relates to specific fields of international relations, *inter alia*, human rights and the maintenance of international peace and security. The legal norms of the second area are embodied by the argument of superiority of UN Charter obligations, the concept of *erga omnes* obligations, and the *jus cogens* principle.

By introducing such principles, the international community sought to preserve the sovereign equality of its members, while at the same time protect the public goods among equal states members by recognizing that each state has an individual interest in protecting such goods. This could be realized by entrusting the protection of each specific public good to a single collective entity. For example, the WTO is responsible for ensuring the free flow of global trade, the Human Rights Council is responsible for human rights, and the security council is responsible for the maintenance of international peace and security. In other words, in contemporary international law, the international community might have intended to bring some order to international law by introducing the previous concepts and principles and entrusting the fulfilment of them, as manifestation of public goods, to international bodies vested with different kinds of enforcement mechanisms. However, states accepted certain limitations, if necessary, on their powers to protect the public goods, but they did not mean to renounce the protection of individual interests underlying the concept of state sovereignty.

### A. UN Charter Obligations

The UN Charter obliged states to apply their obligations under the Charter whenever they conflict with other obligations under any other international agreement. The Charter stressed that its obligations shall prevail over other obligations in international law.[81]

[80] Santiago Villalpando, 'The Legal Dimension of the International Community: How Community Interests are Protected in International Law' (2010) 21(2) The European Journal of International Law 387, 392-393

[81] Charter of the United Nations (adopted 26 June 1945, entered into force 24 October 1945) 1 UNTS XVI art 103

Accordingly, some scholars argued that the UN Charter obligations prevail over all international law obligations. Other scholars remained sceptical about this argument due to the uncertainty about the UN Charter's legal value. The frequent violations of the UN Charter, the possibility of amending its obligations by means of, for example, the UN Security Council when reviewing its resolutions, and the absence of a reliable judicial or executive mechanism to enforce its obligations were all reasons brought to challenge the first opinion.[82]

Lacking a mechanism of invalidity renders the concrete consequences of breaching UN Charter obligations, for example by a treaty provision, unclear. Nevertheless, the UN Charter obligations represent the intention of the international community to consider such obligations as community interests.

### B. *Erga Omnes* Obligations

Internationalists recognized that specific obligations are better placed within the sphere of community interests as they do not fit within the bilateral paradigm. States are obliged to fulfil such obligations towards the community of states as a whole. Those obligations are known as *erga omnes* obligations due to their universality and the undeniable interest in the prevention of their breach. Consequently, third parties, other than those suffering from a breach, have an interest in interfering to ensure compliance with such norms. Internationalists placed these obligations, which are virtually coextensive with the obligations of *jus cogens* norms, at a higher hierarchical status than other norms of international law.[83]

The ICJ first referred to these obligations in the *Barcelona Traction* case. The court stated that it is crucial to differentiate between reciprocal/bilateral obligations which arise *vis-à-vis* another state, like in the field of diplomatic protection, and integral obligations of states which arise towards the international community as a whole. The ICJ stated that all states have a legal interest to protect *erga omnes* obligations due to the importance of the rights and principles that they protect. It mentioned several examples of such obligations in contemporary international

[82] Jack Goldsmith, 'Is the UN Charter Law?' (Lawfare Institute, 16 April 2018) < https://www.lawfareblog.com/un-charter-law> accessed 29 March 2020

[83] Teraya Koji, 'Emerging Hierarchy in International Human Rights and Beyond: From the Perspective of Non-Derogable Rights' (2001) 12(5) European Journal of International Law 917. **See also,** Dinah Shelton, 'Normative Hierarchy in International law' (2006) 100(2) American Journal of International Law 291. **See also**, Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 61. **See also**, International Law Commission, 'The Third Report on State Responsibility by Mr. James Crawford, Special Rapporteur' (15 March 2000) UN Doc A/CN.4/507, para 106(a)

law. Among these examples are the prohibition of acts of aggression and genocide and the obligations to protect the basic human rights including slavery and racial discrimination.[84]

In *South West Africa* cases, the ICJ affirmed the notion of *erga omnes* obligations, where all states possess a subjective right in respect of its fulfilment. It declared that members of the League of Nations have a legal right or interest in the observance by South Africa of its obligations deriving from the mandate over West Africa, regardless of any prejudice of a material kind.[85]

The concept of *erga omnes* obligations became a main principle in international law. The ILC referred to that principle in article 48(1)(b) of the final 2001 Draft Articles on State Responsibility. The article stipulated that "any state other than an injured state is entitled to invoke the responsibility of another state if the obligation breached is owed to the international community as a whole." This infers that *erga omnes* obligations are non-derogable obligations of a general character in which all states have a legal interest in their protection. They arise either directly under general international law or under generally accepted multilateral treaties, like human rights treaties.[86] Also, the VCLT did not explicitly allow modification of agreements with *erga omnes* obligations that protect community interests.[87]

Further, when a treaty obligation is *erga omnes*, the treaty becomes an integral treaty. It cannot be dissolved into a number of virtual bilateral relationships, and its enforcement is not subject to the classical settings of bilateral obligations of treaties. As a treaty of *erga omnes* obligations, a state cannot suspend its obligations in response to certain violation like what happens in the bilateral paradigm.[88]

Accordingly, *erga omnes* obligations are of particular importance to human rights. If a state party violated a human right treaty of an integral type, this does not give other states parties to

[84] The *Barcelona Traction, Light and Power Company, Limited Case (Belgium v Spain)* Second Phase (Judgement) [1970] ICJ Rep 3, paras 33, 34

[85] *South West Africa* Cases *(Ethiopia v South Africa; Liberia v South Africa)* (Judgment) [1962] ICJ Rep 319, 343

[86] International Law Commission, 'The Third Report on State Responsibility by Mr. James Crawford, Special Rapporteur' (15 March 2000) UN Doc A/CN.4/507, para 106(a). **See also**, UN General Assembly, 'Yearbook of the International Law Commission 2001 Vol II Part 2: Report of the Commission to the General Assembly on the Work of its Fifty-Third Session' (2007) UN Doc A/CN.4/SER.A/2001/Add.1 (Part 2), 126-127

[87] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 41(1)(b)

[88] UN General Assembly, 'Yearbook of the International Law Commission 1958 Vol II: Documents of the Tenth Session Including the Report of the Commission to the General Assembly' (1958) UN Doc A/CN.4/SER.A/1958/Add.l, 27, 44. **See also**, Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 19

the treaty, the right to violate the treaty in response. The ICJ regarding the Genocide Convention indicated a similar connotation. It stated that the Genocide Convention was adopted for humanitarian purposes, where the contracting states do not have any individual advantages in concluding the Convention, but rather, they only have common interests. Such interests are manifested in "the accomplishment of the treaty high purposes which is the *raison d'être* of the convention."[89]

Nevertheless, *erga omnes* concept was also challenged. It is not easy to discern international rules that enjoy the status of *erga omnes* obligations except the examples mentioned by the ICJ in the *Barcelona Traction* case. There are no clear standards for differentiating between *erga omnes* obligations and other similar concepts commonly found in international law like *jus cogens* norms and integral obligations. The commentary on the 2001 Draft Articles on State Responsibility emphasized the vagueness of the *erga omnes* obligations when it stated that such obligations are not definite. They could extend to encompass a wide variety of agreements that achieve common interests of states. Recognizing an international norm as *erga omnes* would be a matter of interpretation depending on each case separately due to the difficulty of distinguishing between these obligations, and bilateral obligations.[90]

### C. Jus Cogens Norms

The dissertation in chapter 3 briefly discussed the meaning of *jus cogens* norms within the context of the right to access to life-saving medicines. The dissertation strongly argued that the right to access to life-saving medicines, as a life-saving tool, reaches the status of jus cogens norm since the right to life, stipulated in the ICCPR, is considered a *jus cogens* norm. It is useful to revisit the norms to clarify their nature and content in this sub-section, in order to examine in chapter 5 whether they could be utilized to resolve the tension between pharmaceutical patents and the right to access to medicines.

The clearest instance of *a priori* normative hierarchy in international law is when a norm, whatever its source, contradicts with a *jus cogens* norm. Unlike *erga omnes* obligations, the violation of a *jus cogens* norm voids the treaty that violates it. However, the two concepts are virtually coextensive, yet few differences could be recognized. All *jus cogens* norms are also

[89] *Reservations to the Convention on the Prevention and Punishment of the Crime of Genocide* (Advisory Opinion) [1951] ICJ Rep 15, p 23

[90] UN General Assembly, 'Yearbook of the International Law Commission 2001 Vol II Part 2: Report of the Commission to the General Assembly on the Work of its Fifty-Third Session' (2007) UN Doc A/CN.4/SER.A/2001/Add.1 (Part 2), 118, 126. **See also**, James Crawford, *The International Law Commission's Articles on State Responsibility: Introduction, Text and Commentaries* (Cambridge University Press 2002) 37

*erga omnes* obligations, but the opposite is not correct.[91] Also, *jus cogens* focuses on the higher hierarchical status of specific norms, while the principle of *erga omnes* obligation focuses on which state can invoke the responsibility of the breach of obligations.

The VCLT defined *jus cogens* norms as "peremptory norm of general international law which is accepted and recognized by the international community of states as a whole, as a norm from which no derogation is permitted, and which can be modified only by a subsequent norm of general international law having the same character." This implies that states parties to any treaty violating a *jus cogens* norm are under a duty "to eliminate as far as possible the consequences of any act performed in reliance on any provision which conflicts with the peremptory norm and to bring their mutual relations into conformity with that norm." The duty to void and terminate any treaty in conflict with a *jus cogens* norm is not limited to an existing *jus cogens* norm violated by any subsequent treaty, but also includes any existing treaty conflicting with a new *jus cogens* norm that emerged.[92] As such, the higher value of *jus cogens* norms is not based on its source, but rather, on the acceptance and recognition by the whole international community as a norm from which no derogation is allowed.

In its commentary on *jus cogens* norms, the ILC stated that *jus cogens* norms are universally applicable and hierarchically superior to other norms of international law because they reflect and protect the fundamental values of the international community. A non-exhaustive list of norms of international law emanating from customary rules, treaties, and general principles of international law can constitute basis for *jus cogens* as long as they are recognized and accepted by the large majority of states to have such nature. All international law norms should be interpreted and applied in consistency with *jus cogens* norms. In cases of conflicts, where it is impossible to abide by one obligation without violating the other, the international norm or treaty provisions violating the *jus cogens* norm should be declared null and void. Treaties in such cases should be wholly terminated. Thus, the Commission acknowledged the concept of inseparability of treaty provisions conflicting with a *jus cogens* norm. The only exception to the whole termination of the treaty is when a new *jus cogens* norm emerges conflicting with the provisions of an existing treaty and the conflicting treaty provisions are separable from the rest of the treaty regarding their application. Finally, the Commission noted that the obligations

[91] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 190. **See also**, International Law Commission, 'The Third Report on State Responsibility by Mr. James Crawford, Special Rapporteur' (15 March 2000) UN Doc A/CN.4/507, para 106(a)

[92] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) arts 53, 64, 71

emanating from *jus cogens* norms are obligations owed to the international community as a whole. Therefore, all states have a legal interest in invoking the responsibility of another state for breaching such norms, in compliance with the rules on the responsibility of states for internationally wrongful acts. States cannot invoke any circumstances that preclude wrongfulness, under the rules on state responsibility, regarding any act that violates a *jus cogens* obligation.[93]

Further, the principle of *jus cogens* is recognized in the Draft Articles on State Responsibility which stipulated the "wrongfulness of any act of a state which is not in conformity with an obligation arising under a peremptory norm of general international law."[94]

There are divergent views regarding what sources of international law could create *jus cogens* norms. Many scholars acknowledge that customary law can create *jus cogens* norms, while others opine that only treaties and general principles of law are the possible sources of *jus cogens*.[95]

The ILC commentary on the Articles of State Responsibility listed some examples of *jus cogens* norms. Examples include the basic rules of international humanitarian law, the right to self-determination, the prohibition of aggression, and the prohibitions against slavery, genocide, racial discrimination and torture.[96] It is worth noting in this context that there is no authoritative catalogue that lists all international norms that constitute *jus cogens*. However, a wide range of *jus cogens* are human rights norms, yet there is uncertainty whether all human rights norms belong to *jus cogens*, or only a few.[97]

A critique that could be directed to article 53 of the VCLT is that it declares null and void the whole agreement violating an existing *jus cogens* norm. Modern multilateral treaties include various provisions pertaining to several subject matters that could unintentionally violate a *jus*

[93] UN General Assembly, 'Report of the International Law Commission on the Work of its Seventy-First Session' (2019) UN Doc A/74/10, 142-146
[94] UN General Assembly, 'Yearbook of the International Law Commission 2001 Vol II Part 2: Report of the Commission to the General Assembly on the Work of its Fifty-Third Session' (2007) UN Doc A/CN.4/SER.A/2001/Add.1 (Part 2), 84 art 26. **See also**, International Law Commission, 'Text Adopted by the Commission at its Fifty-Third Session Concerning the Responsibility of States for Internationally Wrongful Acts' (2001) art 26
[95] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 98
[96] UN General Assembly, 'Yearbook of the International Law Commission 2001 Vol II Part 2: Report of the Commission to the General Assembly on the Work of its Fifty-Third Session' (2007) UN Doc A/CN.4/SER.A/2001/Add.1 (Part 2), 112-113 art 40 para 4
[97] Destaw A. Yigzaw, 'Hierarchy of Norms: The Case for the Primacy of Human Rights Over WTO Law' (2015) 38(1) Suffolk Transnational Law Review 33, 34

*cogens* norm in marginal detail. Thus, nullifying the whole agreement instead of the violating part only, undermines the will of its parties to implement the rest of the treaty to the extent that it does not violate a *jus cogens* norm.

Practically, treaties have rarely been declared null and void on account of a conflict with *jus cogens* norms. Generally, states do not accept to accede to a treaty that violates a *jus cogens* norm.[98] This implies that states, in contemporary international law, sought to protect the collective interests. They did not renounce the protection of individual interests, but rather, they try to balance between both interests whenever a potential conflict occurs between them.

In essence, the paradigm of public international law had transformed from protecting reciprocal/bilateral relations between states and ensuring respect to state sovereignty, into protecting public goods and fulfilling the international communal interests. The protection of community interests caused a structural change in the international legal order which has been manifested by the grafting of the concepts of *jus cogens* norms and *erga omnes* obligations into the traditional setting of international law, hence adapting international norms to the new needs of contemporary international relations.

However, this does not mean that states discarded the protection of other bilateral interests or abandoned the principle of sovereignty in their mutual relations, rather, the protection of both interests is considered a manifestation of the contemporary international law. It seems that there is an apparent tension between these conflicting interests. The contemporary international law tries to balance between the continuing preservation of bilateral interests and the emerging need to protect the community interests. However, in certain instances, such balance is unsuccessful, which reflects the status of disorder in public international law. This raises a question regarding how international law should balance between individual and community interests whenever they conflict.

One of the proposed tools to achieve the balance is to revert to the interests involved, whether bilateral/reciprocal or collective/universal, in order to identify the contents of the relevant international norms. Although the protection of human rights is considered a manifestation of community interests, the influence of bilateralism has been more apparent in cases which do not constitute a flagrant violation to the international peace and security. Perhaps such influence is attributed to the unwillingness of states to take actions against other states violating specific

[98] UN General Assembly, 'Report of the International Law Commission on the Work of its Seventy-First Session' (2019) UN Doc A/74/10, 174-175

human rights of its nationals considering them internal matters that do not have essential significance. Also, states may be reluctant to sacrifice their personal interests for the benefit of certain community interests. They might envisage them as less important than other human rights that would undermine the public good.[99]

Indeed, some individual interests are more important to states than community interests in which any violation to the first constitutes serious consequences. For example, the ICJ in an advisory opinion on the Legality of the Threat and Use of Nuclear Weapons supported the individual right of every state to survival. The court stated that it could not "make a determination on the validity of the view that the recourse to nuclear weapons would be illegal in any circumstance owing to their inherent and total incompatibility with the law applicable in armed conflict."[100]

On the other hand, states recognized several human rights as essential community interests, where their violation constitutes serious risk to the maintenance of international peace and security. Acts of terrorism, genocide and piracy are examples of community interests. Also, the UN Security Council considered the fight against HIV/AIDS pandemics a situation of collective interests since it constitutes a threat to the international peace and security. It encouraged states and different UN bodies to take further actions to increase international cooperation in this regard.[101]

Thus, it could be argued that whenever there is a conflict between individual and community interests, the latter would prevail in those cases where the continuing preservation of the first may gravely undermine the public good of the international community. The prevailing of community interests is not attributed to the superiority of community values in relation to individual interests, but to the fact that certain community values cannot be protected except by the unanimous adherence to them whenever they conflict with individual interests. Those community values which cannot be protected except by the unanimous adherence to them are represented by the *jus cogens* norms. Therefore, a sort of structure in the international law system, albeit in a disorderly and haphazard manner, could be recognized in the sense that it

[99] Santiago Villalpando, 'The Legal Dimension of the International Community: How Community Interests are Protected in International Law' (2010) 21(2) The European Journal of International Law 387, 394-399
[100] *Legality of the Threat or Use of Nuclear Weapons* (Advisory Opinion) [1996] ICJ Rep 226, paras 95-96
[101] United Nations Security Council, 'Resolution 1308 (2000) on the Responsibility of the Security Council in the Maintenance of International Peace and Security: HIV/AIDS and International Peace-keeping Operations' (17 July 2000) UN Doc S/RES/1308 (2000) < https://www.unaids.org/sites/default/files/sub_landing/files/20000717_un_scresolution_1308_en.pdf > accessed 18 December 2020

consists of normal norms and *jus cogens* norms, where the latter have hierarchical superior status.

### 4.4 Institutionalization of International law

The introduction of community values into the international law system in order to achieve common goals for the international community resulted in proliferation of diversified international law regimes. States have chosen to endow such regimes with an organizational structure and an adjudication and enforcement system in order to increase their effectiveness. Each adjudicatory body has its own constitutional document restricting the applicable law to the norms of its legal system and its adjudication to claims arising under its own legal regime. This concept is known as constitutionalization of public international law which suggests that states have reached a degree of objectivity after recognizing community interests that transcend bilateral interests of states. The international law system started to move towards an institutionalized system where international organizations became relatively independent of their member states.[102]

Several international organizations were created in order to administer various norms of international law, like the WTO administering the WTO agreements. Nevertheless, the international law as a law of coexistence is still at the core of the present system of international law depending on the sovereign equality of states which is rooted in the UN charter as a fundamental principle.[103]

As such, potential conflicts arise between different tribunals, either due to the application of different rules by each tribunal on the same case, or due to the different interpretation of each tribunal if the same rules are applied. The only exception is the *jus cogens* norm applicable to all tribunals. This creates a *de facto* hierarchy different from the normative hierarchy of norms in international law.

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[102] Anne Peters, 'The Constitutionalization of International Law: Conclusions' (European Journal of International Law Blog, 28 July 2010) < https://www.ejiltalk.org/the-constitutionalization-of-international-law-conclusions/> accessed 3 April 2020. **See also**, Thomas Kleinlein, 'Summary: Constitutionalization in International Law' (Springer Link, 1 November 2011) < https://link.springer.com/chapter/10.1007%2F978-3-642-24884-9_7> accessed 3 April 2020. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 194

[103] Charter of the United Nations (adopted 26 June 1945, entered into force 24 October 1945) 1 UNTS XVI art 2(1)

The adjudicatory body of each regime applies its own rules even if the facts of the case raise questions related to other regimes. Thus, adjudicating bodies will not apply the general international law for normative conflicts. This does not bring normative hierarchy to international law norms, rather, it increases the fragmentation of international law and exposes states to different contradictory rulings regarding the same case. Such problems appeared due to the absence of any hierarchical legally binding relationship between tribunals. They act in clinical isolation from each other, i.e., each tribunal is not bound by the jurisprudence of the other.[104]

The first and most prominent case highlighting the potential problems associated with the multiplication of international tribunals that consider the same matter is the *Mox Plant* case.[105] This case involved a dispute between Ireland and UK concerning certain radioactive wastes (nuclear fuel) produced by Mox plant located in UK and discharged into the Irish sea. After failing to obtain information from UK about the radioactive discharges, Ireland initiated proceedings against UK relying on the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention) in addition to the United Nations Convention on the Law of the Sea (hereinafter referred as UNCLOS). Arbitral tribunals under both conventions were established.[106] The dispute was also brought before the European Court of Justice (ECJ) since it touches on EC law considering that the dispute was between two EC members.[107] Each arbitral tribunal confirmed its jurisdiction and rendered a final award based on their treaty law. They refused to consider any other sources of international law or the EC Law.[108] On the other hand, the ECJ defended its jurisdiction and restricted the applied law to EC law. The ECJ limited the freedom of EC members to choose a dispute settlement body to

[104] Nikolaos Lavranos, 'Regulating Competing Jurisdictions Among International Courts and Tribunals' (2008) 68 Heidelberg Journal of International Law 575, 576-577
[105] Ibid, 583
[106] *The Mox Plant Case* (*No 10*) *(Ireland v United Kingdom) Provisional Measures* (ITLOS Order, 3 December 2001) ITLOS Reports 2001, 95. **See also**, *The Mox Plant Case* (*Ireland v United Kingdom*) (PCA Order No 3, 24 June 2003) ICGJ 366, 126 ILR 310. **See also**, *Dispute Concerning Access to Information Under Article 9 of the OSPAR Convention Between Ireland and the United Kingdom of Great Britain and Northern Ireland* (*Ireland v United Kingdom of Great Britain and Northern Islands*) (PCA Final Award, 2 July 2003) XXIII RIAA 59
[107] *Case C-459/03 Commission of the European Communities v Ireland* [2006] ECR I-4657
[108] *Dispute Concerning Access to Information Under Article 9 of the OSPAR Convention Between Ireland and the United Kingdom of Great Britain and Northern Ireland* (*Ireland v United Kingdom of Great Britain and Northern Islands*) (PCA Final Award, 2 July 2003) XXIII RIAA 59, para 143. **See also**, *The Mox Plant Case* (*No 10*) (*Ireland v United Kingdom*) *Provisional Measures* (ITLOS Order, 3 December 2001) ITLOS Reports 2001, 95

resolve their disputes as long as the EC law was the applicable law. By doing so, the ECJ sought to protect the uniform application of EC law on disputes between EC member states.[109]

The case raised potential overlap of jurisdiction between the two arbitral tribunals of UNCLOS and OSPAR from one side and the ECJ from the other side. This resulted in fragmentation regarding the standard of accessibility to environmental information issues which are regulated under the EC law and the OSPAR Convention. The case shows the jurisprudential overlap taking place between different international legal regimes due to the proliferation of international tribunals. States could face contradictory rulings concerning the same case because each ruling is issued from a different tribunal that applies only the norms of its legal regime.

This institutional structure creates factual hierarchy of international law which is completely independent from the normative hierarchy. This factual hierarchy undermines the human rights regime and places it at a lower level than the WTO regime. On the contrary, under the normative hierarchy, human rights regime was placed at a higher position.

To elaborate more, due to the institutional structure, some legal regimes are endowed with robust enforcement mechanisms, for example, the WTO regime with its robust adjudication and enforcement mechanism, while others do not have any enforcement mechanisms or even adjudicatory bodies. Certainly, states shall comply with the obligations under regimes having the strongest enforcement mechanisms. Probably, their intention is to leave certain legal regimes with weaker mechanisms.[110]

Ernest Petersmann asserted the "constitutional primacy of the inalienable core of human rights" and the obligation of the international organizations, even specialized ones, to respect and promote human rights. He argued that UN member states have committed themselves to inalienable human rights as part of public international law by virtue of the UN Charter and the UDHR, in addition to other UN instruments.[111]

Most of the states recognize human rights in their constitutions which oblige governments to restrict their power in order to protect human rights. The UDHR acknowledges that all human

[109] Nikolaos Lavranos, 'Regulating Competing Jurisdictions Among International Courts and Tribunals' (2008) 68 Heidelberg Journal of International Law 575, 583
[110] Philip Alston, 'Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann' (2002) 13(4) European Journal of International Law 815, 833- 836
[111] Ernst-Ulrich Petersmann, 'Time for a United Nations 'Global Compact' for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration' (2002) 13(3) European Journal of International Law 621, 633

rights set forth in the declaration should be fully realized either socially or internationally, thus acknowledging human rights obligations on international organizations.[112] Also, the ICESCR required states to achieve the full realization of all the human rights set forth in the Covenant including the adoption of legislative measures,[113] albeit progressively and according to the available resources as explained in chapter 3. Further, the VCLT recognized the importance of human rights protection, albeit implicitly, when it provided for interpreting treaties taking into consideration, together with the context, "any relevant rules of international law applicable in the relations between the parties."[114]

The ICJ also recognized the importance of not only individual human rights but also those of *erga omnes* obligations of governments based on general international law or even treaty law. An example is the *Barcelona Traction, Light and Power Company, Limited Case* which was previously discussed in this chapter.

Nevertheless, all UN human rights instruments including the International Bill of Rights either lack judicial safeguards, or suffer from inadequate enforcement mechanisms that ensure effective protection of human rights. Noticeably, only a few regional, not global, human rights instruments provide judicial remedies, for example, the European and Inter-American human rights conventions.[115]

Contrary to the ECJ which interpreted the common human rights guarantees of EC members as constituting general constitutional principles, the ICJ did not specify to what extent human rights entail constitutional limits on the UN and its specialized bodies. Further, the WTO jurisprudence did not clarify the impacts of human rights on interpreting its provisions, for instance, the impact of the right to health on the interpretation of the TRIPS agreement.[116] With all the importance of the UDHR as explained in chapter 3, it is highly doubted that the declaration *in toto* is considered customary law due to insufficient state practice and *opinio juris*. Even the UN

[112] Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR) art 28
[113] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 2(1)
[114] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 31(3)(c)
[115] Ernst-Ulrich Petersmann, 'Time for a United Nations 'Global Compact' for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration' (2002) 13(3) European Journal of International Law 621, 624-625. **See also**, Philip Alston, 'Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann' (2002) 13(4) European Journal of International Law 815, 833
[116] Ernst-Ulrich Petersmann, 'Time for a United Nations 'Global Compact' for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration' (2002) 13(3) European Journal of International Law 621, 634

Charter guarantees are not entirely clear.[117] However, as stated in the VCLT, there is no derogation from a *jus cogens* norm under any reason or by any international rule or principle including the *lex specialis* principle and the *lex posterior* principle,[118] yet the problem still exists regarding other human rights that do not constitute *jus cogens*.

Obviously, the international human rights regime has a weak enforcement mechanism than it should be. Even the statutes of the UN specialized organizations, except the UNESCO, ILO and WHO, do not explicitly refer to human rights. This is derived, as Petersmann assumed, from the reluctance of states or their refusal to develop the human rights regime any further. States tend to weaken human rights considerations in the legal regime of specialized international organizations, like WTO, to maintain their sovereignty when the matter is related to human rights. When acting within the WTO forum, states would take a different attitude to a proposal that achieves the same result as the one which they opposed according to the human rights perspectives.[119]

For an effective role of human rights in specialized organizations, Petersmann proposed that the law of organizations should be interpreted in conformity with human rights law. International courts, like the WTO DSB, and human rights organizations should co-operate with each other in interpreting and progressively developing the law of specialized organizations in conformity with universally recognized human rights."[120] Petersmann referred to the UN Charter, as an example, which includes statutory powers authorizing the General Assembly and the Economic and Social Council to take appropriate steps to obtain regular reports on human rights matters from different international organizations. The reports should explain the contribution of the practices and laws of the organization to the promotion of human rights.[121] To illustrate his proposition, he asserted that the human rights law offers WTO regime "moral, constitutional and democratic legitimacy that may be more important for the parliamentary ratification of

[117] Philip Alston, 'Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann' (2002) 13(4) European Journal of International Law 815, 829

[118] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 53

[119] Ernst-Ulrich Petersmann, 'Time for a United Nations 'Global Compact' for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration' (2002) 13(3) European Journal of International Law 621, 625 footnote 8, 635. **See also**, Philip Alston, 'Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann' (2002) 13(4) European Journal of International Law 815, 833-834

[120] Ernst-Ulrich Petersmann, 'Time for a United Nations 'Global Compact' for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration' (2002) 13(3) European Journal of International Law 621, 625

[121] Ibid, 626. **See also**, Charter of the United Nations (adopted 26 June 1945, entered into force 24 October 1945) 1 UNTS XVI preamble, arts 13, 62-64

future WTO agreements than traditional economic and utilitarian justifications."[122] He opined that all international law provisions, whether trade related or not, "derive their democratic legitimacy from protecting human dignity and inalienable human rights which today constitutionally restrain all national and international rule-making powers."[123]

The dissertation, in chapter 2, supported the inclusion of human rights within the WTO framework when it analysed the philosophical justifications of intellectual property, *inter alia*, patents. It justified IPRs according to both the moral and economic arguments in order to invoke human rights instruments into the intellectual property regime. This would ensure and promote the public accessibility to scientific knowledge and at the same time induce investment in innovations.

It could be argued that the specialized international organizations should place all human rights obligations, *inter alia*, human right to health, at a higher position in the international law system. They should apply human rights law in their adjudicatory systems. Unwilling organizations and governments should ensure their full compliance to such obligations in the same way they comply with human rights obligations constituting *jus cogens* norms. Since health is a fundamental human right indispensable for all human beings to live their life in dignity,[124] it should be given more recognition and effectiveness within the WTO system. Human rights obligations should be invoked in the WTO dispute settlement system as *lex superior* norms, i.e., norms of higher level in international law which derogate lower ones.

Following Petersmann's argument, the dissertation argues that specialized international tribunals, including the WTO, should apply not only the norms of their legal systems but also other international law rules including human rights norms. This entails refusing the notion of incoherence pertaining to contradictory rulings issued from different tribunals. Such argument provides a chance to incorporate human rights law within the WTO regime. Otherwise, contradictory outcomes, as one of the consequences of the institutionalization of international

[122] Ernst-Ulrich Petersmann, 'From Negative to positive Integration in the WTO: Time for Mainstreaming Human Rights into WTO Law' (2000) 37 Common Market Law Reports 1363, 1377
[123] Ernst-Ulrich Petersmann, 'Time for a United Nations 'Global Compact' for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration' (2002) 13(3) European Journal of International Law 621, 635
[124] UN Committee on Economic, Social and Cultural Rights (CESCR), 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, para 1

law, would be an undisputable matter. This would entail accepting the factual hierarchy of international law and its negative impact on the human rights regime.

### 4.5 Normative and Factual Hierarchy of Human Rights and WTO Systems

The dissertation in this part shall explore the effect of the transformation of international law system on both the WTO regime and the human rights regime. The transformation was accompanied by the institutionalization of international law which creates a *de facto* hierarchy completely different from the normative hierarchy.

#### 4.5.1 The Human Rights System

Unlike the WTO system, which is instrumental, the human rights system is moral. It is "derived from the inherent dignity and worth of all persons, with the human person as the central subject and primary beneficiary of human rights" as stated by the CESCR. The CESCR also mentioned that "the human rights are fundamental, inalienable and universal entitlements belonging to individuals," where they are "dedicated to assuring satisfactory standards of human welfare and well-being."[125] So, human rights represent the end in themselves. They represent the essential needs and freedoms of human beings which are inevitable to live a life of dignity.

The normative arguments for human rights protection are deontological in nature. They concentrate on the treatment of people regardless of the consequences. The law is legitimate if its nature does not violate a moral principle regardless of the personally favourable or unfavourable consequences of the law itself. The deontological perspective is reflected in the nature of human rights themselves and also in the language of human rights instruments. They echo the fact that human rights are inalienable and derived from the inherent human dignity for every person.[126] Jack Donnelly expressed the moral nature of human rights by emphasizing that

[125] UN Committee on Economic, Social and Cultural Rights (CESCR), 'Statement by the Committee on Economic, Social and Cultural Rights on Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: Follow-Up to the Day of General Discussion on Article 15 (1) (c)' (14 December 2001) UN Doc E/C.12/2001/15, paras 5,6

[126] Fernado Teson, 'The Kantian Theory of International Law' (1992) 92(1) Columbia Law Review 53, 71-72. **See also**, Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR) preamble. **See also**, International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) preamble. **See also**, International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171 (ICCPR) preamble

"human rights represent a social choice of a particular moral vision of human potentially, which rests on a particular substantive account of the minimum requirements of a life of dignity."[127]

An increasing hierarchy of norms is recognized within the human rights framework. Certain norms are considered normal human rights, while others are non-derogable where states cannot deviate from their obligations even in public emergency cases. The latter are those considered *jus cogens* norms. Generally accepted examples include the right to life, the right to self-defence and the prohibition of aggression, slavery, torture, genocide, and the crimes against humanity.[128] Others have added to the previous rights, the right to live in dignity and bodily integration.[129] This hierarchy among human rights norms and international law in general is explicitly stated in treaty law (the VCLT). The *jus cogens* norms express a tendency towards normative hierarchy in human rights system considering that they are norms from which no derogation is permitted.[130]

Another shape of normative hierarchy within the human rights system is the impermissibility of reservations in human rights treaties. The VCLT allowed states to formulate reservations when acceding to treaties, unless the reservations are prohibited by the treaty itself or they are incompatible with the objects and purposes of the treaty.[131] Nevertheless, the Human Rights Committee stated that the VCLT provisions regarding reservations cannot be applied to human rights treaties.[132] The Committee stipulated that states should accept the full obligations in human rights treaties because "they are the legal expression of the essential rights that every person is entitled to as a human being."[133] Reservations to human rights treaties frustrate their

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[127] Jack Donnelly, *Universal Human Rights in Theory and Practice* (3rd edn, Cornell University Press 2013) 17
[128] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 374
[129] Lisa Forman, 'An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law' (2011) 14(2) The Journal of World Intellectual Property 155, 158-159
[130] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 21. **See also**, Office of the High Commissioner for Human Rights, 'General Comment No 24: Issues Relating to Reservations Made Upon Ratification or Accession to the Covenant or the Optional Protocols Thereto, or in Relation to Declarations Under Article 41 of the Covenant' (4 November 1994) UN Doc CCPR/C/21/Rev.1/Add.6, para 10. **See also,** Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 53
[131] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 19
[132] Office of the High Commissioner for Human Rights, 'General Comment No 24: Issues Relating to Reservations Made Upon Ratification or Accession to the Covenant or the Optional Protocols Thereto, or in Relation to Declarations Under Article 41 of the Covenant' (4 November 1994) UN Doc CCPR/C/21/Rev.1/Add.6, paras 8, 17, 18
[133] Ibid, para 4

objects and purposes which are meant to guarantee the rights of individuals vis-à-vis states. It impedes creating legally binding standards for human rights. The principle of reciprocity between states is not applicable within the human rights framework. Further, the Committee stated that human rights treaties are closely related to each other, where the reservations to one individual right would affect the structure of a whole treaty and impinge its objectives. Human rights "are not a web of inter-state exchanges of mutual obligations. They concern the endowment of individuals with rights."[134]

Also, the principle of human rights primacy is regarded by many scholars and commentators as a manifestation of a normative hierarchy in international law. States should prioritize their obligations to respect, protect and fulfil human rights. They should also protect their individuals from activities that might cause negative impact on the full enjoyment of human rights. Domestic legislators should recognize the various international instruments providing for such principle, either explicitly or implicitly, when enacting legislations. Otherwise, doubts about their legitimacy might be raised.[135]

Considering the International Bill of Human Rights an interpretation to the UN Charter would provide an argument to support the principle of human rights primacy in the hierarchy of norms in international law. The UN Charter stipulated that whenever there is a conflict between the obligations stated in the Charter and obligations under any other international agreement, the former shall prevail.[136] Thus, for example, the obligations enshrined in the ICESCR, *inter alia*, those related to the right to health, are considered to be obligations under the UN Charter, particularly under articles 55 and 56. As such, those obligations should prevail over WTO obligations, *inter alia*, those in the TRIPS agreement.

The normative underpinning of human rights law, which is different from that of WTO law, also supports the principle of primacy of human rights norms. Those underpinnings are based on a variety of theological and philosophical moral theories of human nature. They revolve around: human rights are derived from God; human rights represent the human nature and what is necessary for human beings "to attain their natural end through perfection of their nature;" and

[134] Ibid, paras 7, 17

[135] Destaw A. Yigzaw, 'Hierarchy of Norms: The Case for the Primacy of Human Rights Over WTO Law' (2015) 38(1) Suffolk Transnational Law Review 33, 37-38. **See also**, Frederic Megret, 'Nature of obligations' in Daniel Moeckli et al (eds), *International Human Rights Law* (2nd edn, Oxford University Press 2010) 96, 98-103 **See also**, Frank J. Garcia, 'The Global Market and Human Rights: Trading Away the Human Rights Principle' (1999) 25 Brooklyn Journal of International Law 51, 69-73

[136] Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR) art 103

human rights can be recognized through the concept of moral rights and the nature of human beings, i.e., it is self-evident. The latter is the most accepted rationale, and it is attributed to the UDHR.[137]

Those moral theories formulating the normative underpinning of human rights norms give them the ability to prevail over other norms due to the notion of transcendental standard of justice by which the justness of certain laws is judged if they violate human rights.[138] A human rights-based claim, then, should be able to trump any conflicting counter claims based on utility or any other consequentialists appeals due to the primacy of human rights.[139]

The Sub-Commission on the Promotion and Protection of Human Rights in one of its resolutions reminds governments of the "primacy of human rights obligations over economic policies and agreements."[140] The 2 Special Rapporteurs appointed by the Sub-Commission to undertake a study on the issue of "Globalization and its Impact on the Full Enjoyment of All Human Rights" criticized the WTO in their joint report. They stated that "the assumptions on which the rules of WTO are based are grossly unfair and even prejudiced." They viewed that the "primacy of human rights law over all other regimes of international law is a basic and fundamental principle that should not be departed from."[141]

Moreover, the UN Independent Expert on the Promotion of a Democratic and Equitable International Order, Alfred de Zayas, urged states to ensure that all future trade agreements stipulate the primacy of human rights. As for the existing treaties, he proposed that they should be revised to ensure that they do not conflict with the duty of states to fulfil human rights treaties and achieve health goals. He called on the ICJ to issue an advisory opinion that reaffirm the primacy of the UN Charter over trade agreements.[142]

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[137] Frank J. Garcia, 'The Global Market and Human Rights: Trading Away the Human Rights Principle' (1999) 25 Brooklyn Journal of International Law 51, 70 footnote 73
[138] Joy Gordon, 'The Concept of Human Rights: The History and Meaning of its politicization' (1998) 23(3) Brooklyn Journal of International Law 689, 700-701
[139] Jack Donnelly, *Universal Human Rights in Theory and Practice* (3rd edn, Cornell University Press 2013) 10
[140] UN Sub-Commission on the Promotion and Protection of Human Rights, 'Resolution 2000/7 on Intellectual Property Rights and Human Rights' (17 August 2000) UN Doc E/CN.4/Sub.2/RES/2000/7, para 3
[141] UN Sub-Commission on the Promotion and Protection of Human Rights, 'Globalization and its Impact on the Full Enjoyment of Human Rights: Preliminary Report Submitted by J. Oloka-Onyango and Deepika Udagama, in Accordance with Sub-Commission Resolution 1999/8' (15 June 2000) UN Doc E/CN.4/Sub.2/2000/13, paras 14, 63
[142] 'Mainstream Human Rights into Trade Agreements and WTO Practice – UN Expert Urges in New Report' (Office of the High Commissioner of Human Rights, 13 September 2016) < https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=20473&LangID=E> accessed 19 April 2020

However, whether human rights norms should take precedence over WTO law according to the previous arguments is still controversial for many reasons.

The attempts to bring a normative hierarchy to human rights law in the international order to support the idea that WTO law may not infringe human rights law in case of conflict is an exercise of futility, except for *jus cogens* norms. Even the *jus cogens* notion itself does not provide an effective solution in every case for several reasons. First, there is no authoritative catalogue of *jus cogens* norms as previously illustrated. Only a short list of human rights receiving global consensus are recognized as jus *cogens* norms which cannot possibly reflect the priority of all human rights norms. Second, the requirement of consent of the international community as a whole, as stated in VCLT, stands as an obstacle to recognizing all human rights as *jus cogens* norms. States may oppose inclusion of specific human rights within the ambit of existing jus *cogens* norms either due to political reasons or cultural bias.[143] Third, even the well-recognized human rights norms constituting jus *cogens* seem to have little to do with trade. The WTO law has never been accused of committing torture crimes or genocide. It is only the socio-economic rights that normally come into conflict with WTO law, where such rights are not widely regarded as *jus cogens* norms.[144]

The dissertation argued in chapter 3 that the right to life-saving medicines, as an element of the right to life in the ICCPR, should enjoy the status of *jus cogens* norms. However, the issue is still controversial. Contrary to the broad reading of the right to life, the traditional view still argues that the right to life does not include the right to health. While many states are embracing the broad interpretation of the right to life which encompasses the right to access to life-saving drugs, other states are still adopting the traditional view. This shows that, except for the few human rights that are globally recognized as *jus cogens* norms, any task to set an exhaustive list of *jus cogens* norms seems preposterous.

Furthermore, the normative justifications of human rights according to the moral theories are no longer the only justifications derived by international scholars. Contemporary justifications

[143] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 375. **See also**, Lisa Forman, 'An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law' (2011) 14(2) The Journal of World Intellectual Property 155, 158

[144] Destaw A. Yigzaw, 'Hierarchy of Norms: The Case for the Primacy of Human Rights Over WTO Law' (2015) 38(1) Suffolk Transnational Law Review 33, 34-35

appeared relying on western liberalism, where human rights became linked to liberalism and justified as "liberal commitment to the equal moral worth of each person."[145]

Linking human rights to the liberal theory contradicts with their nature, as moral rights, which is entrenched in various UN instruments. It transformed human rights into "*Homo Economicus* Model." The WTO law relied on such model when it assumed that human rights would be achieved through the satisfaction of individually determined preferences neglecting the fact that human rights are an end in themselves.[146] The focus of human rights as illustrated above is not on the ability to rationally maximize self-interest like the concept of WTO law, but rather, it is focusing on the intrinsic human dignity and worth of all people which are not matters of individual preferences or utility, but matters of moral duty and principle.

Illustratively, the prohibition of slavery is a human right which is justified due to the wrongfulness of the slavery as a direct violation of human dignity. This concept contradicts with the rationale of trade which could, at least in theory, recognize child labour or slavery to be economically advantageous for states' economy due to increasing industrial production. Accordingly, from a trade view, such practice would be considered justiciable rather than a violation of a human right.[147]

The child labour and forced labour in Asia and Pacific represent modern forms of slavery. The Assistant Director-General of the International Labour Organization, Tomoko Nishimoto, warned the international community against such practices, and called for unprecedented measures to combat such unacceptable forms of work that violate human rights.[148]

Additionally, relying on UN documents, whether General Comments, reports, or statements, to justify the primacy of human rights is erroneous because they are non-binding instruments. The dissertation illustrated in chapter 3 that the UDHR, as a General Assembly resolution, is not a binding instrument since it is not a treaty but merely a recommendation to states to recognize

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[145] Jack Donnelly, *Universal Human Rights in Theory and Practice* (3rd edn, Cornell University Press 2013) 68. **See also**, Frank J. Garcia, 'The Global Market and Human Rights: Trading Away the Human Rights Principle' (1999) 25 Brooklyn Journal of International Law 51, 70

[146] Frank J. Garcia, 'The Global Market and Human Rights: Trading Away the Human Rights Principle' (1999) 25 Brooklyn Journal of International Law 51, 71

[147] Ibid, 72

[148] 'Modern Slavery and Child Labour: Asia's Unacceptable Record' (International Labour Organization, 16 November 2017) <https://www.ilo.org/asia/media-centre/news/WCMS_601896/lang--en/index.htm> accessed 18 March 2020. **See also**, Farkhanda Mansoor, 'The WTO Versus the ILO and The Case of Child Labour' (2004) 2 Web Journal of Current Legal Issues < https://www.peacepalacelibrary.nl/ebooks/files/WEBJCLI_MANSOOR_WTO-versus-the-ILO.pdf> accessed 25 March 2020

human rights. Only the two Covenants are considered legally binding documents since they are international human rights treaties. Further, the General Comments provide an authoritative interpretation of obligations under the Covenants which clarify the scope and content of each human right and delineate the obligations of states towards each human right, however, they are not legally binding. The dissertation also showed in chapter 3 that the UN General Assembly does not have the power to issue binding interpretations of the Charter. This rebuts the justifications of human rights primacy in international law based on consideration of the International Bill of Human Rights as an interpretation of the UN Charter. In this regard, it is worth noting that the ICESCR itself, unlike the ICCPR, does not include any provision that prohibits derogations from the human rights enshrined in it. It stated that states may subject the human rights to limitations.[149]

The previous analysis shows that none of the arguments derived were able to justify the view of the primacy of human rights in the normative hierarchy in international law, except for the few ones recognized as *jus cogens* norms. Most human rights, including the human right to health, are on an equal level to other international law norms. This finding reflects the opinion of other scholars who articulated that, except for those few human rights norms that have obtained the status of *jus cogens*, it is difficult to argue that human rights obligations enjoy higher value under international law than other norms regardless of the special nature of human rights norms and values they protect.[150]

These findings emphasize what was elucidated previously in this chapter under the title "Institutionalization of International Law." The dissertation illustrated that the institutionalization process created *de facto* hierarchy independent and completely different from the normative hierarchy. It is the former which is responsible for placing the human rights regime at a lower level than the high level it was placed by the latter. Due to the institutionalization of international law, the WTO system was endowed with a robust adjudication and enforcement mechanism, while the human rights system was left with an ineffective enforcement mechanism and without an adjudicatory body. It seems natural to invalidate the utilitarian and instrumental WTO norms whenever they conflict with human rights norms based on morality and superiority of human rights. However, the current international

[149] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 4

[150] Antenor Hallo de Wolf, 'Human Rights and the Regulation of Privatized Essential Services' (2013) 60 Netherlands International Law Review 165, 199-200

law cannot accommodate such claim according to the normative hierarchy in international law which clashes with the factual hierarchy that resulted from institutionalization. The factual hierarchy favours the WTO system; thus, states shall comply with their obligations under the WTO system with the strongest enforcement mechanism. On the other side, states shall relax their obligations under the human rights system which lacks an effective tool that could impose sanctions in case of human rights violation, except the *jus cogens* ones.

### 4.5.2 The WTO System

The WTO system echoes the world trade order which aims to protect the economic freedom of individuals and to increase welfare. The WTO system is not a value in itself like human rights, i.e., it does not confer trade rights on individuals in the same sense as human rights law does, but rather it is an instrumental order based on utilitarian ideas.[151]

The dissertation shall first analyse the nature of the WTO obligations, then it shall address the WTO law with respect to the normative hierarchy in international law, and finally according to the factual hierarchy in international law which was created after the conclusion of the WTO agreement.

#### 4.5.2.1 The Nature of the WTO Obligations

The WTO obligations are bilateral/reciprocal in nature not collective/integral. Joost Pauwelyn emphasized this nature when he argued that "trade is a bilateral happening," where goods from one country are exported or transferred to another. Since the WTO norms aim to ensure bilateral market access for goods from one country to another, then the WTO obligations are bilateral. Regardless of the collective/universal economic effects of breaching WTO obligations due to the increased economic interdependence between states, the breach does not amount to breaching the collective/universal rights or conscience of all WTO members. In other words, the benefits of WTO market access and the interests of compliance with WTO obligations are spread over all WTO members, though this collective effect does not negate the inherent bilateral/reciprocal character of both the trade and its obligations. In contrast, while human

[151] Joost Pauwelyn, 'The nature of WTO Obligations' (2002) Jean Monnet Working Paper 1/02, 15 < https://jeanmonnetprogram.org/archive/papers/02/020101.html> accessed 19 February 2020. **See also**, Frank J. Garcia, 'The Global Market and Human Rights: Trading Away the Human Rights Principle' (1999) 25 Brooklyn Journal of International Law 51, 64-68

rights, in terms of their objects and implementation, are domestic matters between public authorities of states and their nationals, the interests of protecting human rights are collective/universal interests in terms of the universal values or global commons that they protect.[152] Such values elevate the respect for human rights to an international level, thus any breach to human rights obligations affects the interests of the international community as a whole.

Briefly, WTO obligations are bilateral/reciprocal although trade is inherently international, while human rights obligations are collective/universal although they are inherently national. Accordingly, human rights law should prevail over WTO norms in different situations of conflict.

The ILC reports concerning the distinction between treaties having reciprocal type and those having an integral type support the bilateral/reciprocal type of WTO obligations. It explained that multilateral treaties having reciprocal type are those treaties "providing for a mutual interchange of benefits between the parties, with rights and obligations for each involving specific treatment at the hands of and towards each of the others individually."[153] Meanwhile, multilateral treaties having integral type are those treaties "where the force of the obligation is self-existent, absolute and inherent for each party, and not dependent on a corresponding performance by the others."[154]

In other meaning, integral obligations are those obligations "towards all the world rather than towards particular parties," and "do not lend themselves to differential application, but must be applied integrally."[155] As such, since trade provides for mutual interchange of benefits (products) from market A to market B; and since the specific treatments within the WTO, *inter alia*, trade concessions and tariffs negotiations,[156] are negotiated bilaterally on a reciprocal basis

[152] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 71-73, 316. **See also**, Joost Pauwelyn, 'The nature of WTO Obligations' (2002) Jean Monnet Working Paper 1/02, 14-15 < https://jeanmonnetprogram.org/archive/papers/02/020101.html> accessed 19 February 2020

[153] UN General Assembly, 'Yearbook of the International Law Commission 1958 Vol II: Documents of the Tenth Session Including the Report of the Commission to the General Assembly' (1958) UN Doc A/CN.4/SER.A/1958/Add.l, 27 art 18 para. 2

[154] Ibid, 28 art 19

[155] UN General Assembly, 'Yearbook of the International Law Commission 1957 Vol II: Documents of the Ninth Session Including the Report of the Commission to the General Assembly' (1958) UN Doc A/CN.4/SER.A/1957/Add.l, 54-55 art 19 paras 126-128

[156] General Agreement on Tariffs and Trade (adopted 30 October 1947, entered into force 1 January 1948) 55 UNTS 194 (GATT 1947) arts II, XXVIII bis. Regarding tariffs, the GATT stated in article XXVIII bis that tariff negotiations are conducted on a reciprocal and mutually advantageous basis. Regarding trade concessions, article II of the GATT showed that trade concessions are accorded on a bilateral basis at first.

first then implemented multilaterally; therefore, the WTO obligations are considered bilateral/reciprocal although they are included in a multilateral agreement.

The identification of the nature of an obligation, whether bilateral/reciprocal or collective/integral, is not linked to the source of the obligation. So, it is not sufficient to identify an obligation as integral because it is derived from a multilateral treaty. Hence, the fact that WTO obligations are derived from a multilateral treaty does not mean that such obligations are integral in nature. In emphasizing this meaning, the WTO Appellate Body noted that although the GATT is a multilateral agreement, the tariff commitments and concessions made according to the GATT are bilateral obligations. Their negotiations are processes of reciprocal demands, of "give and take."[157]

The third preamble to the Marrakesh Agreement also emphasized the bilateral/reciprocal nature of the WTO obligations. It expressed the desire of contracting states to contribute to achieve the underlying objectives of the WTO by "entering into reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers and to the elimination of discriminatory treatment in international commerce."[158]

Moreover, the enforcement of the WTO obligations is exclusively bilateral which confirms the reciprocal nature of WTO obligations. The WTO Dispute Settlement System basically tackles nullification of benefits accruing to any member state, either directly or indirectly, under the WTO agreements if such benefits are impaired by measures taken by another member state.[159] The WTO panels and Appellate Body examine only claims made by a WTO member against another. In case the defendant lost and did not comply within a reasonable period of time, the complaining state would be authorized to impose countermeasures against the defendant, *inter alia*, concessions suspension or other obligations under the WTO covered agreement.[160]

Allowing a WTO member to suspend its trade obligations under the WTO, as a form of countermeasures, towards another WTO member proves the reciprocal nature of WTO obligations. If the WTO obligations are integral, their suspension would inevitably affect the

[157] WTO Appellate Body Report, *European Communities - Customs Classification of Certain Computer Equipment* (adopted 22 June 1998) WTO Doc WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R, para 109
[158] Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement) preamble
[159] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 3(3)
[160] Ibid, art 22(2)

rights of all WTO members. Although third parties in the WTO agreements may be economically affected by such suspension of obligations, their WTO rights will not normally be affected. On the contrary, human rights obligations, which are integral in nature, cannot be suspended in case of breach. Their suspension would not only affect the state which committed the breach, but also breach the rights of all other contracting parties.[161]

The Inter-American Court of Human Rights highlighted the difference between human rights obligations and other obligations of the bilateral/reciprocal type in multilateral agreements. It stipulated that human rights treaties "are not multilateral treaties of the traditional type concluded to accomplish the reciprocal exchange of rights for the mutual benefit of the contracting states, rather their object and purpose is the protection of the basic rights of individual human beings, irrespective of their nationality, both against the State of their nationality and all other contracting States."[162]

Asserting the difference between human rights obligations of the integral/collective type and the reciprocal/bilateral trade obligation, the European Commission of Human Rights stated that the aim of concluding the European Convention on Human Rights "was not to concede reciprocal rights and obligations," but "to realize the collective ideals of the Council of Europe." The Commission highlighted the objective integral obligations of member states to protect the fundamental rights of people rather than "to create subjective and reciprocal rights for the states parties themselves."[163] This emphasizes that the common/collective interest represents the *raison d'être* of human rights treaties. Meanwhile the aim of trade agreements is the mutual/reciprocal exchange of benefits between contracting states.

Three arguments could be raised to oppose the bilateral nature of the WTO obligations. The dissertation shall examine them as follows:

First: it could be argued that trade liberalization, as one of the objectives of the WTO, is meant to bring global welfare by expanding the production and exchange of goods. Its aim is to achieve

[161] UN General Assembly, 'Yearbook of the International Law Commission 2001 Vol II Part 2: Report of the Commission to the General Assembly on the Work of its Fifty-Third Session' (2007) UN Doc A/CN.4/SER.A/2001/Add.1 (Part 2), 119 art 42(b)(ii), 131-132 art 50(1)(b). **See also**, International Law Commission, 'Text Adopted by the Commission at its Fifty-Third Session Concerning the Responsibility of States for Internationally Wrongful Acts' (2001) arts 42(b)(ii), 50(1)(b). S**ee also**, Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 60

[162] *Restrictions to the Death Penalty (Arts. 4(2) and 4(4) American Convention on Human Rights)*, Advisory Opinion OC-3/83, IACHR Series A No 3 (8 September 1983) para 50

[163] *Federal Republic of Austria v Government of the Republic of Italy* App No 788/60 (Commission Decision, 11 January 1961) 18-19

the collective interest by raising the standards of living for all people.[164] Consequently, trade obligations are integral/collective in nature. This resembles environmental agreements obligations which aim to improve the global climate system, a matter of general interest to all states, thus its obligations are considered integral.

Indeed, trade liberalization is in the collective interest as it increases the global welfare due to the better allocation of the resources worldwide. However, the interests achieved by the WTO obligations are still a compilation of individual welfare increases which do not achieve a global common.[165] It is not like the environmental obligations having an integral nature to protect the planet's climate system which surpass the individual interest of individual states.

This was emphasized by the ILC when it stated that the collective obligations are those obligations transcending the sphere of bilateral relations of states parties and are found, *inter alia*, in environmental agreements or human rights treaties. To consider an obligation of a collective interest, "it has to foster a common interest, over and above any interests of the states concerned individually."[166] Therefore, to engage in an obligation that is to everyone's individual benefit, including the one engaging in the obligation, does not mean that it is in the collective interest over and above any individual interest of states.

An example to illustrate the previous notion is the Vienna Convention on Diplomatic Relations, which is generally accepted as setting out reciprocal obligations. The fact that its provisions are in the general interest of all states, as confirmed by the ICJ in the case of *Diplomatic and Consular Staff*,[167] does not change the bilateral/reciprocal nature of its obligations.[168]

Second: It could be argued also that the WTO obligations are collective/integral considering the provision of the most-favoured-nation treatment (MFN), which is considered the cornerstone of the multilateral trading system. This obligation is embedded in all WTO agreements. It obliges

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[164] Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement) preamble

[165] Joost Pauwelyn, 'The nature of WTO Obligations' (2002) Jean Monnet Working Paper 1/02, 20 < https://jeanmonnetprogram.org/archive/papers/02/020101.html> accessed 19 February 2020

[166] UN General Assembly, 'Yearbook of the International Law Commission 2001 Vol II Part 2: Report of the Commission to the General Assembly on the Work of its Fifty-Third Session' (2007) UN Doc A/CN.4/SER.A/2001/Add.1 (Part 2), 126 art 48 para 7. **See also**, International law Commission, 'Third Report on State Responsibility by Mr. James Crawford, Special Rapporteur' (15 March 2000) UN Doc A/CN.4/507, para 92

[167] *United States Diplomatic and Consular Stuff in Tehran (United States of America v Iran)* (Judgement) [1980] ICJ Rep 3, para 92

[168] Joost Pauwelyn, 'The nature of WTO Obligations' (2002) Jean Monnet Working Paper 1/02, 25 < https://jeanmonnetprogram.org/archive/papers/02/020101.html> accessed 19 February 2020

WTO member states to ensure that any trade advantage a state member gives to another must be granted to all WTO members. Therefore, the MFN clause renders the bilateral concessions collective/integral in the sense that they must go to all other WTO members. Also, this argument cannot be left uncontested.

Of course, the MFN obligation is owed towards all WTO members, however, this "collectivisation" is only a duplication by the number of WTO members of the original bilateral concession. The concession is granted from one country to another then to all other WTO member states. Transferring the concession to all members does not change its nature from a bilateral obligation into a collective/integral obligation.[169]

Further, when a WTO member X discriminates against only member Y, for example by banning all imports from member Y, such breach can hardly be considered to affect the MFN rights of other WTO member states. They can continue to export to member X. Therefore, the MFN obligation is not collective in nature.

Third: It may be argued that article 3(8) of the WTO DSU supports the collective/universal nature of the WTO obligations. The article stated that in case of an infringement of a WTO obligation, "the action is considered *prima facie* to constitute a case of nullification or impairment. This means that there is normally a presumption that a breach of the rules has an adverse impact on other members parties." As such, all WTO members have a legal standing whenever any WTO obligation is breached irrespective of the states involved in the breach. This renders WTO obligations integral or *erga omnes* obligations.

However, several WTO cases invalidated this argument. In the case of *United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, the WTO Appellate Body stated that article 3(8) is about "what happens after a violation is established." The article does not relate to the issue of the legal standing, whether all WTO members are entitled to complain about any WTO breach or not, rather, it stated that the nullification of benefits is presumed once the breach occurs. The complaining state member should present sufficient evidence and argument to prove that the measure in question nullifies or impairs a benefit accruing to it. In return the respondent party must rebut this presumption.[170]

[169] Ibid, 21
[170] WTO Appellate Body Report, *United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India* (adopted 23 May 1997) WTO Doc WT/DS33/AB/R, 13

Also, in *Uruguay – Recourse to Article XXIII*, the GATT panel nullified the meaning of the phrase holding that any violation of the GATT obligations would be considered a *prima facie* nullification or impairment that allow any WTO state member to bring a claim. It stated that the country invoking the nullification or impairment should demonstrate the grounds and reasons of its invocation and the actual or potential harm the measure had caused to it.[171] This infers that the phrase "*prima facie* inconsistent with the GATT obligation" is only an assumption until proven, i.e., a refutable assumption.[172] Consequently, such argument could not prove that WTO obligations are integral in nature.

Supporting the bilateral/reciprocal nature of WTO trade obligations, the GATT provisions confirm the necessity of a nullification or impairment of benefits accrued to the claimant to have a legal standing.[173]

Another important WTO case concerning the legal standing in WTO disputes is the case of *EC-Bananas*.[174] This case could mistakenly lead to the conclusion that WTO obligations are integral in nature. The dissertation shall analyse the case to ensure the reciprocal/bilateral nature of WTO obligations.

In international law, to have a legal standing to bring claims for the breach of bilateral obligations, the state should not only have a legal interest, i.e., an interest to see the international obligation abided by, but also it should prove the existence of a legal right in doing so. However, in integral obligations or *erga omnes* ones, all states have legal standing since such obligations affect their legal interest to ensure abidance and respect for the international law in general.[175] The dissertation addressed previously, under the sub-section of *erga omnes* obligations, two cases in this regard, namely, the *Barcelona Traction* case and the *South West Africa* cases. In

[171] GATT Panel Report, *Uruguayan Recourse to Article XXIII* (adopted 16 November 1962) GATT Doc L/1923 - 11S/95, paras 14-15
[172] Ho Cheol Kim, 'Burden of Proof and the Prima Facie Case: The Evolving History and its Applications in the WTO Jurisprudence' (2007) 6(3) Richmond Journal of Global Law & Business 245, 247-248
[173] General Agreement on Tariffs and Trade, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187, 33 ILM 1153 (GATT 1994) art XXIII
[174] WTO Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas* (adopted 25 September 1997) WTO Doc WT/DS27/AB/R
[175] International Law Commission, 'The Third Report on State Responsibility by Mr. James Crawford, Special Rapporteur' (15 March 2000) UN Doc A/CN.4/507, para 104

both cases, the ICJ emphasized that all states have legal interest to protect *erga omnes* obligations due to the importance of the rights and principles that they protect.[176]

In *EC-Bananas* case, the WTO Appellate Body decided that the US could bring a claim under the DSU according to legal interest only, i.e., no legal right is required. It rejected the claims of the European Community stating that the US did not suffer from any impairment of its benefit in the sense of articles 3(3) and 3(7) of the WTO DSU. Since the US hardly produces bananas, and its exports are non-existent, then it did not have any legal standing in the claim it was pursuing.[177]

The WTO Appellate Body justified its decision by stating that neither the previous articles nor any other provisions of the DSU "contain any explicit requirement that a member must have a legal interest as a prerequisite for requesting a panel."[178] Further, it stated that it cannot establish "a general rule that in all international litigation, a complaining party must have a "legal interest" in order to bring a case."[179] Each WTO member has "broad discretion in deciding whether to bring a case against another member under the DSU" in case such member considers that any benefit accruing to it is directly or indirectly nullified or impaired.[180]

However, the close reading of the Appellate Body decision suffices to say that it did not mean to refer to legal interest in its usual sense of interest to see the law abided by. Rather, it referred to legal interest to mean the requirement of proof of the actual damage or trade diversion. The decision did not say that a purely legal interest to see the law abided by is sufficient for any WTO member to have a legal standing regarding all possible breaches of WTO obligations. Rather, it stated that there is no requirement of legal interest to bring a case. This does not imply that a legal right is not required. Obviously, like all WTO members, the US has a legal interest to ensure that the WTO obligations are abided by. But this is not the only thing justifying the US claim, the Appellate body referred implicitly to the legal rights of the US when it mentioned that the US is a producer of bananas and its market for bananas was potentially affected by the European Community regime in terms of bananas prices and world supplies.[181]

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[176] The *Barcelona Traction, Light and Power Company, Limited Case (Belgium v Spain)* Second Phase (Judgement) [1970] ICJ Rep 3. **See also**, *South West Africa* Cases *(Ethiopia v South Africa; Liberia v South Africa)* (Judgment) [1962] ICJ Rep 319

[177] WTO Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas* (adopted 25 September 1997) WTO Doc WT/DS27/AB/R, paras 15, 17

[178] Ibid, para 132

[179] Ibid, para 133

[180] Ibid, paras 134-135

[181] Ibid, para 136

In essence, the analysis of the *EC-Bananas* case infers that a purely legal interest is not sufficient for all WTO members to have a legal standing in case of breaching WTO obligations. To have a legal standing, the trade of the WTO member state should at least become affected by the inconsistent measure. The claimant state should submit to the WTO adjudicating bodies some proof that either actual or potential trade restrictions had occurred from the violation of the obligation which affected or shall affect its economy. The US claimed that its potential interests in exporting bananas shall be affected, thus its economy will be affected accordingly, due to the effect of the European Community regime on world supplies and world prices of bananas. This shows that the WTO obligations are reciprocal in nature, not integral. Any WTO member state, other than the injured parties, has to proof the existence of a legal right to justify its interference whenever a WTO member breaches WTO obligations.

This finding is logical. Giving the right to every WTO member to challenge a measure even if it did not nullify or impair its benefits would be problematic. If the WTO law allowed such complaint and it succeeded on purely legal grounds, i.e., due to legal interests only and not due to nullification or impairment of benefits, then in the implementation process, the claimant would not be able to retaliate, by for example suspending any trade concessions, since the level of retaliation authorized by the WTO DSB must be equivalent to the level of the nullification or impairment.[182] Also, if the general legal interest was the only requirement for all WTO members to have legal standing to bring a WTO complaint for breaching a WTO obligation, then only the obligations in the particular national interest of powerful states would only be enforced, thus appointing those states as policemen or public prosecutors.[183]

Nevertheless, a few WTO provisions are considered integral/collective obligations. They are procedural rules related to the operation of the WTO or the harmonization of its agreements into the internal legislation of states members. Examples of the first type are those rules relating to the voting procedures, accession procedures, and nominations of chairpersons of the General Council and the bodies reporting to it.[184] Examples of the second type are the TRIPS provisions requiring states to ensure that the enforcement procedures of IPRs are fair, equitable and applicable under their national legislations in order to "permit effective action against any act

[182] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 22(4)
[183] Joost Pauwelyn, 'The nature of WTO Obligations' (2002) Jean Monnet Working Paper 1/02, 25 < https://jeanmonnetprogram.org/archive/papers/02/020101.html> accessed 19 February 2020
[184] Ibid, 13

of infringement of intellectual property rights."[185] Also the TRIPS provisions requiring that the decisions on the merits of a case related to intellectual property violation should be in writing and reasoned, where "the parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions."[186]

However, such provisions do not affect the whole nature of the WTO obligations, including the TRIPS, because they are related to procedural obligations only rather than substantive trade-related ones. The latter remain reciprocal/bilateral in nature since their breach does not amount to breaching the collective/universal rights or conscience of all WTO members.[187] All WTO agreements are not a value *per se*, like human rights system, but rather, instrumental orders based on utilitarian ideas.[188] The TRIPS agreement itself asserts such concept since it does not protect human rights as the dissertation proved above.

Ultimately, although the WTO system contains few integral obligations beside the majority of its reciprocal ones, this does not imbue the whole nature as being collective/universal.

Resting on the bilateral/reciprocal nature of WTO obligations, if a breach of trade obligation occurs, it does not necessarily affect the rights of all other WTO members. The trade obligations could always be "reduced to a compilation of bilateral state-to-state relationships" regardless of being derived from a multilateral treaty binding on many states. Therefore, changing one of these bilateral relations does not normally affect other bilateral relations in the WTO agreement because each bilateral relationship is detachable from the other. This is contrary to the binding effect of integral/collective obligations which cannot be separated or detached into bilateral components. Therefore, changing one of the integral norms will necessarily have an impact on all states bound by that norm.[189]

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[185] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 41(1)(2)
[186] Ibid, art 41(3)(4)
[187] Joost Pauwelyn, 'The nature of WTO Obligations' (2002) Jean Monnet Working Paper 1/02, 13 < https://jeanmonnetprogram.org/archive/papers/02/020101.html> accessed 19 February 2020
[188] Ibid, 15-17. **See also**, Frank J. Garcia, 'The Global Market and Human Rights: Trading Away the Human Rights Principle' (1999) 25 Brooklyn Journal of International Law 51, 64-68
[189] Joost Pauwelyn, 'The nature of WTO Obligations' (2002) Jean Monnet Working Paper 1/02, 12 < https://jeanmonnetprogram.org/archive/papers/02/020101.html> accessed 19 February 2020

#### 4.5.2.2 The WTO System within the Normative Hierarchy in International Law

Before the adoption of the Marrakesh Agreement Establishing the WTO, the WTO system was represented by the GATT 1947. The GATT obliged contracting parties to afford to each other trade-related rights, *inter* alia, trade concessions, freedom of transit, the MFN treatment and national treatment.

Contrary to the current robust enforcement mechanism under the DSB, the old GATT contained only two brief articles on disputes settlement. They neither referred to disputes settlement nor provided detailed procedures to handle disputes. The first article requires a contracting party at the request of another contracting party to consult and to afford "sympathetic consideration" to representations regarding any matter that affects the operation of the GATT. The other article authorizes a contracting party to make written representations or proposals to another contracting party whenever it considers that "any benefit accruing to it directly or indirectly under the agreement is being nullified or impaired or that the attainment of any objective of the agreement is being impeded." If no satisfactory adjustment is reached within a reasonable time and the circumstances constitute serious injury to the claimant, the GATT authorizes the claimant to suspend the application of trade concessions or any other trade obligations accorded to the infringing party.[190]

Further, the dispute settlement system under the old GATT did not prove to be very effective like the WTO dispute settlement system. Referring a dispute to a panel, adopting a panel report, or authorizing countermeasures need positive consensus in the GATT Council. This means that there had to be no objection from any GATT member to the decisions, pertaining to any of the previous issues, including the parties to the dispute. So, the respondent could block the establishment of the GATT panel, or he could refuse the adoption of the panel report or the authorization of the countermeasure.[191] This turned the GATT Council into a political organ, where the reports reflected political compromises rather than judicial rulings in order to ensure their adoption.[192]

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[190] General Agreement on Tariffs and Trade (adopted 30 October 1947, entered into force 1 January 1948) 55 UNTS 194 (GATT 1947) arts XXII, XXIII

[191] 'Historic Development of the WTO Dispute Settlement System' (WTO) < https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c2s1p1_e.htm#fnt2 > accessed 18 July 2020. **See also**, General Agreement on Tariffs and Trade (adopted 30 October 1947, entered into force 1 January 1948) 55 UNTS 194 (GATT 1947) arts XII (4), XIX (3), XXIV (7)

[192] Holger Hestermeyer, 'International Human Rights Law and Dispute Settlement in the World Trade Organization' in Martin Scheinin (ed), *Human Rights Norms in 'Other' International Courts* (Cambridge University Press UK 2019) 199, 203

Several factors facilitated the prevail of human rights norms over trade norms in case they conflict. First, the GATT's ineffective enforcement mechanism with its limited number of states that signed the agreement (only 23 member states at that time).[193] Second: the conclusion of the VCLT that codified the rules guiding treaty relations between states and provided interpretive solution for conflict of norms in international law. Third: The adoption of the International Bill of Rights. The world was convinced after the second world war that the treatment by a state of its nationals was indeed a proper concern of the whole international community.[194] The dissertation showed in chapter 3, within the context of human right to health, that the Bill of Rights set legally binding obligations on states to respect, protect and fulfill human rights requirements. It was supplemented by several human rights treaties, many of which have been ratified by all countries. Finally, the evolution of customary international law of human rights binding on all states, even those not parties to the human rights conventions. Under this law, some fundamental human rights have attained the status of *jus cogens* norms or *erga omnes* obligations as shown above, where according to the VCLT, no other norm including the trade ones could violate them.

Even if the GATT contains trade-related obligations binding on its member states, for instance affording MFN treatment to all members, under the rules of customary international law the GATT member could be entitled to withhold such benefits in response to a violation of other international law norms including human rights law.[195] If this is the case according to customary international law, then *a fortiori* it is the same if the violation concerns human rights obligations pertaining to *jus cogens* norms or *erga omnes* norms.

In essence, the normative hierarchy in international law distinguished between trade obligations and human rights obligations, giving the latter a big chance to prevail in different situations of conflict. While the breach of trade obligations may affect a group of members individually since they are bilateral/reciprocal obligations in nature, the breach of human rights obligations, as collective/universal in nature, constitutes an offense *per se* to the conscience of all states.[196]

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[193] 'WTO News: 1997 Press Releases: Fiftieth Anniversary of the Signing of the General Agreement on Tariffs and Trade' (WTO, 27 October 1997) < https://www.wto.org/english/news_e/pres97_e/pr81_e.htm > accessed 25 July 2020

[194] Carlos Manuel Vázquez, 'Trade Sanctions and Human Rights: Past, Present, and Future' (2003) 6(4) Journal of International Economic Law 797, 798

[195] Ibid, 801

[196] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 72, 316

The VCLT affirms the prevail of human rights norms whenever they conflict with trade obligations. It provides the following solutions in different situations of conflict:

a) In case the trade agreement is recognized as *lex posterior* and the human rights agreement is recognized as *lex priori*, then the trade provisions of reciprocal nature can deviate from the human rights provisions of integral nature according to the principle of *lex posterior derogat legi priori*. However, by virtue of article 41(1)(b) of the VCLT, such deviation is not permissible, and the *lex priori* human rights provision shall be able to deviate from the *lex posterior* trade norm as only between the parties to both agreements.

Applying article 41(1)(b) of the VCLT would support the application of human rights provisions in cases of conflict between earlier human rights agreements and later trade agreement. Contrary to the *lex posterior* principle, if any of the two conditions stated in article 41(1)(b) of the VCLT is met, the human rights agreement, although it is the *lex priori,* would be able to prevail over the *lex posterior* norm in cases of conflict. Such conditions are that either the modification is not prohibited by the multilateral treaty and does not affect the enjoyment by third parties of their rights and obligations under the treaty; or "does not relate to a provision, derogation from which is incompatible with the effective execution of the object and purpose of the treaty as a whole."[197] Taking into consideration that in cases of conflict between trade provisions and human rights provisions, the first provisions are very likely not to meet the aforementioned VCLT conditions according to the universal/integral nature of human rights obligations. In this case, the *lex posterior* principle cannot be applied. As such, the human rights agreement should prevail in cases of conflict provided that the conditions stipulated in article 41(1)(b) are met.

Arguing that applying article 30(4)(a) of the VCLT in this case allows the application of the trade agreement in all cases as *lex posterior*, is an invalid argument lacking legal accuracy. Article 30(4)(a) stipulates that if the later treaty does not include all the parties to the earlier one, then the earlier treaty applies as between the states parties to both treaties and to the extent that its provisions are compatible with those of the later treaty. However, paragraph 5 in article 30 of the VCLT stated explicitly that the application of paragraph 4 is without prejudice to article 41 of the VCLT which contains the two conditions stated above.[198] Thus, if any of the two conditions is found, then the human rights agreement should be able to prevail over the *lex*

[197] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 41(1)(b)
[198] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 30(4)(a), (5)

*posterior* trade agreement. Therefore, applying article 30(4)(a) does not alter the reached solution.

b) In case the human rights agreement is recognized as *lex posterior* and the trade agreement is recognized as *lex priori,* then according to article 30(4)(a) of the VCLT, the *lex posterior* human rights agreement shall be able to deviate from the trade agreement as only between the parties to both agreements. Such deviation is permissible since the VCLT allowed in article 41, in principle, modification of reciprocal obligations like trade obligations. However, if any of the two conditions stipulated in article 41(1)(b) is met, (in this case, the human rights treaty affects the enjoyment by third parties to their rights or the performance of their obligations under the trade agreement; or the human rights agreement is incompatible with the effective execution of the object and purpose of the trade agreement as a whole), then the deviation shall be impermissible.

However, since the human rights provisions are likely to be legal according to article 41(1)(b) of the VCLT, then it should be able to prevail as lex *posterior*. The *lex priori* trade agreement has to give way to the *lex posterior* human rights agreement.

In essence, regardless of the actual timing of both the trade agreement and the human rights agreement, whenever a trade norm, which is reciprocal in nature, conflicts with a human rights norm, which is integral in nature, the human rights norm shall prevail in the relationship between the two parties that are bound by both norms. This is pursuant to either article 41(1)(b) or article 30(4)(a) of the VCLT.

To illustrate, if for instance, between states that are bound by both norms, there is a conflict between a trade norm obliging states not to restrict trade in product A and a human rights norm that obliges states to restrict trade in product A because it affects the health of people, the human rights norms shall prevail regardless of whether it is *lex posterior* or *lex priori*. If it is *lex posterior*, it shall prevail by virtue of article 30(4)(a) of the VCLT. If the human rights norm is *lex priori*, it shall prevail also according to article 41(1)(b) of the VCLT since it is an integral obligation. It is very likely that the trade provision does not meet the VCLT conditions mentioned in article 41(1)(b) when it conflicts with the human rights norm due to the universal/integral nature of human rights obligations.

The ILC asserted the previous solutions when it demonstrated the consequences of conflicts between reciprocal obligations and other obligations of integral/collective type regarding the

termination or suspension of treaties in conflict with each other. It stated that the later treaty of reciprocal nature could be terminated or suspended in cases of fundamental breach of obligations of another treaty of integral type. Even if the reciprocal treaty is later, it cannot make an earlier one of an integral type null and void. On the contrary, treaties of the integral type have an inherent juridical force that does not depend on the corresponding performance by other parties to the treaty. Thus, such treaties could not be terminated or suspended if a number of their parties breached their obligations. Also, later treaties concluded by the parties to treaties of integral type which "conflicts directly in a material particular with the earlier treaty will, to the extent of the conflict, be null and void."[199]

It is worth noting that whatever the nature of the treaty, the VCLT stated that termination or suspension of a treaty as a result of material breach is not allowed when "the provisions relate to the protection of the human person contained in treaties of a humanitarian character, in particular to provisions prohibiting any form of reprisals against persons protected by such treaties."[200] For this reason, the dissertation showed above, in the first solution considering trade provisions *lex posterior*, that it is very likely that the provisions of a trade agreement do not meet the conditions stipulated under article 41(1)(b) of the VCLT.

Another remark is that the trade norms cannot constitute *jus cogens* norms. Trading requires trade-offs and several negotiations to conclude trade concessions with the possibility to withdraw or to alter trade benefits depending on trading interests. This is totally different from the nature of *jus cogens* norms. The latter are recognized by the international community as rules from which no derogation is permitted. They cannot be modified or deviated from by any international rule except only by a general international law having the same character, i.e., a subsequent *jus cogens* norm.

In conclusion, the normative hierarchy envisages the international trade law as a system protecting individual interests rather than communal interests. The states only set up the trading system in their interests and this does not mean grafting the concepts of *jus cogens* norms or *erga omnes* obligations into trade law. Consequently, human rights norms, as collective/integral

[199] UN General Assembly, 'Yearbook of the International Law Commission 1958 Vol II: Documents of the Tenth Session Including the Report of the Commission to the General Assembly' (1958) UN Doc A/CN.4/SER.A/1958/Add.l, 27-28 arts 18-19. **See also**, UN General Assembly, 'Yearbook of the International Law Commission 1957 Vol II: Documents of the Ninth Session Including the Report of the Commission to the General Assembly' (1958) UN Doc A/CN.4/SER.A/1957/Add.l, 31 art 19(1)(iv)

[200] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 60(5)

obligations, are most likely to prevail whenever they conflict with trade obligations. The dissertation shall examine in the next sub-section whether this concept is the same within the factual hierarchy in international law.

#### 4.5.2.3 WTO System Within the Factual Hierarchy in International Law

With the advent of the WTO in 1995, the WTO system turned to be a more efficacious dispute settlement system than its predecessor (GATT dispute settlement system). A complex dispute settlement system with a robust enforcement mechanism was added to the ineffective system found in the GATT which empowered injured parties to initiate disputes proceedings against any violation of WTO obligations. Some scholars regarded it as the most effective dispute settlement system in international law.[201] Others considered it as an "extraordinary achievement that comes close to a miracle,"[202] and the most successful and most ambitious dispute settlement systems worldwide with a very high level of compliance.[203]

International law professor, Andreas Lowenfeld, depicted this system as "the most complete system of international dispute resolution in history."[204] Renato Ruggiero, the former Director-General of the WTO, described the dispute settlement system provided by the WTO DSU as "the central pillar of the multilateral trading system and the WTO's most individual contribution to the stability of the global economy. The new WTO system is at once stronger, more automatic and more credible than its GATT predecessor."[205]

By contrast, the human rights treaties are widely regarded as weak in comparison to the WTO DSU. It relies on Committees that monitor the implementation of the treaties and have the power to submit reports and recommendations but have no power to adjudicate human rights infringement or award relief. This was emphasized by Louis Henkin when he observed that

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[201] Carlos Manuel Vázquez, 'Trade Sanctions and Human Rights: Past, Present, and Future' (2003) 6(4) Journal of International Economic Law 797, 803

[202] Claus-Dieter Ehlermann, 'Six Years on the Bench of the 'World Trade Court.' Some Personal Experience as Member of the Appellate Body of the World Trade Organization' (2002) 36(4) Journal of World Trade 605, 639. **See also,** Peter Van Den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization* (3rd edn, Cambridge University Press 2013) 160

[203] John H. Jackson, 'International Economic Law: Jurisprudence and Contours' (1999) 93 American Society of International Law Proceedings 98, 102

[204] Andreas F. Lowenfeld, *International Economic Law* (2nd edn, Oxford University Press 2008) 150

[205] 'Trading into the Future' (WTO, March 2001) 38 < https://www.wto.org/english/res_e/doload_e/tif.pdf> accessed 10 June 2020

"enforcement has always been seen as the weak link in the international legal system, and it is surely the weak link of international human rights law."[206]

Indeed, the WTO dispute settlement is considered the most remarkable system of dispute settlement between WTO members concerning their rights and obligations under the WTO agreements. It has been operational for more than 25 years, during which period it has been the most prolific of all international state-to-state dispute settlement systems.[207] Since 1 January 1995 till now, 596 disputes have been brought to the WTO and over 350 rulings have been issued, making it one of the most active international dispute settlement mechanisms worldwide.[208] In contrast, the number of disputes brought to the GATT system from 1948 till 1994 were only 132.[209]

The current WTO dispute settlement system is based on the experience of trade dispute resolution within the GATT 1947. The WTO DSU stipulated that "members affirm their adherence to the principles for the management of disputes heretofore applied under Articles XXII and XXIII of GATT 1947, and the rules and procedures as further elaborated and modified herein."[210] Articles XXII and XXIII of the GATT 1947 did not include detailed rules on disputes settlement nor did they provide a detailed procedure to handle the disputes as shown previously. As such the dispute settlement under the GATT 1947 was described as "rudimentary and power-based system for settling disputes through diplomatic negotiations."[211] The current WTO dispute settlement system has succeeded in transforming the system into an "elaborate rules-based system for settling disputes through adjudication."[212] The new dispute settlement system

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[206] Louis Henkin, 'Human Rights and State sovereignty' (1996) 25 Georgia Journal of International and Comparative Law 31, 41. **See also**, Harold Hongju Koh, 'How Is International Human Rights Law Enforced?' (1999) 74(4) Indiana Law Journal 1397, 1398. **See also**, Carlos Manuel Vázquez, 'Trade Sanctions and Human Rights: Past, Present, and Future' (2003) 6(4) Journal of International Economic Law 797, 804. **See also**, International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) part IV. **See also**, International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171 (ICCPR) part IV

[207] Peter Van Den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization* (3rd edn, Cambridge University Press 2013) 156

[208] 'Dispute Settlement' (WTO) < https://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm#:~:text=The%20WTO%20has%20one%20of,350%20rulings%20have%20been%20issued> accessed 1 September 2020

[209] Peter Van Den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization* (3rd edn, Cambridge University Press 2013) 157

[210] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 3(1)

[211] Peter Van Den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization* (3rd edn, Cambridge University Press 2013) 159

[212] Ibid

under the WTO is characterized by short timeframes, compulsory jurisdiction, appellate review process and a robust enforcement mechanism.

The dissertation shall next address some features of the WTO dispute settlement system which distinguishes it from other international tribunals. It is suggested that such features created a new hierarchy of norms in international law, a factual hierarchy over and above the normative one. Such *de facto* hierarchy is responsible for placing the human rights system at lower level than the WTO system. Joost Pauwelyn suggested that, in the international legal system, "in a sense, a ''two-class society'' does exist, namely, between rules of international law that can be judicially enforced before a court with compulsory jurisdiction and those that cannot."[213] However the human rights norms are integral/collective, they are unlikely to prevail under the factual hierarchy like the situation according to the normative hierarchy.

The features are as follows;

First: One of the serious shortcomings under the GATT 1947 dispute settlement system is the positive consensus to refer a dispute to a panel, to adopt a panel report, or to authorize countermeasures as shown above. The WTO remedied this shortcoming, where the Appellate Body report is automatically adopted by the DSB unless the WTO members "decide by consensus not to adopt the Appellate Body report." Thus, the positive consensus is shifted to a reverse consensus or negative consensus rendering the DSB decisions "quasi-automatic."[214]

Second: The WTO DSU provided for standing Appellate Body (permanent judicial body) to hear appeals from the panels' reports.[215] As such, it is considered among the very few international dispute settlement mechanisms having permanent appellate court and providing for appellate review.[216] The Appellate Body has been described as "harnessing a rule of law revolution." Establishing an Appellate Body enables more judicial and formalized decision-making process and shifts the ultimate control of settling disputes from WTO members to a

[213] Joost Pauwelyn, 'The Role of Public International Law in the WTO: How Far Can We Go?' (2001) 95(3) The American Journal of International law 535, 553

[214] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 17(14). **See also**, Peter Van Den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization* (3rd edn, Cambridge University Press 2013) 159, 307

[215] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 17(1)

[216] Peter Van Den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization* (3rd edn, Cambridge University Press 2013) 231

neutral international tribunal.[217] Claus-Dieter Ehlermann described the WTO Appellate Body as a "World Trade Court."[218]

Third: The jurisdiction of the WTO Dispute Settlement System is distinct from other state-to-state settlement mechanisms, such as the International Tribunal for the Law of the Sea and the ICJ. It is a compulsory jurisdiction. The parties to a dispute arising under the WTO agreements do not have any choice but to accept the jurisdiction of the WTO dispute settlement system to adjudicate the dispute. As a matter of law enshrined in the DSU, a WTO panel has to be established upon the request of the complaining party.[219] All WTO members have to abide by such jurisdiction as a part of their consent to be members in the organization.

It is an exclusive jurisdiction. The DSU stated that the complaining party seeking "redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements" is obliged not to make any determination or to bring any of such complaints except through recourse to the WTO dispute settlement system.[220] As such, the DSU ensured the exclusivity of the WTO *vis-à-vis* other international tribunals. To be a comprehensive system of dispute resolution, the DSU provided for not only adjudication by WTO panels and Appellate Body or consultation between the parties, but also provided for alternative dispute resolution methods, particularly conciliation, mediation, arbitration, and good offices.[221]

It has only contentious jurisdiction. Unlike the ICJ and the International Tribunal for the Law of the Sea, the WTO panels and Appellate Body do not have an advisory jurisdiction. In *US-Wool Shirts and Blouses* case, the WTO Appellate Body stated that "given the explicit aim of dispute settlement that permeates the DSU, we do not consider that Article 3.2 of the DSU is meant to encourage either panels or the Appellate Body to "make law" by clarifying existing provisions of the WTO Agreement outside the context of resolving a particular dispute."[222] The

[217] Isabelle Wenger, 'Making the Dispute Settlement Understanding (DSU) Great Again' (KSLR Commercial and Financial Law Blog, 11 September 2018) <https://blogs.kcl.ac.uk/kslrcommerciallawblog/2018/09/11/making-the-dispute-settlement-understanding-dsu-great-again/> accessed 11 July 2020

[218] Claus-Dieter Ehlermann, 'Six Years on the Bench of the 'World Trade Court.' Some Personal Experience as Member of the Appellate Body of the World Trade Organization' (2002) 36(4) Journal of World Trade 605

[219] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 6(1)

[220] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 23(1)(2a)

[221] Ibid, arts 4-6, 25

[222] WTO Appellate Body Report, *United States — Measures Affecting Imports of Woven Wool Shirts and Blouses from India* (adopted 23 May 1997) WTO Doc WT/DS33/AB/R, 19

WTO dispute settlement system serves to clarify only the existing provisions of WTO agreements in the context of an actual dispute. In *EC-Commercial Vessels* case, the WTO panel refused to address a matter brought before it because it did not consider that an "abstract ruling on hypothetical future measures' was either necessary or helpful to the resolution of that dispute."[223]

Finally, although the right of recourse to the WTO dispute settlement system is restricted to WTO member states and they only have the right to initiate the procedures against breaches of WTO law, the industrial associations and companies play a prominent role in instigating their governments to bring disputes before the WTO. They are the driving force behind the initiation of dispute settlement proceedings in most cases. Not only do they lobby governments to initiate cases, they also play an important role behind the scenes in planning the legal strategy and drafting the submissions in each case.[224] As such, it could be argued that such entities have an indirect access to the WTO dispute settlement system.

The legislations of some WTO members help to entrench such indirect access by explicitly stating that such entities can bring a WTO violation, by another WTO member state, to their attention and induce the government to start the violation procedures on their behalf. In the US, for example, this possibility is provided under Section 301 of the Trade Act 1974.[225] The dissertation showed in chapter 2, the role of that Act in giving authority to the USTR to impose trade sanctions on countries denying adequate and effective intellectual property protection. Within the pharmaceutical field, for instance, the US utilized the Act to impose trade sanctions on large developing countries with pharmaceutical manufacturing capacities, like India, Argentina, South Korea and Thailand, to hinder them from developing their domestic industries and compete with the US pharmaceutical industry. This possibility is also provided by the EU law under the Trade Barrier Regulation.[226]

The WTO Appellate Body also allowed indirect access to industrial associations and companies when it stated in several cases, the possibility of their involvement in panels and Appellate Body

[223] WTO Panel Report, *European Communities – Measures Affecting Trade in Commercial Vessels* (adopted 20 June 2005) WTO Doc WT/DS301/R, para 7.30
[224] Peter Van Den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization* (3rd edn, Cambridge University Press 2013) 177-178
[225] 19 US Code § 2411, Title III ch 1, 88 Stat 2041 (Section 301 of the Trade Act of 1974)
[226] Council Regulation (EC) No 3286/94 of 22 December 1994 Laying Down Community Procedures in the Field of the Common Commercial Policy in Order to Ensure the Exercise of the Community's Rights Under International Trade Rules, in Particular Those Established Under the Auspices of the World Trade Organization [1994] OJ L349/71

proceedings as an assistant by offering information and expertise, i.e., as an *amicus curiae*. For example in *US-Lead and Bismuth II* case, the Appellate Body stated that it has the "legal authority to decide whether or not to accept and consider any information that it believe is pertinent and useful in an appeal."[227] Also, in *EC-Asbestos* case, the Appellate Body accepted "to deal with written submissions received from persons other than the parties and third parties to this dispute."[228] Further, in *EC-Sardines* case, the WTO Appellate Body agreed to accept an *amicus curiae* brief presented by Morocco which is not a party to the dispute. When the complainant Peru opposed, the Appellate Body stated that it has the "authority to receive an *amicus curia* brief from a private individual or an organization."[229]

According to the aforementioned features, the WTO dispute settlement is considered a very effective mechanism in settling disputes between member states. In a short timeframe, the WTO proceedings can ultimately result in the authorization of compensation and suspension of trade concessions.[230] Numerous international trade disputes have been brought to, and settled by the WTO mechanism either in a positive solution without formal consultation or with formal consultation without the formal establishment of a panel. Almost all the disputes that are addressed by WTO panels and Appellate Body, if appealed, result in positive solutions within a reasonable period of time after being adopted by the WTO DSB.[231]

This robust dispute settlement and enforcement mechanism enhanced trade law framework generally by improving legal certainty and fostering effectiveness and efficiency. Accordingly, the WTO dispute settlement mechanism not only led to an outstanding level of compliance, but also made the outcome of WTO proceedings determinative of state's real behaviour whenever any other regime clashes with WTO law and whatever such regime orders. This is what strengthens the WTO law position in the factual hierarchy of international law and makes it occupy a prominent position in matters of regime conflict.

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[227] WTO Appellate Body Report, *United States – Imposition of Countervailing Duties on Certain Hot-Rolled Lead and Bismuth Carbon Steel Products Originating in the United Kingdom* (adopted 7 June 2000) WTO Doc WT/DS138/AB/R, para 39

[228] WTO Appellate Body Report, *European Communities – Measures Affecting Asbestos and Products Containing Asbestos* (adopted 5 April 2001) WTO Doc WT/DS135/AB/R, para 51

[229] WTO Appellate Body Report, *European Communities – Trade Description of Sardines* (adopted 23 October 2002) WTO Doc WT/DS231/AB/R, para 164

[230] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 22

[231] James Bacchus, ' "Woulda, Coulda, Shoulda": The Consolations of WTO Dispute Settlement' (Speech to the International Bar Association, Geneva, 20 March 2003) 6 < http://www.worldtradelaw.net/articles/bacchusconsolation.pdf.download> accessed 17 June 2020

Within the WTO rules and other rules of international law, there is a huge potential for conflict since WTO rules, aiming to liberalize trade and regulate the trade relations between states, cut across all other rules of international law. Within the context of WTO and human rights, states regulations to protect human rights may impose trade barriers hindering the flow of trade. From the other side, states measures to liberalize trade may sometimes jeopardize respect to human rights.[232]

WTO negotiators were not aware of such high potential for conflict between WTO law and other regulatory systems. They included within the GATT system a method to resolve conflict of norms but failed to do so within the TRIPS agreement.

In the GATT, non-trade values are allowed to prevail over GATT rules by virtue of the security exceptions stipulated in article XXI of the GATT and the general exceptions stipulated in article XX. These provisions give states the right to adopt measures, *inter alia*, necessary to protect public morals or to protect human health.[233] Invoking these two provisions justifies a violation of a GATT obligation. Under the GATT 1947 system, usually the appeals to article XX fail because panels adopted a narrow interpretation of the article. For example, in *Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes* case, the GATT panel accepted the WHO experts' opinion stating that smoking constituted a serious risk to human health, thus it stated that the measures taken by Thailand to reduce the cigarettes consumption fell within the scope of article XX(b) of the GATT agreement. The GATT panel noted that the provision allows contracting parties to give priority to human health over trade liberalization.[234] Also, in *Unites States – Restrictions on Imports of Tuna* case, the GATT panel affirmed the rights of contracting states to protect the life and health of humans and animals by virtue of articles XX (b) and XX (g) of the GATT agreement and to regulate the consumption of exhaustible natural resources within their jurisdiction.[235]

As such, article XX of the GATT agreement provides a comprehensive exemption which justify violating any GATT obligations provided that such violation does not "constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail,

[232] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 20
[233] General Agreement on Tariffs and Trade, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187, 33 ILM 1153 (GATT 1994) arts XX- XXI
[234] GATT Panel Report, *Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes* (adopted 7 November 1990) GATT Doc DS10/R-37S/200, paras 72-73
[235] GATT Panel Report, *United States – Restrictions on Imports of Tuna* (adopted 3 September 1991) GATT Doc DS21/R - 39S/155, paras 5.22-5.34

or a disguised restriction on international trade."[236] The article offers a solution for conflicts of norms between human rights system and the trade system.

On the contrary, the TRIPS agreement did not offer such comprehensive exemption from patentability. However, it provided certain measures that seem similar to those falling within the scope of article XX of the GATT, but such measures fall short of achieving the same policy goals as in the GATT. The TRIPS excluded from patentability the commercial exploitation of an invention if it constitutes a risk to *ordre public* or morality including the protection of human life and health. However, such exclusion from patentability applies only for the commercial exploitation of the invention within the territory of the member state.[237] The dissertation demonstrated in chapter 2 that the exclusion should not be made merely because the commercial exploitation of the invention is prohibited by domestic law, rather it should be made because the marketing of the invention for profit (commercial exploitation) poses a risk to one of the stipulated policy goals in the article. The risk emanates from the patentability process *per se*, not from the marketing of the product. Thus, applying the exception in the TRIPS agreement is deemed not necessary to achieve public health goals.[238]

In article 8(1), the TRIPS provided that members may adopt measures necessary to protect public health provided that such measures are consistent with the TRIPS provisions.[239] Contrary to article XX of the GATT which provided for general exceptions for measures inconsistent with the GATT, article 8(1) is limited by the requirement that such measures should be consistent with the provisions of the TRIPS agreement. As such, the TRIPS did not create exceptions for measures that serve public policy objectives like the GATT did, but rather, article 8(1) enunciates a fundamental principle of the TRIPS agreement which has to be taken into account with its objectives when interpreting the TRIPS provisions.[240] This is even clear from the wording of the title of article 8 "Principles" unlike the wording of the title of article XX of the GATT "General Exceptions."

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[236] General Agreement on Tariffs and Trade, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187, 33 ILM 1153 (GATT 1994) art XX
[237] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 27(2)
[238] Eric M. Solovy and Pavan S. Krishnamurthy, 'TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines' (2017) 50(1) George Washington International Law Review 69, 108-109
[239] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 8(1)
[240] Peter Van Den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization* (3rd edn, Cambridge University Press 2013) 955

The dissertation also showed in chapter 2 that the TRIPS flexibilities do not provide for the exclusion from patentability. It only limits the patent rights conferred to the patentees provided that certain conditions are fulfilled.

One of the great achievements of the TRIPS agreement is that it brings intellectual property disputes under the robust WTO dispute settlement mechanism. The TRIPS stipulated that the "provisions of articles XXII and XXIII of GATT 1994 as elaborated and applied by the DSU shall apply to consultations and the settlement of disputes under the TRIPS."[241] To date, 42 disputes have been initiated under the TRIPS agreement.[242]

Consequently, the WTO system including the TRIPS agreement cannot be similar to article XX of the GATT giving preference to certain non-trade values. Therefore, the norms conflict between the TRIPS agreement and human rights norms are less likely to be solved by simply interpreting the TRIPS provisions, otherwise the result shall always be in favour of IPRs.

In essence, the factual hierarchy in international law transformed the WTO system including the TRIPS agreement to an effective system, stronger than its status under the normative hierarchy, with an outstanding level of compliance. In cases of conflict, the WTO system is more likely to prevail over human rights system since the latter under the factual hierarchy is placed at a lower level than the high level it was placed under the normative hierarchy. The previous analysis showed how robust the adjudication and enforcement mechanism of the WTO is, in comparison with the ineffective enforcement mechanism of human rights lacking an adjudicatory body. Unequivocally, states tend to show more compliance to their obligations under the WTO system and relax their obligations under the human rights system. The latter lacks an effective tool for imposing sanctions whenever there is a human rights violation, except for *jus cogens* norms.

It seems natural to grant human rights norms superiority due to the integral/universal nature of its obligations in comparison to the bilateral obligations of WTO obligations. Unfortunately, international law does not accommodate such concept. Due to the factual hierarchy created, it is very apparent that in case of conflict between human rights norms and WTO norms, states shall abide by the WTO DSB decisions. Hence, the vital question is how to accommodate human rights within the WTO system whenever there is a conflict between both regimes. The answer

[241] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 64(1)
[242] 'Disputes by Agreements' (WTO) < https://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A26> accessed 2 August 2020

to this question depends on the definition of conflict, which the dissertation shall demonstrate in the following section.

### 4.6 Conflict or Coexistence Between Accessibility to Medicines in ICESCR & Pharmaceutical Patent Protection in TRIPS

Although the subject of conflict between treaty norms was addressed long ago in the works of Hugo Grotius and Emmerich de Vattel, it did not receive much attention until the recent works of international law scholars on public international law. This is due to the limited number of regimes in public international law before the 20th century, thus conflicts were less common.[243]

The conflict of norms in international law acquired the attention of the ILC. In one of its reports concerning the difficulties arising from fragmentation of international law, the ILC realized that the fragmentation of international law creates the danger of conflict and incompatibility between rules and regimes in a way that may undermine their effective implementation. The ILC explained that the rise of new types of specialized international legal regimes named self-contained regimes, like the WTO system, created problems of coherence in international law. Each new specialized regime usually has its own principles, its own expertise, and its own ethos which may be incoherent with other regimes or with general international law rules, thus affecting the unity of the international law. The Trade law and human rights law, for example, are specialized regimes regulating certain areas, where each regime has highly specific objectives and rely on principles pointing in different directions. Therefore, the ILC study group opined that although fragmentation of international law is inevitable, there is need for a framework which unifies all rules of international law. Such framework can be provided by the rules of treaty interpretation enshrined in the VCLT.[244]

Although the ICJ has rarely addressed the issue of norms conflict in international law, it stipulated in the case of *Jurisdictional Immunity of States*, that there is no conflict when both norms address different matters.[245] Therefore, a precondition for a conflict to arise between international law norms is that the state is bound by two norms addressing the same subject

[243] Theodore Christov, 'Liberal Internationalism Revisited: Grotius, Vattel and the International Order of States' (2005) 10(6) The European Legacy 561
[244] UN General Assembly, 'Report of the International Law Commission to the General Assembly on the Work of its Fifty-Eighth Session' (2006) UN Doc A/61/10, paras 245-249
[245] *Jurisdictional Immunities of the State (Germany v Italy: Greece Intervening)* (Judgement) [2012] ICJ Rep 99, para 93

matter (*ratione materiae*). Another precondition is that both norms are applied to the same state and at the same time (*ratione personae* and *ratione temporis*).[246] As such, for a conflict to arise between ICESCR and TRIPS agreement, there should be some overlap in terms of subject matter and in terms of states parties. At least one state should be bound by the provisions of the ICESCR and the TRIPS at the same time, and both provisions should address the same subject matter.

The dissertation clearly demonstrated the link between accessibility to medicines as an integral component of the human right to health in the ICESCR and the patentability of medicines in the TRIPS agreement. It clarified that states have a minimum core obligation to immediately guarantee the accessibility, availability and acceptability of essential medicines and also to progressively realize accessibility to non-essential medicines. On the other hand, the TRIPS agreement sets out minimum standards for pharmaceutical patents protection and obliges all WTO member states to implement those standards in their national systems. States should grant patent protection to pharmaceuticals for at least 20 years as a minimum standard if they satisfy the patentability requirements as stipulated in the TRIPS agreement. Thus, both systems are addressing the same *ratione materiae*, which is conferring protection to medicines and ensuring accessibility to medicines. Also, more than 80 percent of WTO member states are also parties to the ICESCR,[247] and the two multilateral treaties are valid and still in force. This means that a huge number of states are bound by their provisions at the same time. Thus, both systems are addressing the same *ratione personae* and *ratione temporis*.

As such, the preconditions set by the ICJ for a conflict to arise are fulfilled. The dissertation shall seek to answer the last question as to the type of conflict between pharmaceutical patents in TRIPS and accessibility to medicines in ICESCR.

To do so, the dissertation shall examine the two definitions of conflict of norms in international law, namely, the strict/narrow definition and the broad/wide definition. It shall explicate that the strict definition of conflict viewed the TRIPS and ICESCR as devoid of any mutually exclusive obligations, thus the two treaties do not conflict with each other. However, the broad definition of conflict realized that frustrating the goals of the ICESCR by the TRIPS due to the factual

[246] Joost pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 164-165. **See also**, Hans Morten Haugen, 'Patent Rights and Human Rights: Exploring their Relationships' (2007) 10(2) World Intellectual Property Journal 97, 102
[247] 'Members and Observers' (WTO) < https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm> accessed 1 July 2020. **See also,** 'International Covenant on Economic, Social and Cultural Rights' (UN Treaty Collection, 12 May 2021) < https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-3&chapter=4&clang=_en> accessed 12 May 2021

hierarchy created by the WTO agreement leads to a conflict between both treaties. Accordingly, the dissertation shall adopt the broad definition since it identifies the appropriate type of conflict between pharmaceutical patents and accessibility to medicines.

If the dissertation addresses only the strict/narrow definition of norms conflict, then it would conclude from the beginning that invoking the TRIPS flexibilities would prevent any conflict since there is no direct incompatibility between the norms of TRIPS and ICESCR. However, to focus only on the strict definition of conflict means to ignore the complexity of the interface between pharmaceutical patents and accessibility to medicines. As Pauwelyn stated, this "essentially solves part of the problem by ignoring it."[248]

Therefore, for a better understanding of the study, the dissertation had to conduct an in-depth analysis of the development of the structure of international law norms and the impact of the fragmentation phenomenon on WTO law and human rights norms. The *de facto* hierarchy created by the WTO agreement, as a result of fragmentation, constitutes a conflict between both regimes according to the broad/wide definition of conflict of norms in international law.

It is worth clarifying the functions of norms in international law to provide a better understanding of the two definitions of conflict when examining them.

Pauwelyn and Hans Kelsen categorized almost all norms in international law according to their functions into four categories. The first two categories are obligations. Either norms imposing positive obligations on states to do something, which are called commands, or norms imposing negative obligations on states not to do something, which are called prohibitions. The second two categories are rights. Either norms granting states the right to do something, which are called permissions, or norms granting states the right not to do something, which are called exemptions.[249] The obligations imposed, or the rights conferred upon states may also be imposed or conferred upon other subjects of international law, *inter alia*, international organizations. However, for the purpose of this dissertation, only the rights and obligations in relation to states will be addressed.

[248] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 167, 171

[249] Ibid, 158-159. **See also**, Hans Kelsen, *General Theory of Norms* (Clarendon Press UK 1991) chapter 1

### 4.6.1 The Strict/Narrow Definition of Conflict in International Law

Wilfred Jenks was the first to adopt the strict definition (traditional view) of conflict in 1953. He expressed that "a conflict in the strict sense of direct incompatibility arises only, where a party to the 2 treaties cannot simultaneously comply with its obligations under both treaties."[250] Other divergences, according to Jenks, are not considered conflicts even if they "defeat the object of one or both of the divergent instruments" or "they prevent a party to both of the divergent instruments from taking advantage of certain provisions of one of them."[251]

Although Jenks recognized that in some cases such divergences are as serious as conflicts, he insisted on the strict definition of conflicts. In his opinion, there is no conflict when "one instrument eliminates exceptions provided for in another instrument, or conversely relaxes the requirements of another instrument," even if the "practical effect of the coexistence of the 2 instruments makes one of them loses much or most of its practical importance."[252]

Many authors, *inter alia*, Wolfram Karl, Hans Kelsin, and Klein, followed Jenks in adopting the strict definition of conflicts as only covering mutually exclusive obligations.[253] Wolfram Karl mentioned that "technically speaking, there is a conflict between treaties when two or more treaty instruments contain obligations which cannot be complied with simultaneously."[254] Similarly, Kelsen and Klein adopted the narrow definition of conflict covering only mutually exclusive obligations. They excluded any incompatibility between rights, either permissions or exemptions, and obligations.[255]

Gabrielle Marceau, a senior legal councillor in the WTO, defended Jenks' strict definition of conflict by arguing that the strict definition supports the coherence of the international legal order and the general principle of good faith which obliges states to interpret and apply conflicting norms in a manner that promote their harmonization. Further, she contended that the strict definition of conflict keeps as much as possible, the agreement of the parties since the

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[250] Clarence Wilfred Jenks, 'The Conflict of Law-Making Treaties' (1953) 30 British Yearbook of International Law 401, 426
[251] Ibid
[252] Ibid, 426-427
[253] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 104
[254] Wolfram Karl, 'Conflicts Between Treaties' in Rudolf Bernhardt (ed), *Encyclopedia of Public International Law*, Vol 7 (North Holland, 1984) 467, 468; cited in Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 167
[255] Erich Vranes, 'The Definition of 'Norm Conflict' in International Law and Legal Theory' (2006) 17(2) The European Journal of International Law 395, 402. **See also**, Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 167

main objective of interpretation is to identify the intention of the parties to an agreement. Moreover, she referred to the WTO adjudicating bodies' reports to show that in most WTO cases, (examples of such cases shall be demonstrated shortly), the WTO adjudicating bodies interpreted WTO provisions in a way that avoid conflict with other international obligations of WTO members. This implies that the WTO adjudicating bodies favour the strict definition of conflict, where they limit conflicts to cases containing irreconcilable conflicts.[256]

Marceau noted that the WTO panels and Appellate Body are prohibited from adding to or diminishing the rights and obligations provided in the covered WTO agreements. This would impede their capacity to conclude that a provision in another treaty prevails over a WTO provision. As such, they would apply the strict definition in order to avoid, as much as possible, cases of conflicts with other international law provisions.[257]

It follows logically from Marceau's point of view that whenever a multilateral agreement authorizes its members to use trade restrictions which is prohibited under WTO agreements, i.e., a tension between an obligation (prohibition) and a right (permission), there would be no conflict according to the strict definition. In such case, the conflict could be avoided by simply not exercising the permission, thus the strict definition "will often favour the most stringent obligations."[258]

The ILC in one of its reports about fragmentation of international law emphasized that conflicts could be strictly, or more widely interpreted. It stated that "a strict notion would presume that conflict exists if it is possible for a party to two treaties to comply with one rule only by thereby failing to comply with another rule."[259] Such strict definition reflects the traditional unduly narrow understanding of conflict between norms in international law. It establishes a high threshold for identifying a conflict since it requires a direct incompatibility between treaties provisions.[260]

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[256] Gabrielle Marceau, 'Conflicts of Norms and Conflicts of Jurisdictions: The Relationship Between the WTO Agreement and MEAs and Other Treaties' (2001) 35(6) Journal of World Trade 1081, 1082-1083, 1086

[257] Ibid, 1082. **See also,** Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 19

[258] Gabrielle Marceau, 'Conflicts of Norms and Conflicts of Jurisdictions: The Relationship Between the WTO Agreement and MEAs and Other Treaties' (2001) 35(6) Journal of World Trade 1081, 1085-1086

[259] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising From the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 24

[260] Hans Morten Haugen, 'Patent Rights and Human Rights: Exploring their Relationships' (2007) 10(2) World Intellectual Property Journal 97, 102

The WTO panels in *Indonesia - Automobile Industry*, *Turkey - Textiles*, and *Guatemala - Cement* cases recognized that conflicts exist between two treaties when their provisions impose mutually exclusive obligations. They adopted the strict definition of conflict which matches the presumption against conflicts in public international law.

This presumption was adopted by many WTO panels and Appellate Body in which parties do not normally intend to incur conflicting obligations. It is a principle embodied in the VCLT which requires interpretation of treaties "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose." This presumption is relevant in the WTO context since all WTO agreements were negotiated at the same time by the same members and in the same forum. Thus, according to the principle of effective interpretation, all provisions of WTO agreements should be given meaning using the ordinary meaning of words. Any interpretation of WTO provisions that would lead to a conflict between them should be avoided.[261]

In *Indonesia - Automobile Industry* case,[262] a claim was brought against Indonesia from European Communities, Japan and the US under the national treatment provision of the GATT (article III). Indonesia defended by stating that it is a developing country and has a right (permission) to provisionally maintain certain subsidies under the WTO Agreement on Subsidies and Countervailing Measures. The WTO panel referred to the writings of Wilfred Jenks and Wolfram Karl in addition to others adopting the strict definition of conflict in international law. It concluded that the obligations in the GATT and the WTO Agreement on Subsidies and Countervailing Measures are not mutually exclusive, thus it was possible for Indonesia to practice its rights under the latter without violating its obligations under the first. The panel stated that a conflict exists only when "two (or more) treaty instruments contain obligations which cannot be complied with simultaneously."[263] Thus, the panel limited conflicts in situations of mutually exclusive obligations, excluding the possibility of conflicts occurring between obligations and permissions. The practical consequence is that the panel did not even

[261] WTO Panel Report, *Indonesia - Certain Measures Affecting the Automobile Industry* (adopted 23 July 1998) WTO Doc WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R, paras 5.349, 14.28, 14.49. **See also**, WTO Panel Report, *Turkey - Restrictions on Imports of Textile and Clothing Products* (adopted 19 November 1999) WTO Doc WT/DS34/R, paras 9.93 - 9.95, footnote 324. **See also**, WTO Appellate Body Report, *Canada - Certain Measures Concerning Periodicals* (adopted 30 July 1997) WTO Doc WT/DS31/AB/R, para 3.42. **See also**, Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 31(1)

[262] WTO Panel Report, *Indonesia - Certain Measures Affecting the Automobile Industry* (adopted 23 July 1998) WTO Doc WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R

[263] Ibid, paras 14.28 footnote 649, 14.99

examine whether the permission invoked by Indonesia constitutes *lex specials* that would prevail in such case. In other words, the panel refused to address the claim of Indonesia because it did not consider situations of conflict except those occurring due to the strict definition of conflict.[264]

In *Turkey - Textiles* case,[265] India challenged the quantitative restrictions imposed by Turkey on Indian textiles and clothing after the formation of custom union between European Communities and Turkey. The latter defended by stating that such quantitative restrictions did not violate neither the GATT provisions nor the WTO Agreement on Textiles and Clothing. Turkey was of the view that such restrictions were justified by the GATT rules as "*lex specialis* for the rights and obligations of WTO members at the time of formation of a regional trade agreement," i.e., the restrictions were consistent with Turkey – European Communities custom union.[266] The WTO panel also referred to the writings of Wilfred Jenks regarding the strict definition of conflict. It stated that "a conflict of law-making treaties arises only where simultaneous compliance with the obligations of different instruments is impossible. There is no conflict if the obligations of one instrument are stricter than, but not incompatible with, those of another, or it is possible to comply with the obligations of one instrument by refraining from exercising a privilege or discretion accorded by another."[267] After analysing the GATT articles invoked by Turkey, *inter alia*, article XXIV, the panel concluded that it does not permit a departure from the relevant obligations prescribed in the Agreement of Textiles and Clothing and in the GATT. Thus, the panel refused Turkey's claim due to the denial of an existing conflict. The panel was of the view of the presumption against conflicts, where any interpretation of WTO provisions that would lead to a conflict between them should be avoided.[268]

Also, in *Guatemala - Cement* case, the Appellate Body adopted the strict definition of conflict when it viewed that the *lex specialis* provision can prevail over a WTO DSU provision only in a situation where "adherence to one provision will lead to a violation of the other provision, i.e., in the case of a conflict between them." Thus, there must be an inconsistency or a difference between both provisions before concluding that the *lex specialis* rule prevails and the DSU

[264] Erich Vranes, 'The Definition of 'Norm Conflict' in International Law and Legal Theory' (2006) 17(2) The European Journal of International Law 395, 400
[265] WTO Panel Report, *Turkey - Restrictions on Imports of Textile and Clothing Products* (adopted 19 November 1999) WTO Doc WT/DS34/R
[266] Ibid, para 9.88
[267] Ibid, para 9.92
[268] Ibid, paras 9.95, 9.97, 9.188, 9.189, 9.192

provision does not apply.[269] It is worth noting, as Pauwelyn mentioned, that the terms "conflict" and "inconsistency" can be used interchangeably in the context of conflict of norms in international law. Both terms can be reduced to "one norm being, having led, or potentially leading to a breach of the other."[270]

According to Jenks' strict definition of conflict, a conflict can only arise between the provisions of the TRIPS agreement and the ICESCR if their obligations are mutually exclusive, where a party to the two treaties cannot simultaneously fulfil its obligations regarding pharmaceutical patents without violating its obligations regarding the right to access to medicines, and vice versa.

It is clear that both treaties do not contain mutually exclusive obligations since they allow states parties to utilize a number of flexibilities in the manner of implementation. The dissertation showed in chapter 3 that the ICESCR grants states parties certain measure of discretion in the implementation of human right to health. The ICESCR introduced the minimum core obligations to ensure minimum essential levels of each human right, while the full realization of the right is subject to the financial status of each state. Also, the TRIPS agreement provides substantial flexibilities, assuming that they are sufficient, in the application of intellectual property with a view to protect public health as the dissertation showed in chapter 2. This was emphasized by the Doha Declaration stating that WTO members have the right to use the exceptions and flexibilities in the TRIPS agreement to balance between pharmaceutical patenting and the accessibility to medicines.

Consequently, under the strict definition of conflict of norms, states can simultaneously comply with their obligations in both treaties by simply following the obligation, either command or prohibition, and not invoking the permission or the exemption (flexibility). However, this makes the permission or the flexibility useless, thereby running counter to the principle of effective interpretation stating that every provision of a treaty should be given meaning using the ordinary meaning of words.

Furthermore, the TRIPS agreement permits states to use certain flexibilities, either ex-ante or ex-post as shown in chapter 2, in order to limit the states' obligations regarding pharmaceutical

[269] WTO Appellate Body Report, *Guatemala - Anti-Dumping Investigation Regarding Portland Cement from Mexico* (adopted 25 November 1998) WTO Doc WT/DS60/AB/R, para 65
[270] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 190

patents with the proviso that certain conditions are met. Such permission to make use of the flexibilities, conceptually, constitutes both a right to use them and a right not to use them. In other words, it is an option to invoke the flexibilities when needed; it is not an obligation to use them. The dissertation proved early in this chapter that pharmaceutical patents in developing countries unjustifiably interfere with access to medicines. Thus, developing countries could only escape from violating their human rights obligations to ensure accessibility and affordability to medicines by making use of the exceptions, assuming that such flexibilities are sufficient, albeit they are not. Hence, the right of the state, according to its discretion, to use the permission (flexibilities) or not to use them had turned out to be an obligation to invoke them. This is a conflict *per se* between patents and human right to health because the obligation to use the flexibilities nullifies the right of the state not to use the flexibilities, i.e., a conflict between an obligation to use and a right not to use according to the wide definition of conflict as shall be illustrated in the following sub-section. However, according to the strict definition of conflict, this is not a conflict since conflicts arise only between mutually exclusive obligations. As Pauwelyn indicated, adopting the strict definition of conflict would mean, then, that the WTO agreements elevate the obligations of WTO members over and above their rights.[271] Such analysis explicates the argument presented in the introduction of this chapter showing that the TRIPS flexibilities constitute *per se*, before assessing its effectiveness, a conflict between the patent system in TRIPS and the right to health according to the definition of norms conflict in public international law. The nature of the TRIPS flexibilities are obligations to utilize them rather than a right to invoke them whenever needed.

Furthermore, the strict definition ignores the fact that the factual hierarchy of the TRIPS, as one of the WTO agreements, undermines or frustrates the object and purpose of the ICESCR because the factual hierarchy suggests ways to deal with the subject matter, (medicines), differently, and arguably contradictory, than that suggested under the normative hierarchy.

To put it practically, patents increase the prices of pharmaceuticals rendering them unaffordable and inaccessible to a large number of people in developing countries. All States are obliged to comply with the TRIPS obligations and to confer patent protection to pharmaceuticals, whether products or processes, for a minimum of 20 years. However, complying with the TRIPS provisions may constitute a breach, either to the right to health under the ICESCR or the right

[271] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 197-198

to life under the ICCPR, assuming that the right to access to life-saving medicines as an element of the right to life in the ICCPR reaches the status of *jus cogens* norms as previously argued in chapter 3. The price increase of pharmaceuticals due to patenting negatively affect the capabilities of developing countries to abide by their obligations, either under the ICESCR to ensure the accessibility to affordable essential medicines, or under the ICCPR to guarantee the accessibility of life-saving medicines to all people as a part of their obligation to safeguard the right to life. According to the strict definition of conflict, there shall be no conflict since conflicts arise only in case of mutually exclusive obligations. The TRIPS flexibilities in this case, assuming that they are sufficient, provide curve outs that could be invoked to prevent the conflict between both regimes. However, the flexibilities, as shown above, are not obligations but rather rights. So, applying the strict definition entails that the conflict could be avoided by simply not exercising the flexibility (permission) or at least relax it. This solution ignores the complexity of the interface between pharmaceutical patents in TRIPS and accessibility to medicines. Recalling Pauwelyn's statement above, this "essentially solves part of the problem by ignoring it."[272]

Moreover, other objections have been directed towards the strict definition of conflicts. They are as follows:

First: According to the strict definition, there is no conflict between an obligation, either a command or a prohibition, and a right to do something (permission). The strict definition identifies conflict between two treaties only when their provisions impose mutually exclusive obligations. As such, it resolves several contradictions in favour of the strictest norm, i.e., the obligation, by simply adhering to the obligation and not invoking the permission. In such situation, the alleged conflict is not solved by identifying a rule to solve conflicts but by the very definition of conflict. In some cases, it is necessary to allow the more lenient rule to prevail, i.e., the permission, if it constitutes a *lex specialis* for instance or *lex posterior*.[273] These principles are mentioned in the VCLT as tools to solve conflict of norms in international law (conflict-solving techniques). They are described as "devices for approximating the probable intentions of the contracting parties on the basis of objective factors (time and specialty)." As such, it seems problematic to restrict the scope of conflicts on obligations and exclude other contradictions between permissions, constituting *lex specialis* or *lex posterior*, and obligations

[272] Ibid, 171
[273] Ibid, 170-171, 174

by simply not allowing the permissions to prevail. This runs counter to the basic principle stating that international norms have to be interpreted in a way that does not reduce them to inutility.[274]

Second: Applying the strict definition of conflict may violate article 30 of the VCLT which provides for *lex posterior derogat legi priori*. The strict definition of conflict allows an earlier treaty imposing a prohibition to prevail over a later one granting a permission since it denies the existence of a conflict in this situation. However, it may be the intention of the states to conclude a later treaty with permissions to overrule or to detract from an earlier one with a prohibition.[275]

Third: Applying the strict definition of conflict may violate articles 53 and 64 of the VCLT stipulating that any treaty conflicting with a *jus cogens* norm shall be voided. Contrary to these articles, the strict definition of conflict may allow a treaty conflicting with a *jus cogens* norm to be applied if the norms of the treaty and the *jus cogens* norm are not mutually exclusive. This is the case when a permission in a treaty conflicts with a prohibition in a *jus cogens* norm. According to the VCLT, the treaty is void due to conflict with a *jus cogens* norm. However, under the strict definition, there would be no conflict since there is no obligation on the state to apply the permission under the treaty. Hence, there would be no conflict by not exercising the permission in the treaty. According to the strict definition, conflicts arise only when there are mutually exclusive obligations.

Pauwelyn gave an example of a treaty between states permitting trade in slaves without an obligation to do so. According to the strict definition of conflict, there would be no conflict with the *jus cogens* norm prohibiting trade in slaves because the treaty does not oblige states to engage in the slave trade. So, there is no mutually exclusive obligations and the apparent conflict, according to the strict definition, can be solved by not exercising the permission in the treaty. If the treaty contains an obligation to trade in slaves, then there would be a conflict with the *jus cogens* norms according to the strict definition.[276] This deprives *jus cogens* norm of its meaning and runs counter to articles 53 and 64 of the VCLT which void any treaty norm, whatever its function, if it conflicts with a *jus cogens* norm of general international law. Therefore, in the example, the treaty norm allowing states to trade in slaves has to be voided from the beginning.

[274] Erich Vranes, 'The Definition of 'Norm Conflict' in International Law and Legal Theory' (2006) 17(2) The European Journal of International Law 395, 404
[275] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 174
[276] Ibid, 173-174

Fourth: International law authors adopting the strict definition of conflict consider conflicts as an imperfection in the international legal system, so they try to avoid their occurrence. Therefore, they defined conflicts strictly in order to cover only situations where the legal system does not offer lucid solutions to the apparent contradiction. However, recognizing conflicts only when they cannot be resolved confuses the definition of conflict with the tool available to resolve it. One conflict may be easily solved, while another may be impossible. Clear rules have to be established to solve conflicts rather than assuming from the beginning that there is no conflict.[277]

Fifth: International authors adhering to the strict definition of conflict justify their view according to the domestic law, where obligations either, commands or prohibitions, imposed by the state prevail over individual rights, either permission or exemption. However, transposing domestic law principles into international law is erroneous. Whereas in domestic law, an individual cannot contract out of any obligation by exercising his rights, in international law, states have the power to detract from their previous obligations by concluding agreements in order to grant each explicit rights (permissions or exemptions).[278] Unlike domestic law, international law recognizes instances of conflict between obligations and rights. The resolution of such instances does not depend on the nature of the norm, but rather, it depends on other principles that resolve conflicts in international law, *inter alia*, the principles of *jus cogens*, *lex specialis*, *lex superior*, and *lex posterior* as mentioned in the VCLT.

Sixth: The WTO panels and Appellate Body adopting the strict definition of conflict regarded the presumption against conflicts in international law as a technique to avoid conflicts, where the conflict occurs only if the presumption fails. However, the application of such presumption shows that this approach is circular. Applying the presumption means that the interpretation that has to be chosen is that which provides for no conflict between the two international norms in question. It implies also, as a starting point, that the two norms in question have to be considered as consistent and the burden of proof lies on the party who claims otherwise.[279] Thus, the

[277] Ibid, 173
[278] Emer de Vattel, *Natural Law and Enlightenment Classics: The Law of Nations, Or, Principles of the Law of Nature, Applied to the Conduct and Affairs of Nations and Sovereigns, With Three Early Essays on the Origin and Nature of Natural Law and on Luxury* (Knud Haakonssen, Béla Kapossy and Richard Whatmore eds, Liberty Fund Indianapolis 2008) 443, 445 < http://files.libertyfund.org/files/2246/Vattel_1519_LFeBk.pdf> accessed 22 June 2020
[279] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 240-244

presumption is activated only when a conflict exists. Meanwhile, before it can be determined that there is a conflict, the presumption should be applied. A circular paradoxical situation.

Seventh: The WTO is a multilateral agreement with obligations and equally important rights. It has to take into account both the WTO member states' obligations to ensure trade liberalization, and also their legitimate interests which justify their right to restrict trade. Thus, the obligations to liberalize trade should be equal to the right to restrict trade. The first cannot systematically prevail over the second according to the strict definition of conflict which ignores the existence of a conflict in such situation by simply adhering to the obligation and relaxing or not invoking the right. This implies that, under the strict definition, all WTO obligations are given their full meaning, whereas the WTO rights are not. As such, they are consistently overruled by contradictory obligations.[280] As previously noted, this concept ignores the existence of other types of conflicts and recognizes only conflicts between two mutually exclusive obligations. In other words, it ignores the complexity of the potential forms of interactions between international norms. In an indication that the rights and obligations in the WTO agreements should be equally considered in norms conflict, the WTO Appellate Body stressed that the negotiated language of the WTO agreements "reflects an equally carefully drawn balance of rights and obligations of members."[281]

Finally: The dissertation refers to Erich Vranes' criticism to the arguments derived by Gabrielle Marceau, illustrated above, to defend the strict definition of conflict of norms. He highly doubted that the international legal order would be more coherent by neglecting as much as possible, situations of conflict and restricting it only on mutually exclusive obligations. Further, he opposed the argument that the strict definition is necessary to keep, as much as possible, the agreement of the parties which reflects their intention. It seems impossible, as Vranes mentioned, to see why automatically subordinating permissions to obligations better conforms to the intention of the parties. Moreover, he refuted the argument of effective interpretation to justify the strict definition of conflicts. Vranes stated that "the effective interpretation is a two-edged device" requiring first to give reasons for choosing one norm to be interpreted narrowly,

[280] Ibid, 198-199

[281] WTO Appellate Body, *United States - Restrictions on Imports of Cotton and Man-Made Fibre Underwear* (adopted 25 February 1997) WTO Doc WT/DS24/AB/R, 15. **See also**, WTO Appellate Body, *United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India* (adopted 23 May 1997) WTO Doc WT/DS33/AB/R, 16

while the other is interpreted extensively. Hence, the suitability of the effective interpretation principle as a sufficient device for avoiding conflict is doubtful.[282]

It is clear from the previous analysis that the strict/narrow definition of conflict limits cases of conflicts to mutually exclusive obligations, whether commands or prohibitions, neglecting cases of conflicts between obligations and rights. Accordingly, a norm granting states the right to restrict trade, for example for public health, would not conflict with another norm obliging states to liberalize trade. Simply, the obligation shall prevail over the right.

Also, there is no conflict when two WTO norms impose different commands on states to liberalize trade and one of them is stricter than the other, since they are not mutually exclusive. The one with stricter obligation shall be applied. This leads to predetermined solutions to conflict even before identifying the conflict. As such, many international law authors, including Pauwelyn, rejected the strict definition and opted for a broad/wide definition.

### 4.6.2 The Broad/Wide Definition of Conflict in International Law

Several authors have explicitly opted for a wider definition of norms conflict to avoid the outcomes of the strict definition. As shown above, the strict definition leads to contradictions since it excludes the existence of conflicts between obligations and permissions.

Hans Aufricht, for example, adopted the wide definition of conflict which encompasses divergences between obligations and permissions. He opined that "a conflict between an earlier and a later treaty arises if both deal with the same subject matter in a different manner."[283] Similarly, Erich Vranes argued that the wide definition of conflict of norms is the appropriate one since it relies on the test of violation. He was of the view that a conflict between norms occur "if in obeying or applying one norm, the other norm is necessarily or potentially violated."[284] Also, Sir Humphrey Waldock, the former special rapporteur on the law of treaties,

[282] Erich Vranes, 'The Definition of 'Norm Conflict' in International Law and Legal Theory' (2006) 17(2) The European Journal of International Law 395, 405
[283] Hans Aufricht, 'Supersession of Treaties in International Law' (1952) 37(4) Cornell Law Review 655, 655-656
[284] Erich Vranes, 'The Definition of 'Norm Conflict' in International Law and Legal Theory' (2006) 17(2) The European Journal of International Law 395, 418

held a broad view of conflict noting that two treaties are said to be in conflict if "their clauses or some of them could not be reconciled with one another."[285]

Koskenniemi, the chairman of the ILC study group on fragmentation of international law, also favoured the broad definition of conflict. He noted that conflicts not only exist in situations of direct incompatibility between two obligations, but also exist in other situations when one treaty frustrates the goals of another. The strict definition neglected the fact that "two treaties or sets of rules may possess different background justifications or emerge from different legislative policies or aim at divergent."[286]

To justify adopting the broad definition of conflict, the ILC drew an illustrative example including trade law and human rights law as two sets of rules emerging from different types of policy. Applying only the strict definition of conflict, i.e., limiting the situation of conflict to two norms imposing mutually exclusive obligations, ignores other situations of conflict that exist "without there being any strict incompatibility" between both norms. This is when a treaty norm frustrates the goals of another treaty or when two norms "suggest different ways of dealing with a problem."[287]

Pauwelyn also criticized the strict notion which limited cases of conflicts to mutually exclusive obligations. He argued that focusing on one type of conflicts only ignores the complexity of the potential forms of interactions between norms.[288] He opted for the wider definition, where two norms are in conflict "if one constitutes, has led to, or may lead to, a breach of the other."[289] Pauwelyn identified all possible situations that could raise questions of conflicts. His opinion is that "no situation should be excluded *a priori* from the field of conflict of norms, otherwise one risks solving a conflict by not realizing that there is one."[290] Thus, he referred to 4 situations of conflicts including those identified under the strict definition. The 4 situations are: 1- Conflicts between two commands, either merely different (A) or mutually exclusive (B). 2- Conflicts

[285] UN General Assembly, 'Yearbook of the International Law Commission 1964 Vol I: Summary Records of the Sixteenth Session' (1965) UN Doc A/CN.4/SER.A/1964, 125
[286] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 24
[287] Ibid, paras 24-25
[288] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 170-171
[289] Ibid, 175-176
[290] Ibid, 176

between a command and a prohibition. 3- Conflicts between a command and an exemption. 4- Conflicts between a prohibition and a permission.[291]

Pauwelyn demonstrated that situations of conflict between mutually exclusive commands (situation 1 B) or between a command and a prohibition (situation 2) are considered necessary conflicts. In both situations only, it is impossible for one state to comply with both norms at the same time, i.e., compliance with one norm leads to breaching the other. Such conflicts meet the requirements of conflicts according to the strict definition since it restricted conflicts on mutually exclusive obligations, either commands or prohibitions. There are no examples of such situations within the WTO rules for the reasons which shall be illustrated in the following paragraph. On the other side, the conflict is potential in situations of conflict between two norms imposing commands that are merely different but not mutually exclusive (situation 1 A), between a command and an exemption (situation 3), or between a prohibition and a permission. In such situations, if the states decided to exercise the rights granted to them, upon their discretion, a breach of the obligations occur, leading to a potential conflict. According to the strict definition of conflict, situations of potential conflict are not considered conflict.[292]

As explained previously, according to the strict definition, the situations of two norms imposing merely different commands, but not mutually exclusive, are not considered conflicts since the norm imposing the stricter command shall be applied. Also, the obligation, either a command or a prohibition, shall prevail over the right according to the strict definition. For example, a WTO norm obliging states to confer patent protection for a minimum of 20 years, while another WIPO rule obliges states to confer patent protection for a minimum of 15 years only. Although both norms are imposing different commands, they are not mutually exclusive. Under the strict definition, states can comply with both norms by granting patent protection for 20 years, thus applying the stricter command without breaching the other. Another example is where a WTO norm prohibits states from imposing trade restrictions, while another WTO norm is granting states the right to restrict trade in certain circumstances, *inter alia*, public health. Under the strict definition, there would be no conflict. Simply the obligation not to restrict trade shall prevail over the right to restrict it. This leads to predetermined solutions to a conflict even before identifying its existence. States may wish to exercise the rights granted to them or to comply

[291] Ibid, 179
[292] Ibid, 175-188

with the more lenient norm rather than the strict one. That is why the broad definition of conflict is favoured in such situations.

Within the WTO regime, necessary conflicts are rarely identified since almost all WTO norms are about negative integration (prohibitions) rather than positive harmonization (commands).[293] The TRIPS agreement is considered the only WTO agreement that includes commanding obligations, for instance the provisions obliging states to confer patent protection for at least 20 years counted from the filing date, or to confer copyright protection for not less than 50 years from the end of the calendar year of authorized publication.[294]

To elaborate the previous issue, almost all WTO norms are prohibitions (negative obligations) to restrict trade, like the MFN treatment or the national treatment on internal taxation. The GATT prohibits WTO members from discrimination regarding like products of different WTO members or between imported products and like ones.[295] Only very few WTO norms impose commands and they are related to procedural or institutional rules, like the commands of the WTO panels and Appellate Body recommending members to bring measures into conformity with the WTO agreements or the commands about time-frames for WTO DSB decisions to be respected.[296] There are no WTO norms imposing commands on WTO members to restrict trade, but rather they grant conditional rights to restrict trade when certain requirements are fulfilled, like the general exception clause in the GATT giving states the right to adopt or enforce measures that restrict trade in order to protect human health, provided that all the requirements stipulated in the clause are met, *inter alia*, non-discrimination and necessity.[297]

As such, WTO norms have two functions: A permissive function as they grant the right to restrict trade due to health reasons; and at the same time a prohibition function since they prohibit states from exercising the previous right if it constitutes any means of "arbitrary or unjustifiable discrimination between countries" or a "disguised restriction on international

[293] Ibid, 160, 161, 183, 184
[294] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) arts 12, 33. **See also**, Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 108
[295] General Agreement on Tariffs and Trade, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187, 33 ILM 1153 (GATT 1994) arts I, III
[296] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) arts 19(1), 20
[297] General Agreement on Tariffs and Trade, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187, 33 ILM 1153 (GATT 1994) art XX(b)

trade."[298] Consequently, if the prohibition part is not met, then the permissive part cannot be activated and the initial prohibition (negative obligation) not to restrict trade prevails. The fact that most WTO provisions include prohibitions explains why it is considered a system of negative obligations. Accordingly, WTO regime does not identify necessary conflicts since such type of conflicts require norms of the command type that are rarely found within the WTO system, except for TRIPS agreement which contains few commanding obligations as demonstrated above.

By favouring the stricter command or the prohibition, the strict definition of conflict runs counter to the object and purpose of the WTO agreements which express the drafters' intentions to create rights and obligations.[299] States may wish to exercise the rights granted to them or to comply with the more lenient norm rather than the strict one, thus all WTO norms should be given their full meaning. The obligations to liberalize trade should be equal to the rights to restrict trade. That is why the broad definition of conflict is favoured in such situations because it realizes the existence of a conflict before suggesting a solution to it.

Within the context of the TRIPS agreement and the right to health in ICESCR, the former imposes commanding obligations on states to grant patent protection for a certain period by making their domestic laws comply with the TRIPS provisions. Meanwhile the latter also imposes commanding obligations on states to ensure the availability, accessibility, acceptability of medicines in good quality. Consequently, two commands are found that may produce either necessary conflict if they are mutually exclusive (situation 1 B) or potential conflict if the two commands are merely different but not mutually exclusive (situation 1 A) according to the broad definition of conflict.

Whether there is a necessary or potential conflict in the case of TRIPS and ICESCR lies in the demonstration that compliance with TRIPS commands necessitates violation of human right to health commands. For a necessary conflict to occur, such demonstration has to show that they are mutually exclusive commands. It has been demonstrated that both regimes do not contain mutually exclusive obligations due to the TRIPS flexibilities that could be invoked in the manner of implementation. Therefore, there is no necessary conflict between both regimes, but rather a potential one which is only identified under the broad definition of conflict.

[298] Ibid, art XX
[299] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 191-192

Under the strict definition, as previously noted, potential conflicts between TRIPS and the right to health are not considered conflicts. Simply, the TRIPS provisions of the command type shall prevail over the flexibilities provisions that grant states the right to restrict patents for public health considerations; or in situations of two norms imposing merely different commands, but not mutually exclusive, the stricter command of the TRIPS agreement shall be applied.

Apart from Pauwelyn's theory of necessary and potential conflicts, another kind of conflicts called systemic conflicts could be recognized between the TRIPS and the right to access to medicines according to the broad definition of conflict. Systemic conflicts reflect the clash between the underlying principles or goals deeply rooted in each regime, rather than focusing merely on norms conflicts. The existence of the TRIPS flexibilities, assuming that they are effective, albeit they are not, allowing states to take certain measures in order to promote and protect the right to health may not preclude the conflict between TRIPS and the right to access to medicines. It is not an indication, *per se*, that the TRIPS agreement takes a human rights approach to pharmaceutical patent protection because there are fundamental differences between the approaches of IPRs and human rights to the TRIPS agreement.[300] The High Commissioner on the Impact of the TRIPS agreement on Human Rights highly asserted this view in one of his reports, where he doubted that "the TRIPS strikes a balance that is consistent with human rights," regardless of the TRIPS flexibilities.[301]

The intellectual property approach to the TRIPS agreement is that the agreement induces innovation through commercial incentives, where it puts the promotion of public health as an exception to its provisions rather than a guiding principle to its rules. Meanwhile, the human right to health approach to the TRIPS explicitly places the promotion and protection of human health at the heart of the objectives of the TRIPS, rather than only a permission to the states to utilize certain flexibilities or exceptions in specific situations, i.e., subordinating such flexibilities or exceptions to other TRIPS provisions.

To illustrate the difference, a human rights approach to the TRIPS agreement might set out a minimum core obligation in the TRIPS agreement to protect human right to health against pharmaceutical patenting. This would be similar to the requirement under article 15 of the

[300] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016) 193. **See also**, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 180

[301] UN Sub-Commission on the Promotion and Protection of Human Rights, 'Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual property Rights on Human Rights' (27 June 2001) UN Doc E/CN.4/Sub.2/2001/13, paras 21-22

ICESCR to balance the moral and material interests of the inventor in his inventions with the right to enjoy the benefits of scientific progress and its applications. However, this is not found in the TRIPS agreement, where it achieves only the intellectual property approach by setting out only minimum standards for patent protection. As such, it is inevitable to recognize a conflict between the object and purpose of both treaties, although they are not conflicting within the meaning of the strict definition.

A conflict is realized under the wide definition if one treaty suggests a different way to deal with the problem than that suggested by the other treaty, leading to frustration of the goals of one of the treaties. Therefore, it is obvious that there is a systemic conflict between the TRIPS agreement and the ICESCR concerning medicines under the broad definition of conflict. The strict definition of conflict of norms cannot capture this kind of conflicts between TRIPS and human right to health. Indeed, as the Special Rapporteur on the Right to Health noted, the "TRIPS bears upon crucial elements of the right to health."[302]

Recalling the previous findings above, the factual hierarchy of WTO law resulting from institutionalization of international law is responsible for identifying such conflict since it placed the WTO concepts at a higher level than the human rights concepts, thus allowing pharmaceutical patents to prevail over the human right to health. This was buttressed by the robust adjudication and enforcement mechanism of the WTO in comparison with the ineffective enforcement mechanism of the human rights system which is responsible for its weakness. Obviously, states shall relax their human right to health obligations and show more compliance to patents obligations in cases of conflicts, except when the norms constitute *jus cogens* obligations as previously noted. For example, by virtue of the WTO DSU, if a WTO member state is found to be in violation of its TRIPS obligations, the WTO DSB shall issue recommendations or rulings to bring the inconsistent measure into compliance with the TRIPS provisions. In the event that the rulings and recommendations are not implemented, the DSB authorizes the complaining party to suspend trade concessions or grants this party the right to compensation.[303] The possibility of such cross-retaliation measures under the DSU was mainly introduced at the behest of developed states. They believed that these measures would provide

[302] UN Commission on Human Rights, 'Report of the Special Rapporteur, Paul Hunt, on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of physical and Mental Health, Submitted in Accordance with Commission Resolution 2002/31' (13 February 2003) UN Doc E/CN.4/2003/58, para 86
[303] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 22

a powerful incentive to comply with the obligations of WTO agreements, *inter alia*, protection of IPRs by developing countries.[304]

It seems natural to allow human right to health concepts to prevail over pharmaceutical patents concepts in cases of conflict. The dissertation supported this notion when it opined in chapter 2 that in order to invoke human rights when drafting patent legislations and policy frameworks in pharmaceuticals, it is crucial to combine moral arguments promoting public accessibility to inventions, with economic incentives arguments which induce investment in innovations and enhance the technological and economic development. This perception renders the TRIPS agreement flexible enough to allow states to give preference to health considerations whenever they conflict with their patents obligations, rather than being an exception to patents provisions. The primacy of human rights over patents was further asserted by the UN Sub-Commission on the Protection and Promotion of Human Rights when it reminded governments of the "primacy of human rights obligations over economic policies and agreements."[305]

Nevertheless, there is no evidence that suggests that the right to access to medicines is considered a priority norm under international law, except, arguably, for the right to access to life-saving medicines which reaches the status of *jus cogens* norm as the dissertation explained in chapter 3. As such, the UN Sub-Commission on the Protection and Promotion of Human Rights declared the existence of a potential conflict between the IPRs in the TRIPS agreement and the international human rights regime because the implementation of the TRIPS agreement "does not adequately reflect the fundamental nature and invisibility of all human rights including the right to health."[306]

The broad definition of conflict approach has been adopted in several WTO cases. In *EC - Bananas* case, the WTO panel stated that conflicts include situations, where there is an explicit authorization in an agreement that is prohibited in another agreement,[307] i.e., a conflict between a right (permission) and an obligation (prohibition). Also, the WTO Appellate Body in *US - Cotton* mentioned that an "explicit carve-out or exemption" in the WTO Agreement on Agriculture would prevail if it conflicted with the obligations of the WTO Agreement on

[304] Andrew D. Mitchell and Constantinos Salonidis, 'David's Sling: Cross-Agreement Retaliation in International Trade Disputes' (2011) 45(2) Journal of World Trade 457, 466
[305] UN Sub-Commission on the Promotion and Protection of Human Rights, 'Resolution 2000/7 on Intellectual Property Rights and Human Rights' (17 August 2000) UN Doc E/CN.4/Sub.2/RES/2000/7, para 3
[306] Ibid, para 2
[307] WTO Panel Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas* (adopted 25 September 1997) WTO Doc WT/DS27/R/ECU, para 7.159

Subsidies and Countervailing Measures,[308] thus emphasizing cases of conflicts between obligations and rights.

Ultimately, a potential conflict and a systemic conflict exist between pharmaceutical patents in the TRIPS agreement and human right to health in ICESCR according to the broad definition of conflict. After identifying the type of conflict between both regimes, the conflict thereby becomes an objective question revolving around whether there is a way to accommodate human rights regime within the WTO system, i.e., whether there is a way to overcome the factual hierarchy of the TRIPS agreement, as part of the WTO law, by implementing human rights norms into the TRIPS agreement.

Abbot and Pauwelyn suggested that customary rules of treaty interpretation including the use of the principle of consistent interpretation would provide a suitable way to resolve the conflict between both regimes. Treaty interpretation would realize the rights and obligations in both regimes and their underlying goals in order to give adequate normative weight to human rights norms in the WTO system.[309]

As shall be shown in the next chapter, the WTO adjudicating bodies can only apply and interpret WTO law. They are not mandated to interpret human rights norms or apply non-WTO law in WTO disputes other than those provisions included in the general exceptions of the WTO agreements. Thus, claims of human rights violations could not be pursued before the WTO adjudicating bodies.[310] The WTO DSU emphasizes this fact by stipulating that WTO panels and Appellate Body are prohibited from adding to, or diminishing the rights and obligations of the WTO agreements.[311] This is a real manifestation of the factual hierarchy of the WTO system which is independent of any normative hierarchy in international law. The next chapter shall seek to find ways to accommodate access to medicines in the WTO system.

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[308] WTO Appellate Body Report, *United States – Subsidies on Upland Cotton* (adopted 21 March 2005) WTO Doc WT/DS267/AB/R, para 532

[309] Frederick M. Abbott, 'The 'Rule of Reason' and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS' in Thomas Cottier, Joost Pauwelyn and Elisabeth Bürgi (eds), *Human Rights and International Trade* (Oxford University Press 2003) 279, 280. **See also**, Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 176

[310] Gabrielle Marceau, 'WTO Dispute Settlement and Human Rights' (2002) 13(4) European Journal of International Law 753, 763

[311] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) arts 3(2), 19(2)

## 4.7 Conclusion

The chapter conducted an in-depth analysis to the WTO and the human rights systems in order to examine whether the pharmaceutical patents in the TRIPS agreement conflicts or coexists with the right to access to medicines as an indispensable component of the right to health in the ICESCR. It showed that the obligations to grant pharmaceutical patents unjustifiably interfere with the obligations of states to ensure the availability and accessibility to medicines, particularly in developing countries. Thus, pharmaceutical patents violate the right to access to medicines.

The pharmaceutical patents violation of the right to health echoes the conflict between the WTO system and the human rights system. It is the consequence of the structural development of international law which shifted international law from a law of co-existence without any normative hierarchy which protects reciprocal/bilateral relations between states, into a law of cooperation and community interests which protects public goods and achieves international communal interests. Within the latter, states regulate different international law systems independently endowing each system with an organization to regulate it. This process is called fragmentation of international law and is responsible for institutionalization of international law. The process created a factual hierarchy entirely different from the normative hierarchy. The factual hierarchy transformed the WTO system into an effective system stronger than its status under the normative hierarchy. Such *de facto* hierarchy is responsible for undermining the human rights system, placing it at a lower level than that of the WTO system. This is due to the WTO robust adjudication and enforcement mechanism in comparison with an ineffective enforcement mechanism of human rights which lacks an adjudicatory body. Certainly, states shall abide more with the WTO system and relax their obligations under the human rights system, except for the *jus cogens* norms which represents the clearest instance of a normative hierarchy in international law, albeit there is no authoritative catalogue listing all international law norms that constitute *jus cogens*.

The strict definition of conflict of norms in international law does not realize the existence of any conflict between the patent system in TRIPS and the human right to health in ICESCR. According to that definition, a conflict only arises between mutually exclusive obligations. Therefore, the TRIPS obligations shall prevail over the flexibilities that grant states the right to restrict patents for public health considerations. Also, in situations of two norms imposing merely different commands, but not mutually exclusive, the stricter command of the TRIPS

agreement shall be applied. This deprives states from utilizing the rights granted to them by always favouring the stricter TRIPS obligations in situations of conflicts. The strict definition of conflict also ignores the fact that the factual hierarchy of the TRIPS agreement undermines or frustrates the object and purpose of the ICESCR because the factual hierarchy suggests ways to deal with medicines different, and arguably contradictory, than that suggested under the normative hierarchy.

However, the dissertation showed that according to the broad definition of conflict, two types of conflicts are recognized between pharmaceutical patents in the TRIPS agreement and the right to access to essential medicines in the ICESCR. The first is a potential conflict since the commands in both regimes are merely different commands rather than mutually exclusive. This is due to the TRIPS flexibilities that could be invoked in the manner of implementation, assuming that such flexibilities are effective, albeit they are not as the dissertation proved in chapter 2. The second type is systemic conflict reflecting the clash between the underlying principles or goals deeply rooted in each regime.

However, it seems natural to allow human rights concepts to prevail over pharmaceutical patents concepts in situations of conflicts, yet there is no evidence that suggests the supremacy of the right to access to medicines under international law except, as the dissertation argues, for the right to access to life-saving medicines since it reaches the status of *jus cogens* norms.

The question now becomes an objective one which is whether the TRIPS agreement could incorporate access to medicines, i.e., whether human rights law could be applied within the WTO system. The next chapter shall examine several approaches tackling that issue. An in-depth analysis shall be conducted to different arguments on each approach in order to find the suitable approach, if any, that would overcome the factual hierarchy of the WTO system.

## Chapter 5: Trying to Resolve the Potential Conflict Between Human Rights Law and WTO Law: The Case of Access to Medicines and TRIPS Pharmaceutical Patents

### 5.1 Introduction

The dissertation explained the potential conflict between the right to access to medicines and the pharmaceutical patent system. The first is an indispensable component of the right to health obliging states to guarantee the accessibility and availability of essential medicines to all people. Meanwhile, the latter is provided by the TRIPS agreement which obliges WTO member states to incorporate into their domestic laws, the minimum standards of patent protection stipulated in the TRIPS. This conflict echoes the conflict between the WTO system and the human rights system. Due to the robust adjudicating and enforcement system in WTO, states are likely to comply with their WTO obligations, allowing them to prevail over their human rights obligations.

The WTO law is a whole unit that should be interpreted in consistency with each other. Examining how the WTO law interacts with other international law norms is also an examination of whether the TRIPS Agreement, as a part of WTO agreements, accommodates human right to health within its ambit, or otherwise.[1]

Determining the role of public international law in WTO dispute settlement system has major ramifications on both systems. It delineates whether international law's future is furthering fragmentation or increased unity. Further, it shows whether WTO is a self-contained regime delinked from the wider corpus of public international law, or it is a system that considers other general international law norms, *inter alia*, human rights law. Therefore, examining the role of public international law in WTO system is the cornerstone for finding a solution, if any, to the conflict between pharmaceutical patents in TRIPS agreement and the right to access to essential medicines.

Academic scholars have discussed different approaches regarding the interplay between human rights law and the WTO dispute settlement system. Such approaches generally revolve around three main views. Either endorsing full or partial application of general international law in

[1] Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement) art II(2). **See also**, Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 239

WTO disputes settlement or not entirely permitting the invoking of international law in such disputes.

This chapter will soberly re-examine the role of human rights law in WTO disputes settlement system. An in-depth analysis to different views in this regard shall be conducted in order to find an answer to whether and to what extent the WTO normative framework allows human right to health to prevail over pharmaceutical patents in TRIPS in different situations of conflicts.

The chapter will proceed in several steps. First, it will examine whether the conflict resolution techniques, namely *lex posterior derogat legi priori*, *lex specialis derogat legi generali*, and *lex superior derogat legi inferirio*, could resolve the conflict between human rights and WTO law or not. Then, it will analyse the argument viewing the WTO as a self-contained regime or a closed-legal circuit outside the wider corpus of public international law, applying only its own WTO law. Further, the chapter will scrutinize the approach trying to resolve the conflict between human right to health and pharmaceutical patents in the TRIPS agreement by considering the DSU normative framework. Two sets of rules are decisive when analysing the arguments that have been put forth in this regard, namely; the jurisdiction of the WTO adjudicating bodies, and the applicable law in WTO disputes settlement. The chapter will describe the role of the WTO dispute settlement mechanism in resolving WTO disputes, then it will explicate the difference between the WTO jurisdiction and the applicable law in WTO disputes. Mistakenly, some scholars used both terms interchangeably to argue either in favour of, or against applying human rights law in WTO disputes settlement.

Further, the chapter will explore whether the WTO law could provide more indication regarding invoking human rights law in the WTO system. Is the WTO jurisprudence counted as applicable law in WTO disputes settlement? To answer this question, the chapter will use Hubert Hart's theory about the secondary rules of recognition to construct a new definition for WTO law which is the actual and rhetorical practice of the WTO adjudicating bodies when they use international law in interpreting WTO provisions. Accordingly, the chapter will explicate the VCLT rules of interpretation, namely articles 31 and 32, to explore whether the WTO adjudicating bodies in their interpretation practice, applied the principle of systemic integration, thus advancing the coherence and unity of international law, or otherwise. Finally, the chapter will analyse the WTO cases that refer to the tension between pharmaceutical patents and the right to access to medicines to explore the reality of the use of the latter in the interpretation process in TRIPS

disputes. The chapter will conclude with a critical note regarding the role of human rights law in WTO disputes settlement system.

### 5.2 The Conflict-Resolution-Techniques in the VCLT

The three most common conflict resolution techniques widely accepted by legal scholars and mentioned in several ILC reports are: *lex specialis derogat legi generali*, *lex posterior derogat legi priori*, and *lex superior derogat legi inferiori.* The latter two are stated explicitly in the VCLT under the names of successive treaties and peremptory norms (*jus cogens*) respectively.[2] It is suggested that the *lex specialis* principle is stated implicitly in the VCLT as well, either referred to among the factors of treaty interpretation found in articles 31 to 33 of the VCLT, or when dealing with the issue of successive treaties provided in article 30 of the VCLT.[3] The dissertation shall explore whether any of them could provide an appropriate solution to the conflict between the right to health and patent protection.

#### 5.2.1 The Principle of *Lex Posterior Derogat Legi Priori*

The *lex posterior* principle is a conflict resolution technique which relies on the time factor as an important variable in international law. It means that a later international norm can in principle overrule an earlier one contradicting with it.[4] This principle is related to the contractual freedom of states which is borrowed from the civil law principle *pacta sunt servanda* widely used in contracts. It reflects the notion of state sovereignty which grants states the full freedom to change their will at any time depending on how they perceive their national interests.[5] *A fortiori*, the later norm representing the later expression of state should overrule the earlier norm representing its earlier expression.

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[2] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) arts 30, 53, 64, 71. **See also**, International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, paras 27-36

[3] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 65

[4] Jennifer Anna Sellin, 'Does One Size Fit All? Patents, the Right to Health and Access to Medicines' (2015) 62 Netherlands International Law Review 445, 457

[5] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 14, 96, 97. **See also**, Bruno Simma and Dirk Pulkowski, 'Of Planets and the Universe: Self-Contained Regimes in International Law' (2006) 17(3) The European Journal of International Law 483, 486-487

This principle is stipulated in the VCLT which states that a new treaty may overrule an older one of the same subject matter provided that all the parties to the earlier treaty are also parties to the later one. If not all the parties to the old treaty are parties to the new one, then the new treaty shall overrule the old one only between states parties to both treaties.[6] According to the principle of *pacta tertiis nec nocent nec prosunt,* states that are not parties to the new treaty are not bound by its provisions.

The *lex posterior* principle could be applied whenever there is a conflict between two treaty norms having the same subject matter, or between a customary rule and a treaty norm. In all cases, the later norm shall overrule the older one. The theory of *acte contraire*, used in domestic law, where a norm could not be modified except by another one from the same source or higher, is not applicable in international law. This was emphasized by the ILC in its comments regarding the provisions on the termination and suspension of treaties. The ILC refused the theory saying that for an agreement to terminate a treaty, it must be of the same and equal weight. This theory, as the ILC illustrated, reflects the constitutional practice within the national law of states which cannot be applied in international law.[7] The only exception to the absence of *acte contraire* in international law is the *jus cogens* norms which can only be modified, as stated by the VCLT, by a "subsequent norm of general international law having the same character." This is due to the general acceptance and recognition by the international community as a whole, of *jus cogens* as norms from which no derogation is permitted.[8]

Nevertheless, practically, the *lex posterior* principle proved that it has limited usage. Unlike treaties which have specific dates of adoption and entry into force, customary law and general principles do not have a precise date determining their emergence. They are often characterized as vague, where they continue to emerge with time and change gradually. As such, conflicts

[6] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 30

[7] UN General Assembly, 'Yearbook of the International Law Commission 1966 Vol II: Documents of the Second Part of the Seventeenth Session and of the Eighteenth Session Including the Reports of the Commission to the General Assembly' (1967) UN Doc A/CN. 4/SER.A/1966/Add. 1, 249. **See also**, Ulf Linderfalk, *On the Interpretation of Treaties: The Modern International Law as Expressed in the 1969 Vienna Convention on the Law of Treaties* (Springer Publishing Netherlands 2007) 138-139 < https://www.corteidh.or.cr/tablas/r32592.pdf> accessed 3 December 2019

[8] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 53

between a treaty norm and a customary rule or a general principle of international law which entail the usage of the *lex posterior* principle would be exceptional.[9]

Further, both treaties should emanate from the same lawmaker, i.e., the treaties should be institutionally linked or form part of the same regime. In cases of conflict between treaties in different regimes, "the question of which of them is later in time would not necessarily express any presumption of priority between them." States bound by both treaties should "try to implement them as possible with a view of mutual accommodation and in accordance with the principle of harmonization."[10]

Accordingly, the *lex posterior* principle does not provide an appropriate solution to the conflict between the right to access to medicines and pharmaceutical patents. The TRIPS agreement and the ICESCR neither emanate from the same lawmaker nor have the same subject matter. While the TRIPS belongs to the WTO regime and is meant to protect IPRs, the ICESCR constitutes a part of the human rights law aiming to protect the basic rights and fundamental freedoms of all human beings.

Even if the right to medicines in the context of pandemics constitutes, arguably, customary international law, as the dissertation showed in chapter 3, the principle of *lex posterior* shall also not be applicable. Customary law does not have a precise date determining its emergence. Therefore, it is almost impossible to rely on the time factor to resolve conflicts between accessibility to medicines, as a customary rule, and pharmaceutical patents provisions in the TRIPS.

### 5.2.2 The Principle of Lex Specialis Derogat Legi Generali

Another conflict resolution technique is the *lex specialis* principle, where a special norm in international law prevails over a general one. Although international law in its traditional setting lacks any inherent hierarchical order between its norms, as the dissertation showed in chapter 4, in some instances it recognized some norms as *lex specialis* in relation to other general rules of

[9] Joost Pauwelyn, 'The Role of Public International Law in the WTO: How Far Can We Go?' (2001) 95(3) The American Journal of International law 535, 536. **See also**, Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 97

[10] International Law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (18 July 2006) UN Doc A/CN.4/L.702, para 26

international law. This principle is a prerogative inherent to the notion of state sovereignty which grants states the full freedom to express their sovereign will by including special treaty provisions.[11]

The *lex specialis* principle has a long pedigree in international jurisprudence dating back to Hugo Grotius. He indicated that preference should be given to more specific rules in a subject matter because they are more effective and approach nearer to the point in question than general rules about the same subject matter.[12] Pauwelyn confirmed the same concept when he argued that special provisions should enjoy priority over the general rules since it is the closest expression of the state will.[13]

Further, Martti Koskenniemi, the chairman of the ILC study group on fragmentation of international law, explained that the *lex specialis* principle is an "exception or a pattern of exception regarding some subject matters of special properties which deviate from the general law." As such, whenever a matter is regulated by a general and a special norm at the same time, then the latter should take precedence over the former.[14]

Not only is the *lex specialis* principle applicable on norms conflict between treaties, but also on conflicts between customary norms and treaties. This was shown in the *Right of Passage over Indian Territory* Case, where the ICJ established the right of transit through the Indian territory relying on a clearly established practice between India and Portugal. The ICJ considered that the practice constitutes a special custom (*lex specialis* rule) that prevails over any treaty norm on the same subject matter.[15]

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[11] Bruno Simma and Dirk Pulkowski, 'Of Planets and the Universe: Self-Contained Regimes in International Law' (2006) 17(3) The European Journal of International Law 483, 486-487. **See also**, Clarence Wilfred Jenks, 'The Conflict of Law-Making Treaties' (1953) 30 British Yearbook of International Law 401, 446

[12] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 59. **See also**, Clarence Wilfred Jenks, 'The Conflict of Law-Making Treaties' (1953) 30 British Yearbook of International Law 401, 446-447. **See also**, Bruno Simma and Dirk Pulkowski, 'Of Planets and the Universe: Self-Contained Regimes in International Law' (2006) 17(3) The European Journal of International Law 483, 487 footnote 12

[13] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 388-389

[14] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, paras 54, 56

[15] Bruno Simma and Dirk Pulkowski, 'Of Planets and the Universe: Self-Contained Regimes in International Law' (2006) 17(3) The European Journal of International Law 483, 487. **See also**, *Case Concerning Right of Passage Over Indian Territory (Portugal v India)* (Merits) 1CJ Rep 1960, 6, 44

The ILC noted that there are two forms of *lex specialis*. The first is when the special rule is considered an application of the general rule in certain circumstances, such as giving instructions regarding the requirements of the general rule. The second form is when the special rule is conceived as an exception to the general rule, i.e., the special rule derogates or overrules the general rule. An example is the rules on derogation from human rights obligations under the ICCPR in matters of public emergency which threatens the life of nations. However, such derogation is not permissible when the obligation pertains to some human rights, including the right to life.[16]

Most international law scholars restricted the usage of the *lex specialis* principle, as a conflict resolution technique, to normative conflicts resulting from an overlap or interference between two norms. In such cases, the special norm prevails since it is an exception or derogation from the general rule. The first form involving the simultaneous application of the general and the special rule is unlikely to produce normative conflicts that require the application of the *lex specialis* principle.[17]

This position was adopted by the WTO DSB in several WTO cases. In *Turkey - Restrictions on Imports of Textile and Clothing Products*, the WTO panel stated that a special provision should prevail only over a DSU provision when "adherence to one provision will lead to a violation of the other." The panel referred to many panels and appellate body reports in several WTO cases stating the same concept.[18]

The ILC also asserted that the *lex specialis* principle should be applied only when there is "actual inconsistency" between two provisions or when there is "a discernible intention that one provision is to exclude the other."[19] The ILC supported its view by relying on the case of

[16] Jan B. Mus, 'Conflict Between treaties in International Law' (1998) 45(2) Netherlands International Law Review 208, 218. **See also**, International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, paras 56, 57, 88, 105. **See also**, International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171 (ICCPR) art 4

[17] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 386. **See also**, Paul Reuter, *Introduction to the Law of Treaties* (Jose Mico & Peter Haggenmacher trs, Routledge UK 2011) para 201. **See also**, Clarence Wilfred Jenks, 'The Conflict of Law-Making Treaties' (1953) 30 British Yearbook of International Law 401, 447-448. **See also**, Myres S. McDougal, Harold D. Lasswell, and James C. Miller, *The Interpretation of International Agreements and World Public Order: Principles of Content and Procedure* (New Haven Press 1994) 200-206

[18] WTO Panel Report, *Turkey - Restrictions on Imports of textile and Clothing Products* (adopted 19 November 1999) WTO Doc WT/DS34/R, para 9.93

[19] UN General Assembly, 'Yearbook of the International Law Commission 2001 Vol II Part 2: Report of the Commission to the General Assembly on the Work of its Fifty-Third Session' (2007) UN Doc A/CN.4/SER.A/2001/Add.1 (Part 2), 140

*Neumeister* which was brought before the European Court of Human Rights.[20] In that case, the court held that the obligation for compensation stipulated in article 5(5) of the European Convention on Human Rights for unlawful arrest or detention does not constitute *lex specialis* in relation to the general rule on compensation mentioned in article 50 of the Convention. To prevail as a *lex specialis* rule over the more general provision for compensation, the former has to clearly show that it is replacing or setting aside the latter. Since it appears that the two provisions are working concurrently, then the *lex specialis* principle shall not be applied and the general rule has to be taken into account when applying the special one.[21]

From the previous demonstration, it is clear that the *lex specialis* principle cannot be used to resolve the conflict between the right to access to medicines and pharmaceutical patents. The application of the principle requires a special norm in international law replacing a general one. Both the WTO law and the human rights law are considered general norms in public international law. The WTO law is not a self-contained regime outside the ambit of public international law. Its rules do not form special rules that exclude the application of the human rights law. The dissertation in the following section shall show that the WTO law is a part of the wider corpus of public international law. It shall refute the arguments perceiving WTO law as special norms in international law.

Arguing that the right to medicines in the context of pandemics constitutes customary international law does not change the situation. The *lex specialis* principle shall not be applicable also because the right to medicines perceived as customary law does not form a special rule that contracts out or replaces a general one. *A fortiori*, the principle is not applicable with regard to the argument stating that the right to life-saving medicines could reach the status of *jus cogens* norm. Such norms are not special rules, but rather they form part of the general rules in international law.

Moreover, the subject matter of the ICESCR and the TRIPS is different. Like the *lex posterior*, the *lex specialis* principle requires that the norms in conflict should have the same subject matter. If both provisions deal with different subject matters, there would be no overlap and both provisions should be applied in parallel.[22]

[20] *Neumeister v Austria (article 50)* (1974) Series A 17
[21] Ibid, paras 29-30
[22] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 164-165

It could be argued that the *lex specialis* as well as the *lex posterior* principles are suitable for application on traditional international treaties consisting mostly of bilateral/reciprocal obligations. However, human rights treaties are different since they set out obligations of the collective/integral type. That is why both principles do not provide appropriate solution for conflicts between the ICESCR and the TRIPS agreement.[23]

### 5.2.3 The Principle of *Lex Superior Derogat Legi Inferiori*

The principle of human rights primacy is regarded by many scholars and international documents as a manifestation of the superior status of human rights norms in international law. States have to prioritize their obligations to respect, protect and fulfil human rights. Whenever, there is a conflict between states' obligations enshrined in the UN Charter and their obligations under any other international agreement, the former obligations should prevail.[24] This principle is further supported by several theological and philosophical moral theories considering human rights norms superior to other international law norms. Therefore, human rights norms should be able to trump any conflicting treaty.[25]

The Sub-Commission on the Promotion and Protection of Human Rights and the 2 Special Rapporteurs appointed by the Commission have indicated in several reports, the primacy of human rights treaties over other international law norms. The reports emphasized that human rights are basic and fundamental principles that should not be departed from.[26]

However, relying on UN documents whether reports or statements to support the human rights superiority over other international law norms is erroneous. Such documents are non-binding

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[23] Xavier Seuba, 'Mainstreaming the TRIPS and Human Rights Interactions' in Carlos M.Correa (ed), *Research Handbook of the protection of Intellectual Property Under WTO Rules: Intellectual property in the WTO*, Vol 1 (Edward Elgar Publishing UK 2010) 192, 210-214

[24] Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR) arts 1(3), 55, 56, 103. **See also**, Destaw A. Yigzaw, 'Hierarchy of Norms: The Case for the Primacy of Human Rights Over WTO Law' (2015) 38(1) Suffolk Transnational Law Review 33, 37-38. **See also**, Frederic Megret, 'Nature of obligations' in Daniel Moeckli et al (eds), *International Human Rights Law* (2nd edn, Oxford University Press 2010) 96, 98-103. **See also**, Frank J. Garcia, 'The Global Market and Human Rights: Trading Away the Human Rights Principle' (1999) 25 Brooklyn Journal of International Law 51, 69-73

[25] Jack Donnelly, *Universal Human Rights in Theory and Practice* (3rd edn, Cornell University Press 2013) 10. **See also,** Joy Gordon, 'The Concept of Human Rights: The History and Meaning of its politicization' (1998) 23(3) Brooklyn Journal of International Law 689, 700-701

[26] UN Sub-Commission on the Promotion and Protection of Human Rights, 'Resolution 2000/7 on Intellectual Property Rights and Human Rights' (17 August 2000) UN Doc E/CN.4/Sub.2/RES/2000/7, para 3. **See also**, UN Sub-Commission on the Promotion and Protection of Human Rights, 'Globalization and its Impact on the Full Enjoyment of Human Rights: Preliminary Report Submitted by J. Oloka-Onyango and Deepika Udagama, in Accordance with Sub-Commission Resolution 1999/8' (15 June 2000) UN Doc E/CN.4/Sub.2/2000/13, paras 14, 63

instruments with no legal force. While the two Covenants are legally binding documents since they are international human rights treaties, the ICESCR, unlike the ICCPR, does not include an article that prohibits derogations from the rights enshrined in it. The ICESCR allows states to subject their human rights obligations to certain limitations as determined by their domestic laws.[27] Therefore, the ICESCR does not support the superiority of human rights over other international law norms.

Moreover, the argument that human rights obligations would enjoy primacy based on article 103 of the UN Charter is untenable. This article gives superiority to states' obligations under the Charter whenever they conflict with obligations under any other international agreement. However, the article is directed to those obligations expressly mentioned in the UN Charter. Most notably the Security Council Resolutions stated in article VII of the Charter pertaining to actions with respect to threats to the peace, breaches of the peace, and acts of aggression. It is not directed to human rights obligations since the UN Charter does not contain, *per se*, obligations related to human rights treaties, like those found in the two covenants.[28]

Further, international law recognizes *jus cogens* norms as the only normative hierarchy in international law. As stated by the VCLT, *jus cogens* are superior norms from which no derogation is allowed.[29] However, the dissertation showed in chapter 4 that there is no authoritative catalogue listing all international norms that constitute *jus cogens*. Only few human rights norms are accepted and recognized by the whole international community as *jus cogens* norms and the human right to health is not one of them. It is only the socio-economic rights that normally come into conflict with WTO law and such rights are not widely regarded as *jus cogens* norms.[30] Therefore, the *jus cogens* principle does not support the argument of human right to health superiority over pharmaceutical patents.

Even the argument that the right to access to life-saving medicines reaches the status of *jus cogens* norms is still controversial. As the dissertation argued in chapter 3, since the right to life is considered a *jus cogens* norm, then its components (right to access to life-saving medicines) should also enjoy the same status. However, contrary to such broad reading of the right to life,

[27] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 4
[28] Jennifer Anna Sellin, 'Does One Size Fit All? Patents, the Right to Health and Access to Medicines' (2015) 62 Netherlands International Law Review 445, 459
[29] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 53
[30] Destaw A. Yigzaw, 'Hierarchy of Norms: The Case for the Primacy of Human Rights Over WTO Law' (2015) 38(1) Suffolk Transnational Law Review 33, 34-35

some scholars still adopt the traditional view that the right to life does not include the right to health. State practice shows that not all states treat the right to access to life-saving medicines as a *jus cogens* norm.

Consequently, there is no international consensus to extend the status of *jus cogens* to the right to health or to specific elements of the right to life. This was asserted by Papadopoulou, where he indicated that there is no evidence to propose that the current list of *jus cogens* includes the right to access to either essential medicines or life-saving medicines or even the right to health in general.[31] Therefore, the *lex superior* rule also cannot resolve the conflict between the right to access to medicines and the pharmaceutical patents.

Ultimately, none of the three conflict resolution methods stated above could provide a suitable solution to the conflict between the right to access to medicines in the ICESCR and the patent protection to medicines in the TRIPS agreement. They pose several challenges whenever they are utilized; also, they suit genuine conflicts between the norms of treaties rather than potential ones. The latter is the type recognized in the tension between accessibility to medicines and TRIPS pharmaceutical patents as the dissertation concluded in chapter 4.

### 5.3 Is the WTO Law a Self-Contained Regime Delinked from the Wider Corpus of Public International Law System?

A few WTO scholars and trade lawyers portrayed the WTO law as a "self-contained regime" or a closed legal circuit that is delinked from the public international law. They relied on this conception to resolve the conflict between the right to health and patent protection in TRIPS in favour of the latter. Their argument is that since the WTO system is outside the wider corpus of public international law and applies only its own law, then the human rights obligations shall not be taken into account whenever they conflict with WTO law. This argument was rebutted by most scholars asserting that the WTO law is a part of the wider corpus of public international law. Like human rights law, WTO law creates international obligations that are part of public international law, and legally binding on states parties to the WTO agreements.[32]

[31] Frantzeska Papadopoulou, 'TRIPS and Human Rights' in Annette Kur and Marianne Levin (eds), *Intellectual property Rights in a Fair World Trade System. Proposals for Reform of TRIPS* (Edward Elgar UK 2011) 262, 270

[32] Donald M. McRae, 'The WTO in International Law: Tradition Continued or New Frontier?' (2000) 3(27) Journal of International Economic Law 27. **See also**, Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 25-40.

The supporters of the argument envisaging WTO law as a self-contained regime referred to the concepts of the founders of international economic law. The founders headed by Georg Schwarzenberger, the first to use the term "self-contained" regime in defining international economic law, thought of establishing a world trade regime that is not linked to international law. Other legal scholars followed Schwarzenberger in using the term "self-contained" to argue that certain international law regimes, like international environmental law and international trade law, are sufficiently coherent and self-contained. They are specialized regimes that contracted out of the wider corpus of public international law, except for *jus cogens* norms. Such specialized systems apply only their own rules regarding enforcement, settling disputes, and the amendment of their provisions.[33] Accordingly, as they argued, non-WTO law cannot be taken into account when resolving WTO disputes.

Similarly, Donald McRea, an international law expert and a member of several WTO panels, opined that WTO law is outside the wider corpus of public international law. He argued that the rationale behind international trade is different from the one behind public international law. The first relies on "the primary value of promoting individual economic exchanges, the value of specialization, and the economic welfare that results from specialization and exchange." Meanwhile, the public international law defines itself in terms of preserving peace and security. It is guided by the principle of state sovereignty which allows states to achieve individual objectives only, to exercise plenary authority, and to preserve their personal interest within their own territory. Thus, general international law and international trade law are two regimes addressing different matters.[34]

McRea's argument is erroneous for several reasons.

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**See also**, Mariano Garcia Rubio, *Unilateral Measures as a Means of Enforcement of WTO Recommendations and Decisions* (The Hague Academy of Intentional Law 2001) 22. **See also**, Joost Pauwelyn, 'Enforcement and Countermeasures in the WTO: Rules are Rules-Toward a More Collective Approach' (2000) 94(2) American Journal of International Law 335, 336. **See also,** Lorand Alexander Bartels, 'Applicable Law in WTO Dispute Settlement Proceedings' (2001) 35(3) Journal of World Trade 499. **See also**, David Palmeter and Petros C. Mavroidis, 'The WTO Legal System: Sources of Law' (1998) 92(3) American Journal of International Law 398

[33] Steve Charnovitz, 'What is International Economic Law?' (2011) 14(1) Journal of International Economic law 3, 13-16. **See also**, P. J. Kuyper, 'The Law of GATT as a Special Field of International Law: Ignorance, Further Refinement or Self-Contained System of International Law' (1994) 25 Netherlands Yearbook of International Law 227, 257. **See also**, Holger Hestermeyer, 'International Human Rights Law and Dispute Settlement in the World Trade Organization' in Martin Scheinin (ed), *Human Rights Norms in 'Other' International Courts* (Cambridge University Press UK 2019) 199, 207-208

[34] Donald M. McRae, 'The Contribution of International Trade Law to the Development of International Law' (1996) 260 Collected Courses of the Hague Academy of International Law 99, 116-117 < https://referenceworks.brillonline.com/entries/the-hague-academy-collected-courses/*A9789041105172_02#A9789041105172_02-106> accessed 2 August 2020

First: McRae's argument relied on the comparison between international trade law and general international law. He referred to international law as a law of co-existence rather than a law of co-operation. However, the dissertation elucidated in chapter 4 that the international law had developed from a law of co-existence and reciprocity into a law of co-operation and community interests seeking to protect public goods. McRae failed to observe that international law as a law of co-operation seeks to harmonize states' interests in order to tackle common problems. International human rights law, international environmental law, and international trade law are all new branches of international law reflecting its development and expressing international co-operation. In other words, McRae is not comparing international law with trade law, but rather, traditional international law with modern international law.

Second: Regardless of the development of international law from a law of co-existence to a law of co-operation, the basic principles of international law did not change. State sovereignty is still one of its basic principles. McRae's argument that international trade law has nothing to do with the principle of state sovereignty was refuted by several WTO cases. In *EC-Hormones* case, the arbitrators decided that "WTO members, as sovereign entities, can be presumed to act in conformity with their WTO obligations. A party claiming that a member has acted inconsistently with WTO rules bears the burden of proving that inconsistency."[35] Also, in *Chile-Taxes* case, the WTO Appellate Body stated that "members of the WTO have sovereign authority to determine the basis or bases on which they will tax goods… provided that the members respect their WTO commitments."[36] Further, in *US-Tax Treatment* case, the Appellate Body mentioned that "a member, in principle, has the sovereign authority to tax any particular categories of revenue it wishes. It is also free not to tax any particular categories of revenues. But, in both instances, the member must respect its WTO obligations."[37]

Third: Judith Bello asserted that the principle of state sovereignty does not contradict with the WTO system. She noted that according to the modern concept of international law, "sovereign states choose to co-operate across borders because, without such co-operation, in the interdependent global economy they are helpless to promote economic growth and prosperity

[35] WTO Arbitrators Decision, *European Communities – Measures Concerning Meat and Meat Products (Hormones), Recourse to Arbitration by the European Communities Under Article 22.6 of the DSU* (12 July 1999) WTO Doc WT/DS26/ARB, para 9

[36] WTO Appellate Body Report, *Chile – Taxes on Alcoholic Beverages* (adopted 12 January 2000) WTO Doc WT/DS87/AB/R, WT/DS110/AB/R, para 60

[37] WTO Appellate Body Report, *United States – Tax Treatment for "Foreign Sales Corporations"* (adopted 20 March 2000) WTO Doc WT/DS108/AB/R, para 90

most effectively. Sovereign nations do not relinquish their sovereignty by virtue of their membership in the WTO, including its dispute settlement proceeding"[38]

This infers that the principle of state sovereignty is recognized in the WTO system, same as in international law in its modern concept. The WTO is not a system against state sovereignty, as McRae contended, but rather it is a trade-off between restricting the sovereignty of states, to regulate commercial activity, and increasing their economic well-being. States realised that co-operation, with a view to liberalize mutual trade, would best serve their self-interests even if such co-operation would entail restricting their sovereign rights by imposing specific trade barriers. Thus, states limit their sovereignty by their own will, i.e., limiting the sovereignty is a consequence of exercising the sovereignty, not an underlying assumption of WTO law. McRae's argument was erroneous because it confuses the assumption underlying WTO law with the consequences of applying WTO law.[39]

The dissertation shall address the other argument that excludes the WTO system from the ambit of international law, relying on the misnomer of "WTO is a self-contained regime." The dissertation shall prove that such argument is untenable.

Being a self-contained regime does not mean that the regime is outside the international legal system. This term was used by the Permanent Court of International Justice in the *Wimbledon* case[40] and by the ICJ in the *Tehran Hostages* case[41] to refer to specific rules, in certain issues, having priority over other more general rules of international law. However, this does not mean that such specific rules are detached from the whole system of international law. It means that states can contract out of one or more of the rules of international law, except the rules giving rise to *jus cogens*, and establish a functionally specialized regime, but they cannot contract out of the whole system of public international law.[42] Given that the vast majority of WTO members have at least ratified one of the two Covenants, it would seem illogical that they intended to set up a trade system that is utterly separated from human rights law.

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[38] Judith Hippler Bello, 'The WTO Dispute Settlement Understanding: Less is More' (1996) 90(3) The American Journal of International law 416, 417

[39] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 33

[40] *Case of the S.S. "Wimbledon" (United Kingdom, France, Italy & Japan v Germany)* (judgment) [1923] PCIJ Rep Series A No 1, 24

[41] *Case Concerning United States Diplomatic and Consular Staff in Tehran (United States of America v Iran)* (judgment) [1980] ICJ Rep 3, 38-40

[42] International Law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 152

Martti Koskenniemi, the chairman of the ILC Study Group on the Fragmentation of International Law, emphasized this understating in several reports. He stated that "none of the treaty-regimes in existence today is self-contained in the sense that the application of general international law would be generally excluded. On the contrary, treaty bodies in human rights and trade law, for example, make constant use of general international law in the administration of their special regimes."[43] In another report assigned to the study of *lex specialis* rules and self-contained regimes, Koskenniemi suggested that the term "self-contained" is an inappropriate term and its notion "is simply misleading." He argued that there are no specialized regimes in international law that form "closed legal circuits" fully isolated from general international law.[44]

Furthermore, the VCLT emphasized that the WTO law is a branch or a sub-system of public international law. It defined treaties as "international agreements concluded between states in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments."[45] Further, the ICJ Statute stipulated that international treaties are one of the primary sources of public international law.[46]

However, the WTO DSU restricted the jurisdiction of the WTO adjudicating bodies to disputes arising under the WTO covered agreements,[47] as shall be shown in detail later, yet the DSU clearly showed that the WTO members did not contract out of the international law as a whole. It stipulated that the WTO dispute settlement system serves to clarify the provisions of the WTO agreements "in accordance with customary rules of interpretation of public international law."[48]

The WTO jurisprudence considered the VCLT a codification of such customary rules as the dissertation showed in chapter 2. The reference to the VCLT as a starting point for the interpretation of WTO agreements explicitly confirms that the WTO law is not a self-contained regime. If the WTO law should be interpreted in accordance with the rules of public

[43] Ibid, para 172
[44] International Law Commission, 'Preliminary Report by Martti Koskenniemi on the Study of the Function and Scope of the *Lex Specialis* Rule and the Question of Self-Contained Regimes' (4 May 2004) UN Doc ILC(LVI)/SG/FIL/CRD.1/Add.1, para 134. **See also**, International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 152(5)
[45] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 2(a)
[46] Statute of the International Court of Justice (adopted 26 June 1945, entered into force 24 October 1945) 3 Bevans 1179, 59 Stat 1031, TS 993 (ICJ) art 38/1(a)
[47] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) arts 1(1), 7(1)(2), 11, 19(2), 23(1)
[48] Ibid, art 3(2)

international law, then certainly the WTO law is a part of the wider corpus of public international law. Accordingly, it should interact with other non-WTO rules that are part of the public international law.

To emphasize this notion, the WTO Appellate Body, in *US - Gasoline* case, stated that the general rule of interpretation stipulated in article 31(1) of the VCLT "has attained the status of a rule of customary or general international law." By virtue of article 3(2) of the DSU, the WTO adjudicating bodies are directed to apply article 31(1) of the VCLT when seeking to clarify the provisions of the WTO covered agreements. This direction "reflects a measure of recognition that the WTO agreements are not to be read in clinical isolation from public international law."[49]

Moreover, the TRIPS agreement itself contains several references to other international agreements forming part of the general international law. Examples of such agreements, as stipulated in part 1 of the TRIPS, are the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works.[50] Reference to such agreements infers that the WTO law did not contract out of the general international law.

Further, according to article 55 on the Responsibility of States for Internationally Wrongful Acts, the general rules on state responsibility would be applicable by default. However, if states agreed on more specialized rules pertaining to international wrongful acts or the content or implementation of the international responsibility of a state, then such specialized rules would be applied, and the general rules are excluded from application.[51] The commentary on article 55 explicitly mentioned that the article reflects the legal principle of *lex specialis derogat legi generali*. It is one of the approaches to determine which rule of public international law, potentially applicable, is to prevail or whether they shall simply coexist. Thus, the special rules, like the general ones, are still within the ambit of public international law. The commentary on article 55 explicitly referred to the WTO DSU as an example of such specialized rules which

[49] WTO Appellate Body Report, *United States - Standards for Reformulated and Conventional Gasoline* (adopted 20 May 1996) WTO Doc WT/DS2/AB/R, 17

[50] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 1(3)

[51] UN General Assembly, 'Yearbook of the International Law Commission 2001 Vol II Part 2: Report of the Commission to the General Assembly on the Work of its Fifty-Third Session' (2007) UN Doc A/CN.4/SER.A/2001/Add.1 (Part 2), 140-141 art 55. **See also**, International Law Commission, 'Text Adopted by the Commission at its Fifty-Third Session Concerning the Responsibility of States for Internationally Wrongful Acts' (2001) art 55

displace the more general rules on state responsibility. Nevertheless, it noted that the DSU is still part of the general international law.[52]

Therefore, excluding, in certain instances, the rules of general international law concerning states responsibility and applying the WTO law as specialized rules, does not mean that the WTO rules are detached from the whole system of international law. It does not also mean that other sub-systems of international law, like human rights law, cannot influence the WTO law. It means that the WTO dispute settlement system may apply, in some instances, specialized rules and exclude the application of the primary or general rules. This rebuts the arguments that the WTO is a self-contained regime not belonging to the wider corpus of public international law. It has to be stressed again that contracting out of some rules of public international law does not mean contracting out of the whole system of international law.

This understanding of public international law which prohibits creation of sub-systems completely delinked from international law, is crucial to avoid turning such sub-systems, *inter alia*, WTO law, into closed systems not related to public international law. This would render these sub-systems safe havens for states to escape from their obligations under public international law. Analogously, prohibiting the setting up of treaties outside the public international law system resembles prohibiting a group of individuals, under national law, from enacting their own laws and regulations. Such prohibition is intended to avoid contracting out of the state legal system, otherwise some individuals would "set up their own state within the state."[53]

Moreover, interpreting WTO law in isolation from international law would run contrary to the presumption against conflicts in public international law. This principle is embodied in the VCLT requiring effective interpretation of treaties. The VCLT stated that treaties have to be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose."[54] The dissertation showed in chapter 4 that the WTO adjudicating bodies adopted this principle in several cases. It has been demonstrated that the presumption is relevant in the WTO context since all WTO agreements

[52] UN General Assembly, 'Yearbook of the International Law Commission 2001 Vol II Part 2: Report of the Commission to the General Assembly on the Work of its Fifty-Third Session' (2007) UN Doc A/CN.4/SER.A/2001/Add.1 (Part 2), 140-141. **See also**, Bruno Simma, 'Self-Contained Regimes' (1985) 16 Netherlands Yearbook of International Law 111, 117

[53] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 37

[54] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 31(1)

were negotiated at the same time by the same members and in the same forum. This emphasizes that WTO law is not a self-contained regime delinked from public international law, but rather a sub-system of international law that has to interact with other systems of international law.

More significantly, the preamble of the WTO Agreement infers that the WTO law is not a self-contained regime, but rather a part of the wider corpus of public international law. The preamble commits WTO member states to the "optimal use of the world's resources in accordance with the objectives of the sustainable development."[55] To achieve such objectives, the WTO law has to update itself continuously responding to the social development, otherwise it would impede the flow of international trade and consequently fall into being disregarded by WTO members. The international law is capable of offering continuous update to the WTO law since the first is characterized by the continuous development of its norms. As such, the WTO law has to interact with the rest of international law because the latter achieves the objectives of sustainable development.[56]

Another proof for the link between WTO law and other norms of international law is the environmental and health exceptions in the WTO obligations.[57] Article XX of the GATT, for instance, provides a number of exceptions to the application of the GATT. The article provides for measures necessary to protect human health and animal and plant life, in addition to the conservation of exhaustible natural resources.[58] These exceptions show that the WTO law has to take into consideration other areas of international law.

In essence, the WTO system is not a self-contained body of law, but rather a part of the larger corpus of public international law. The former WTO Director-General, Pascal Lamy, noted that the effectiveness and legitimacy of the WTO system depend on its relation to international law. As a part of international law, the WTO law "participates in the construction of international coherence and reinforces the international legal order."[59]

Nevertheless, recognizing WTO system as a part of the wider corpus of public international law does not simply mean that the WTO adjudicating bodies can apply international law *in toto*

[55] Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement) preamble
[56] Jiaxiang Hu, 'The Role of International Law in the Development of WTO Law' (2004) 7(1) Journal of International Economic Law 143, 148-149
[57] Ibid, 144
[58] General Agreement on Tariffs and Trade, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187, 33 ILM 1153 (GATT 1994) art XX (a)(b)(e)(g)
[59] Pascal Lamy, 'The Place of the WTO and its Law in the International Legal Order' (2007) 17(5) The European Journal of International Law 969, 977

when resolving WTO disputes. The applicable law issue in WTO dispute settlement system is always a matter of continuous debate as shall be demonstrated later in this chapter.

### 5.4 The Normative Framework of the DSU

Another approach tried to resolve the conflict between human right to health and pharmaceutical patents in the TRIPS agreement by considering the DSU normative framework. Different arguments have been put forth in this regard. Two sets of rules are decisive when analysing the arguments. They are the jurisdiction of the WTO adjudicating bodies and the applicable law in WTO dispute settlement. Analysing the arguments is necessary to explore whether the WTO system takes into consideration general international law, including human rights law, when resolving WTO disputes, or it considers only the provisions of the WTO "covered agreements."

Notably, the WTO legal system neither contains human rights obligations, nor explicitly refer to them. A few WTO obligations may resemble those of human rights, for example, the non-discrimination clause in the GATT. However, such obligations benefit the trade interests of individuals which differ fundamentally from human rights.[60] Scholars opined that such omission reflects the WTO negotiations, when drafting the WTO agreements, which focused only on trade law and did not think of public international law. This reveals an underlying tendency to grant WTO law a privileged status in international law.[61]

Even the argument stating that the TRIPS agreement contains human rights reference according to article 15(1)(c) of the ICESCR is invalid. The dissertation rebutted this argument in chapter 4 showing that the rights protected under article 15(1)(c) differ substantially from IPRs. This article is meant to protect the fundamental human rights of persons as illustrated by the General Comment number 17.

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[60] Holger Hestermeyer, 'International Human Rights Law and Dispute Settlement in the World Trade Organization' in Martin Scheinin (ed), *Human Rights Norms in 'Other' International Courts* (Cambridge University Press UK 2019) 199, 206. **See also**, General Agreement on Tariffs and Trade, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187, 33 ILM 1153 (GATT 1994) art I

[61] Anja Lindroos and Michael Mehling, 'Dispelling the Chimera of Self-Contained Regimes International Law and the WTO' (2006) 16(5) The European Journal of International Law 857, 859. **See also**, Holger Hestermeyer, 'International Human Rights Law and Dispute Settlement in the World Trade Organization' in Martin Scheinin (ed), *Human Rights Norms in 'Other' International Courts* (Cambridge University Press UK 2019) 199, 205

It is helpful to understand the WTO dispute settlement system before exploring the DSU normative framework.

### 5.4.1 A Short Premiere of the WTO Dispute Settlement System

This sub-section shall address the WTO dispute settlement system showing its structure, distinctive features, and the dispute settlement procedures. The features of the WTO dispute settlement system have been demonstrated previously in chapter 4. In this sub-section, only two distinctive features shall be highlighted due to their importance in understanding the discussion on the interplay between human rights law, as a non-WTO law, and WTO law.

#### 5.4.1.1 The Structure and Features of the WTO Dispute Settlement System

One of the most significant functions of the WTO is to administer a dispute settlement system for the WTO agreements.[62] The prime purpose of the system is to provide "security and predictability to the multilateral trading system."[63] The dispute settlement system is "essential for the effective functioning of the WTO" because it promptly settles disputes between WTO members concerning their respective rights and obligations under the WTO covered agreements.[64]

This dispute settlement system is conducted under the WTO DSU and administered by the WTO DSB, namely the Ministerial Meeting (WTO General Council). The DSB consists of representatives of all WTO member states. It has the "authority to establish panels, adopt panels and Appellate Body reports, maintain surveillance of implementation of rulings and recommendation, authorize suspension of concessions, and other obligations under the covered agreements."[65]

The WTO panels are composed of "well-qualified governmental and/or non-governmental individuals" with "sufficiently diverse backgrounds and wide spectrum of experience." Panel members are selected in a manner that guarantees their independence. Citizens of member states

[62] Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement) arts III(3), IV(3)
[63] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 3(2)
[64] Ibid, art 3(3)
[65] Ibid, art 2(1)

whose governments are parties to the dispute, or third parties, are not selected in the panel established for such dispute, unless the parties to the dispute agree otherwise. Each panel is composed of 3 or 5 panellists depending on the choice of the parties to the dispute.[66]

The WTO Appellate Body is a standing body, i.e., a permanent judicial body, which is appointed by the WTO General Council. It is "composed of 7 persons, three of whom shall serve on any one case. Persons serving on the Appellate Body shall serve in rotation as determined in the working procedures of the Appellate Body." The members of the Appellate Body are "experts in law, international trade and the subject matter of the covered agreements generally." They should be "unaffiliated with any government" and they should not "participate in the consideration of any disputes that would create a direct or indirect conflict of interest." Finally, "the Appellate Body shall be provided with appropriate administrative and legal support as it requires."[67]

The WTO dispute settlement system has two distinctive features:

First: It is a judicial system that builds a consistent WTO case law. The fact that the reports of the WTO adjudicating bodies only become binding upon adoption by the WTO DSB does not change the judicial nature of the system. The dissertation showed in chapter 4 that the reports are automatically adopted by the DSB unless the WTO members decide to reject them by negative consensus. Thus, the possibility to reject any report is merely a theoretical possibility since at least one WTO member, either the claimant or respondent, shall have an interest in the outcome of the dispute settlement. This differs from the GATT dispute settlement system, where the reports have to be adopted by positive consensus in the GATT Council.[68]

Second: Its jurisdiction is compulsory, exclusive, and contentious. Recalling what the dissertation demonstrated in chapter 4, the parties to a WTO dispute do not have any choice but to accept the jurisdiction of the WTO dispute settlement system. Seeking the "redress of violation of obligations or other nullification or impairment of benefits under the WTO covered agreements" should be done exclusively through recourse to the WTO DSU, rather than resorting to unilateral actions or any other dispute resolution systems. Finally, unlike the ICJ or

[66] Ibid, art 8(1)(2)(3)(5)
[67] Ibid, art 17(1)(2)(3)(7)
[68] Peter Van den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization* (3rd edn, Cambridge University Press 2013) 159, 160, 205, 207, 209. **See also**, Holger Hestermeyer, 'International Human Rights Law and Dispute Settlement in the World Trade Organization' in Martin Scheinin (ed), *Human Rights Norms in 'Other' International Courts* (Cambridge University Press UK 2019) 199, 203

other international tribunals, the WTO adjudicating bodies only have contentious, rather than advisory, jurisdiction. They serve to clarify the existing provisions of WTO agreements, listed in Appendix 1 and 2 to the WTO DSU, in the context of an actual dispute.[69]

#### 5.4.1.2 The WTO Dispute Settlement procedures

The WTO DSU provides a range of dispute settlement options, *inter alia*, consultations, conciliation, mediation, and the request by the complaining parties to establish judicial *ad hoc* panels with the possibility to appeal to the Appellate Body.

After attempting to settle a dispute via consultations, the complaining party can make a request to the WTO DSB to establish a panel. Accordingly, the DSB establishes the panel unless it decides by consensus not to do so.[70] The complaining party has to identify the specific measure/measures inconsistent with the WTO covered agreements and provide a brief summary of the legal basis of the complaint.[71] The established WTO panel has its own terms of reference which could be refused by the parties to the dispute within a specified period.[72]

The procedures before the panel entail written submissions from both parties as well as hearings. This renders the panel procedures similar to court proceedings. If the "parties to the dispute have failed to develop a mutually satisfactory solution, the panel shall submit its findings in the form of a written report to the DSB." Such report shall "set out the findings of fact, the applicability of relevant provisions, and the basic rationale behind any findings and recommendations that the panel makes. Where a settlement of the matter among the parties to the dispute has been found, the report of the panel shall be confined to a brief description of the case and to reporting that a solution has been reached."[73]

Before the DSB adopts the final report of the panel, the parties to the dispute have the chance to submit written comments on the interim report issued by the panel. Such comments include the panel's findings and conclusions as well as the descriptive sections of the interim report. If

[69] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) arts 1, 3(2), 6(1), 23(1)(2a). **See also**, Peter Van den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization* (3rd edn, Cambridge University Press 2013) 160-162

[70] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 6(1)

[71] Ibid, art 6(2)

[72] Ibid, art 7(1)

[73] Ibid, art 12(2)(3)(5)(6)(7)

there are no comments on the interim report within the specified period assigned by the panel, the interim report shall be considered final and circulated to the WTO members. If the panel received any comments on the interim report, it has to review the parts that received comments or hold further meetings with the parties to identify specific issues written in such comments.[74] The report is then adopted automatically by the WTO DSB unless one of the parties appealed to the Appellate Body or the DSB decided by consensus not to adopt the report.[75]

The WTO Appellate Body is only empowered to hear appeals on the issues of law stated in the panel report and the legal interpretations developed by the panel.[76] It may "uphold, modify or reverse the legal findings and conclusions of the panel.[77] The Appellate Body sets up its working procedures in consultation with the chairman of the WTO DSB and the Director-General. The WTO members are notified whenever there are any changes to such procedures.[78]

The appeal process commences by a written notification to the DSB including, among others, a brief statement identifying the alleged errors in the issues of law mentioned in the panel report and/or in the legal interpretations developed by the panel.[79] After the oral hearings and the written submissions, the Appellate Body issues its report which becomes binding upon its adoption by the WTO DSB. Similar to the Panel report, the Appellate Body report can be prevented only by negative consensus.[80]

When the final binding report of the panel or the Appellate Body concludes that a measure is inconsistent with the WTO law, it recommends that the member state brings its measure into conformity with its obligations. The panel and Appellate Body, in addition to their recommendations, "may suggest ways in which the member concerned could implement the recommendations."[81] In such recommendations, the WTO adjudicating bodies "cannot add to or diminish the rights and obligations provided in the covered agreements."[82] In order to induce compliance, the WTO DSB is tasked with "maintaining surveillance of implementation of

[74] Ibid, art 15(1)(2)
[75] Ibid, art 16(4)
[76] Ibid, art 17(6)
[77] Ibid, art 17(13)
[78] Ibid, art 17(9)
[79] Working Procedures for Appellate Review (adopted 16 August 2010) WTO Doc WT/AB/WP/6, rule 20
[80] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 17(14)
[81] Ibid, art 19(1)
[82] Ibid, art 19(2)

rulings and recommendations," in addition to "authorizing the suspension of concessions and other obligations under the WTO covered agreements."[83]

### 5.4.2 The Jurisdiction of the WTO Dispute Settlement System

When discussing the applicability of international law within the WTO system, the distinction between the jurisdiction and applicable law should be recognized. They are two distinct matters that need to be seen in strict separation.[84] While jurisdiction is a threshold issue that determines whether the WTO adjudicating bodies have competence to rule on the subject matter of the WTO dispute, the applicable law informs them which law they are empowered to apply when examining the case.[85] So, the panels and Appellate Body have to decide first whether they have jurisdiction on the subject matter before deciding the applicable law on the dispute. Therefore, limiting the jurisdiction of the dispute settlement system to WTO covered agreements does not imply that the WTO law has contracted out of the wider corpus of international law.[86]

The WTO panels and Appellate Body have limited jurisdiction *ratione materiae*, i.e., their jurisdiction is limited to disputes brought pursuant to WTO covered agreements. This follows from several straightforward provisions in the DSU stipulating that the WTO dispute settlement system is limited to "claims of violation of obligations, or other nullification or impairment of benefits brought pursuant to the WTO covered agreements, or an impediment to the attainment of any objectives of the WTO covered agreements."[87] This limited jurisdiction is further affirmed by stating that the dispute settlement system "serves to preserve the rights and obligations of members under the WTO covered agreements."[88] Consequently, the jurisdiction

[83] Ibid, art 2(1)
[84] Lorand Alexander Bartels, 'Applicable Law in WTO Dispute Settlement Proceedings' (2001) 35(3) Journal of World Trade 499, 501. **See also,** Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 460-463
[85] Holger Hestermeyer, 'International Human Rights Law and Dispute Settlement in the World Trade Organization' in Martin Scheinin (ed), *Human Rights Norms in 'Other' International Courts* (Cambridge University Press UK 2019) 199, 212
[86] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 460-461
[87] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) arts 1, 7(1)(2), 11, 23(1)
[88] Ibid, art 3(2)

of the WTO dispute settlement system is not extended to claims of violation of non-WTO law including human rights law, customary law, and *jus cogens* norms.[89]

The WTO Appellate Body recognized its limited jurisdiction in *Mexico – Taxes on Soft Drinks* case, where it held that "we see no basis in the DSU for Panels and the Appellate Body to adjudicate non-WTO disputes."[90] So, they refused a claim brought to the WTO dispute settlement system based on the North American Free Trade Agreement (NAFTA) since it was not a WTO law.[91] Also, in *EC - Poultry* case, the Appellate Body did not apply the Oilseeds Agreement invoked as a claim in a WTO dispute between the European Communities and Brazil. The Appellate Body stated that such agreement is not a WTO covered agreement within the meaning of articles 1 and 2 of the DSU.[92]

However, it has to be noted that the WTO adjudicating bodies have jurisdiction to rule on claims of violation of non-WTO provisions that are explicitly incorporated in the WTO covered agreements. For example, the Paris Convention and the Berne Convention are non-WTO agreements which are regarded as part of the TRIPS agreement. Therefore, the adjudicating bodies have jurisdiction to rule on claims of their violation.[93] Further, in *US – Copyright* case, the WTO panel had jurisdiction to rule over a dispute brought by the European Communities alleging that the US Copyright Act violated its obligations under the Berne Convention.[94]

Pauwelyn argued that parties to a WTO dispute can agree to enlarge the scope of the jurisdiction of panels to include non-WTO law claims. This could be done by the mutual consent of the parties to the dispute on non-standard terms of reference by virtue of article 7(3) of the DSU. It could also be achieved by referring the dispute including non-WTO claims to arbitration pursuant to article 25 of the DSU.[95] To support his argument, Pauwelyn referred to the

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[89] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 444. **See also**, Holger Hestermeyer, 'International Human Rights Law and Dispute Settlement in the World Trade Organization' in Martin Scheinin (ed), *Human Rights Norms in 'Other' International Courts* (Cambridge University Press UK 2019) 199, 204-205. **See also**, Anja Lindroos and Michael Mehling, 'Dispelling the Chimera of Self-Contained Regimes International Law and the WTO' (2006) 16(5) The European Journal of International Law 857, 860

[90] WTO Appellate Body Report, *Mexico - Tax Measures on Soft Drinks and Other Beverages* (adopted 24 March 2006) WTO Doc WT/DS308/AB/R, para 56

[91] Ibid, paras 72, 73, 75

[92] WTO Appellate Body Report, *European Communities - Measures Affecting Importation of Certain poultry Products* (adopted 23 July 1998) WTO Doc WT/DS69/AB/R, paras 79-80

[93] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 1(3)

[94] WTO Panel Report, *United States – Section 110(5) of the US Copyright Act* (adopted 27 July 2000) WTO Doc WT/DS160/R

[95] Joost Pauwelyn, 'The Role of Public international Law in the WTO: How Far Can We GO?' (2001) 95(3) The American Journal of International law 535, 554

arbitration procedures of *Canada - European Communities* that was brought under the old GATT system. The arbitrator examined claims under a bilateral agreement between the two parties rather than the claims that were made under the GATT.[96]

However, Pauwelyn's argument is defeated by the explicit text of article 1(1) of the DSU which does not provide for such exception in cases of non-standard terms of reference. Also, the arbitration case derived by Pauwelyn was decided in 1990 before the conclusion of the WTO agreement, thus it was not considered under the WTO DSU. Pauwelyn himself changed his argument later by stating that the WTO adjudicating bodies do not have jurisdiction to adjudicate disputes completely unrelated to WTO covered agreements even under arbitration or mutual consent on non-standard terms of references. In all cases, there should be a close connection with some WTO claims.[97]

Beside violation complaints, the DSU, GATT, and TRIPS provide for another two types of complaints, namely, non-violation complaints and situation complaints.[98] It is argued that such types could be used to construct a complaint based on human rights law violation under the WTO dispute settlement system. Nevertheless, this appears to be a misguided attempt to circumvent the limited jurisdiction of the WTO dispute settlement system. The non-violation complaints are extremely exceptional, and the situation complaints have never been raised under the WTO dispute settlement mechanism.[99] As such, extending the jurisdiction of WTO panels to human rights law has no basis in the WTO system.

The only precedent of non-violation complaint is found in the old GATT jurisprudence when the US imposed trade sanctions on Brazil in 1988. The dissertation referred to this case in chapter 2 showing that the US used the "Special 301" process in its Trade Act to impose trade sanctions on Brazil in retaliation for refusing to grant patent protection for American

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[96] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 444. **See also**, Award by the Arbitrator, *Canada/European Communities – Article XXVIII Rights* (26 October 1990) DS12/R- 37S/80

[97] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 444

[98] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 26. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) art 64. **See also**, General Agreement on Tariffs and Trade, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187, 33 ILM 1153 (GATT 1994) art XXIII(1)

[99] Holger Hestermeyer, 'International Human Rights Law and Dispute Settlement in the World Trade Organization' in Martin Scheinin (ed), *Human Rights Norms in 'Other' International Courts* (Cambridge University Press UK 2019) 207. **See also**, Gabrielle Marceau, 'WTO Dispute Settlement and Human Rights' (2002) 13(4) European Journal of international Law 753, 767-768

pharmaceuticals. The US vindicated those measures according to the non-violation nullification of benefits (NVNB) argument. It claimed that the lack of intellectual property protection by Brazil impaired or nullified the trade concessions the US had obtained.[100]

Another argument in this context, is to extend the jurisdiction of WTO panels to human rights complaints to enhance the weak enforcement mechanism of the human rights system by utilizing the robust one of the WTO.[101]

This argument is untenable due to the differences in nature and philosophy between human rights values and trade values previously demonstrated in chapter 4. Human rights are collective/integral values inherent to human persons. They are a timeless expression of fundamental entitlements of the human person, where states have to impose non-negotiable standards in order to protect such entitlements. On the contrary, trade values are bilateral/reciprocal in nature not integral. The philosophy of world trade is based on trade-offs and negotiations to conclude trade concessions with the possibility to withdraw or alter trade benefits depending on trading interests, thus it differs completely from human rights.

Further, the current WTO dispute settlement system as explained above does not allow such assumption. The DSU has to be amended to provide for the possibility of invoking human rights within its jurisdiction. Nevertheless, WTO states, particularly developing countries, have persistently refused to extend the WTO jurisdiction to encompass human rights complaints. Developing countries fear that developed ones would utilize human rights claims as a guise for protectionism. This would preclude their products from accessing developed countries' market.[102]

It is clear that the jurisdiction of the dispute settlement system is strictly limited to claims under WTO covered agreements. Similarly, some scholars argued that the WTO system cannot take into account non-WTO law when resolving WTO disputes.[103] This argument is erroneous

[100] Peter Drahos, 'Four Lessons for Developing Countries from Trade Negotiations over Access to Medicines' (2007) 28(1) Liverpool Law Review 11, 15. **See also**, 19 US Code § 2411, Title III ch 1, 88 Stat 2041 (Section 301 of the Trade Act of 1974)

[101] Ernst-Ulrich Petersmann, 'Time for a United Nations 'Global Compact' for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration' (2002) 13(3) European Journal of International Law 621

[102] Philip Alston, 'Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann' (2002) 13(4) European Journal of International Law 815, 833-834. **See also**, Ernst-Ulrich Petersmann, 'Human Rights and the Law of the World Trade Organization' (2003) 37(2) Journal of World Trade 241, 280

[103] Anja Lindroos and Michael Mehling, 'Dispelling the Chimera of Self-Contained Regimes International Law and the WTO' (2006) 16(5) The European Journal of International Law 857, 862-863

because the jurisdiction and the applicable law are two issues different from each other as previously illustrated. They cannot be used interchangeably to argue that the WTO adjudicating bodies do not take into account general international law.

In the same vein, other scholars argued that the WTO system cannot take into account all rules of international law that are not expressly confirmed or included by WTO states parties. They relied on the principle of *expressio unius est exclusio alterius,* meaning that what is not mentioned explicitly in the WTO DSU is thus excluded. Since the phrase "covered agreements" is explicitly mentioned in several DSU provisions as discussed above, then, non-WTO law cannot be accommodated in the WTO dispute settlement system.[104] This argument is untenable as well. It seems difficult to contain the influence of international law by resorting to an overstated interpretation of the DSU in light of specific legal principles.[105]

Ultimately, the WTO dispute settlement system does not have jurisdiction over human rights violations complaints. Therefore, the jurisdiction cannot be relied upon to resolve the conflict between human rights to health and pharmaceutical patents. The dissertation then seeks to find a solution to the conflict by exploring the applicable law in WTO dispute settlement.

### 5.4.3 The Applicable Law in WTO Disputes Settlement

The WTO adjudicating bodies have to decide the applicable law in WTO disputes settlement. Unlike the limited jurisdiction *ratione materiae* of the WTO adjudicating bodies, the DSU does not contain an explicit provision regarding the sources of applicable law. This renders the applicable law issue a matter of continuous debate. Opinions diverge into three groups: either restricting the applicable law to WTO law, endorsing full applicability of non-WTO law, or allowing partial application of non-WTO law in WTO disputes settlement.

Before addressing the three approaches, it should be clear that they diverge with regard to the substantive norms raised as a defense against claims of WTO law violation. In other words, when the respondent party invokes a non-WTO obligation, for instance a human rights

[104] Joel P. Trachtman, 'The Domain of WTO Dispute Resolution' (1999) 40(2) Harvard International Law Journal 333, 342. **See also**, Gabrielle Marceau, 'A Call for Coherence in International Law: Praises for the Prohibition Against "Clinical Isolation" in WTO Dispute Settlement' (1999) 33(5) Journal of World Trade 87, 110

[105] Robert Howse, 'From Politics to Technocracy and Back Again: The Fate of the Multilateral Trading Regime' (2002) 96(1) American Journal of International Law 94, 106. **See also**, Anja Lindroos and Michael Mehling, 'Dispelling the Chimera of Self-Contained Regimes International Law and the WTO' (2006) 16(5) The European Journal of International Law 857, 863

obligation, to defend violating the WTO norm. The different views regarding the applicable law are not related to claims raised before the WTO adjudicating bodies since such claims have to be based initially on the allegation of violation of WTO covered agreements. As shown previously, the WTO adjudicating bodies have limited jurisdiction *ratione materiae*. Even if the claiming party invokes a substantive non-WTO norm, it is used only to support an already existing claim of violation based on a WTO norm.

Furthermore, the three approaches diverge regarding the substantive norms only. The procedural rules are undisputed. The WTO adjudicating bodies applied in many cases the procedural rules of general international law. In *US - Wool Shirts and Blouses*, the Appellate Body applied the general principle stating that the "burden of proof rests upon the party who asserts the affirmative of a particular claim or deference."[106] In *India - Autos* case, the WTO panel applied the doctrine of *res judicata* stating that it is a widely recognized international law principle that should be "applicable in WTO dispute settlement, particularly concerning fundamental procedural matters."[107]

In essence, the opinions diverge regarding whether or not the substantive non-WTO law invoked as a defence for a WTO complaint could prevail over WTO obligations. Exploring the different approaches to such question shows the extent to which it is permitted to apply human rights law, including the human right to health, within the WTO system.

The first group argued that the WTO law did not contract out of the wider corpus of international law, an argument that has been emphasized above. Therefore, public international law norms form part of the applicable law when resolving WTO disputes. The dissertation previously demonstrated that the WTO agreements are not to be read in clinical isolation from public international law. By virtue of article 3(2) of the DSU, the WTO adjudicating bodies are directed to apply the customary rules of interpretation of public international law enshrined in the VCLT when seeking to clarify the provisions of the WTO covered agreements.

Pauwelyn strongly favors the previous view. He pointed out that articles 3(2), 7, 11 of the WTO DSU implicitly confirm that the entire body of public international law is applicable in WTO disputes settlement. However, the application of non-WTO law in WTO disputes is confined to

[106] WTO Appellate Body Report, *United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India* (adopted 23 May 1997) WTO Doc WT/DS33/AB/R, 14
[107] WTO Panel Report, *India – Measures Affecting the Automotive Sector* (adopted 5 April 2002) WTO Doc WT/DS146/R, WT/DS175/R, para 7.57

the respondents' defenses to claims of breaching their WTO obligations. Pauwelyn stated that such justification is valid only if the parties to the WTO dispute are at the same time bound by the non-WTO law and the latter prevails over the WTO law according to the rules of conflict in international law. Thus, in that case, the public international law fills the gaps that are left open by the WTO treaty in question.[108]

The second group rejected the previous view and maintained a restrictive opinion that the WTO law is the only applicable law in WTO disputes. Proponents of this view assume that such an approach would preserve the independent nature of the trade regime. They supported their position by referring to the standard terms of reference of the WTO panels in article 7 of the DSU. They also invoked articles 3(2) and 19(2) of the DSU obliging the WTO adjudicating bodies not to add or diminish the rights and obligations provided in WTO covered agreements when issuing their rulings and recommendations. This means, as they argue, that international law, including human rights, cannot be part of the applicable law in WTO disputes, otherwise the language of the previous articles would be absurd. Invoking other international law would certainly affect the rights and obligations of WTO member states.[109]

However, they noted that customary international law could only be used in WTO dispute settlement in the context of interpretation to clarify the WTO provisions as mentioned by article 3(2). But this does not mean that the international law is part of the applicable law in the WTO system since interpretation is different from the applicable law. Further, they derived several WTO case law showing that international law cannot be enforced by WTO adjudicating bodies, thus the applicable law in WTO disputes is the WTO covered agreements only.[110]

The third group called for a balanced or intermediate approach, where the applicable law in WTO disputes encompasses non-WTO law. However, in case of conflict between WTO and non-WTO law, the conflict is resolved in favor of the WTO law by virtue of articles 3(2) and

[108] Joost Pauwelyn, 'The Role of Public international Law in the WTO: How Far Can We GO?' (2001) 95(3) The American Journal of International law 535, 562, 566, 577

[109] Gabrielle Marceua, 'WTO Dispute Settlement and Human Rights' (2002) 13(4) European Journal of International Law 753, 773-777. **See also**, Anja Lindroos and Michael Mehling, 'Dispelling the Chimera of Self-Contained Regimes International Law and the WTO' (2006) 16(5) The European Journal of International Law 857, 862. **See also**, Joel P. Trachtman, 'The Domain of WTO Dispute Resolution' (1999) 40(2) Harvard International Law Journal 333, 342-343

[110] WTO Appellate Body Report, *European Communities - Measures Affecting Importation of Certain poultry Products* (adopted 23 July 1998) WTO Doc WT/DS69/AB/R, para 79. **See also**, WTO Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas* (adopted 25 September 1997) WTO Doc WT/DS27/AB/R, para 184. **See also**, WTO Panel Report, *Korea - Measures Affecting Imports of Fresh, Chilled and Frozen Beef* (adopted 10 January 2001) WTO Doc WT/DS161/R, WT/DS169/R, para 539

19(2) of the DSU. So, the WTO law takes precedence in application over human rights law whenever a conflict between both norms arises.[111]

All foregoing views claim to support their position by using the same provisions in the DSU, namely articles 3(2), 7, 11 and 19(2). These articles are a matter of continuous debate and controversy. They may be used to argue either in favour of, or against a wider scope of applicable law in WTO dispute settlement. With the difficulty in identifying a mainstream view, the dissertation shall conduct a cautious analysis of the previous DSU articles to try to identify the most compelling argument, if any.

#### 5.4.3.1 Articles 3(2) and 19(2) of the WTO DSU

Article 3(2) of the DSU specifies the central object and purpose of the WTO dispute settlement system in "providing security and predictability to the multilateral trading system." The article added that the system preserves the rights and obligations of WTO members under the covered agreements and clarifies their provisions according to customary rules of interpretation of public international law. In consistency with article 19(2) of the DSU, article 3(2) noted that the findings and recommendations of the WTO judicial bodies "cannot add to or diminish the rights and obligations provided in the WTO covered agreements." This means that the judicial bodies cannot create new law for WTO member states. Amending the existing WTO norms or enacting new ones is the responsibility of the WTO members only. Also, they cannot issue authoritative interpretations that bind all WTO member states. Those interpretations are assigned only to the Ministerial Conference and the General Council by virtue of article IX (2) of the WTO Agreement and article 3(9) of the WTO DSU.

Consequently, permitting the applicability of non-WTO law in WTO disputes settlement threatens the security, stability, and predictability of the WTO system. The system is based on trade interests reflecting different levels of development of member states. In order to achieve mutual benefit, states passed through long periods of negotiations involving huge economic and political bargains in order to strike a balance between their rights and obligations under the WTO agreements. Therefore, disturbing the balance would result in undermining or damaging

[111] Lorand Alexander Bartels, 'Applicable Law in WTO Dispute Settlement Proceedings' (2001) 35(3) Journal of World Trade 499, 506

the WTO trade system, specifically for developing and least-developed countries.[112] Indeed, the WTO panel stated that threatening the European Communities by Section 301 of the US Trade Act constitutes unilateral trade sanctions that affect the stability and predictability of the multilateral trading system. The US, as such, violated article 23 of the DSU which provided that seeking the redress of a violation of WTO obligations shall be made only by recourse to the rules and procedures in the WTO DSU.[113]

The following illustration will be used to show that invoking human rights law as a defense against claims of violations of WTO obligations disturbs the balance of the rights and obligations of WTO members under the WTO covered agreements. It creates new obligations that are not contained in the WTO covered agreements. The WTO law does not permit the modification of its provisions in that manner.

Assume that a country X refused to grant a patent right to a medicine invented in country Y. Country Y challenged that action in front of the WTO DSB claiming that country X violated article 27 of the TRIPS agreement which prohibited discrimination as to the place of invention. In its defence, country X claimed that it refused to grant the patent right to the invention because country Y does not fulfil its human right to health obligations stipulated in the ICESCR to which both countries X and Y are parties. In other words, country X invoked human rights law in its defence concerning a claim of violation of WTO law. Is such defence permissible?

According to Pauwelyn and other scholars advocating for full applicability of international law in WTO disputes, the defence of country X is permissible since both countries are members of the ICESCR at the time of complaint. However, recognizing articles 3(2) and 19(2) is sufficient to rebut this view. Country X cannot take that defence or any other related to human rights, except *jus cogens* norms, because its movement away from the non-discrimination clause stipulated in article 27(1) of the TRIPS does not fall under any of the exceptions provided in the same article 27 paras (2) and (3). If the defence of country X is accepted, then this means that the medicines invented in country Y can be patented only in country X, if country Y fulfilled its human rights obligations in the ICESCR. In other words, the WTO adjudicating bodies would recommend in that case, that country Y fulfils its human rights obligations in the ICESCR, thus

[112] Gabrielle Marceua, 'WTO Dispute Settlement and Human Rights' (2002) 13(4) European Journal of International Law 753, 760 footnote 20. **See also,** Joel P. Trachtman, 'Jurisdiction in WTO Dispute Settlement' in Rufus Yerxa and Bruce Wilson (eds), *Key Issues in WTO Dispute Settlement: The First Ten Years* (Cambridge University Press 2005) 132, 133-143

[113] WTO Panel Report, *United States - Section 301-310 of the Trade Act 1947* (adopted 27 January 2000) WTO Doc WT/DS152/R, paras 7.71, 7.94

adding to its trade obligations. Such a scenario is prohibited by the DSU according to articles 3(2) and 19(2). If the WTO adjudicating bodies permitted that defence, they would be acting in contravention of the DSU provisions.

Further, accepting the previous defence and applying human rights norms leads to creating new obligations that varies from a WTO member state to another. If another state Z is not party to the ICESCR, then its invented medicines shall be patented if the patentability requirements are met, regardless of its human rights violations. Meanwhile, since state Y is party to the ICESCR, then its medicines may not be patented if it violated any of its human rights obligations.

Moreover, when examining the defence of country X, the WTO adjudicating bodies will be actually examining whether country Y is in compliance with its human rights obligations. Such examination implies that the WTO judicial bodies extend their jurisdiction to non-WTO disputes, a matter which is impermissible as previously explained. This is not to suggest that fulfilling WTO obligations is more important than human rights obligations, or that WTO law is superior to human rights law. These examples illustrate the consequences of adopting the approach endorsing full applicability of non-WTO law in WTO disputes settlement. The approach adds new obligations on WTO members contrary to what is stipulated in article 3(2) and 19(2) of the WTO DSU.

Finally, allowing non-WTO law to be invoked in the defence of some WTO member states while denying that option from others, depending on whether or not they are party to the treaty containing the non-WTO law, creates a system with distinct rules for different WTO members. This runs counter to the basis of the WTO agreement requiring WTO member states to "develop an integrated, more viable and durable multilateral trading system."[114] Invoking non-WTO rules, as such, creates a segregated multilateral trading system. It affects the durability of the system by frustrating the economic gains that the WTO members expect to flow from the system. In essence, invoking non-WTO law in WTO disputes would render the WTO trading system neither integrated nor durable.

Nevertheless, restricting the applicable law raised as a defense against claims of WTO law violation to WTO covered agreements does not mean that the WTO law had contracted out from the entire system of international law. Rather, international law can be resorted to in the interpretation process when seeking to clarify the existing provisions of WTO covered

[114] Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement) preamble

agreements in accordance with customary rules of interpretation of public international law as stipulated in article 3(2). However, taking into account international law when interpreting WTO provisions does not mean that it is part of the applicable law in WTO disputes. It does not mean that the WTO adjudicating bodies can apply non-WTO law when it is invoked as a defence for a WTO complaint. An important distinction has to be drawn between the use of international law in interpretation and the use of international law as applicable law in WTO disputes. The first is supported by evidence as shall be demonstrated later in this chapter, meanwhile, the latter is untenable. This understanding is in line with what the dissertation proved above, that WTO law is not a self-contained regime, but rather a part of the wider corpus of public international law. Thus, it cannot be read in clinical isolation from public international law.

#### 5.4.3.2 Article 7 of the DSU

This article describes the terms of reference of the WTO panels. It stipulates that the panels shall have to examine the matter in light of the relevant provisions of the WTO "covered agreements" cited by the parties to the dispute. After the examination, the panel shall "make "such findings" as will assist the DSB in making the recommendations or in giving the rulings provided in the covered agreements."[115]

Several authors regarded the phrase "covered agreements" as limiting the applicable law in WTO disputes to "covered agreements" as mentioned by the exact wording of the article.[116] Others contended that the phrase "such findings" in paragraph 1 of the article implies that the panels may need to refer to, and apply rules of international law beside WTO law. Hence, to deduce from the explicit references to "covered agreements" that all other non-WTO law is thereby implicitly excluded from being applied is erroneous.[117] They supported their argument by referring to *Korea - Government Procurement* case in which the customary rules of international law were used to examine non-violation complaint before the WTO panel. The

[115] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 7(1)(2)

[116] Gabrielle Marceau, 'WTO Dispute Settlement and Human Rights' (2002) 13(4) European Journal of international Law 753, 767. **See also**, Joel P. Trachtman, 'The Domain of WTO Dispute Resolution' (1999) 40(2) Harvard International Law Journal 333, 342. **See also**, Gabrielle Marceua, 'A call for Coherence in International Law - Praises for the Prohibition Against "Clinical Isolation" in WTO Dispute Settlement' (1999) 33(5) Journal of World Trade 87, 110

[117] Joost Pauwelyn, 'The Role of Public international Law in the WTO: How Far Can We GO?' (2001) 95(3) The American Journal of International law 535, 562. **See also**, Lorand Alexander Bartels, 'Applicable Law in WTO Dispute Settlement Proceedings' (2001) 35(3) Journal of World Trade 499, 505

panel noted in that case that it does not see any basis for arguing that article 7(1) of the DSU about the terms of reference of the panel is "meant to exclude reference to the broader rules of customary international law in interpreting a claim properly before the panel."[118] This argument is untenable for several reasons.

The phrase "such findings" has to be read with the preceding words and within the overall context of article 7(1). The context of this article explicitly shows that the applicable law is that of the WTO "covered agreements." Arguing that the applicable law encompasses non-WTO law renders the phrase "covered agreements" unnecessary which runs counter to the principle of effective interpretation. According to that principle, as stipulated in the VCLT, every term in a treaty has a meaning that should be considered in its context.[119]

Further, accepting the argument that considers the text of article 7 implies the application of non-WTO rules, leads to a strange situation. According to the terms of reference under article 7, the panel examines the WTO measure and the claims for its violation. Either the panel considers the measure in compliance with the WTO "covered agreements" and dismisses the compliant, or it concludes that a violation occurred and uphold the complaint. In the first case, the respondent shall continue applying the measure, while, in the second case, he has to remove or modify the measure found in violation of the WTO "covered agreements." However, a third situation shall occur according to the latter argument, where a contested measure is found in violation of WTO covered agreements, yet the complaint pertaining to such violation cannot succeed. This is due to invoking the measure as an applicable law, provided that the measure (non-WTO norm) is binding on the claimant and the respondent.

In other words, invoking a human rights obligation binding on two parties to a WTO dispute causes a strange situation to occur. The WTO panel will make a finding that the measure is in violation of one or more provisions of WTO covered agreements. Nevertheless, it rules that the measure is permissible because it is consistent with the human rights obligation (non-WTO law). According to the understanding of article 7, the panel cannot adjudicate in this way. Nothing in the DSU permits the application of a measure that violates WTO provisions, even if such measure is consistent with human rights obligations.

[118] WTO Panel Report, *Korea - Measures Affecting Government Procurement* (adopted 19 June 2000) WTO Doc WT/DS163/R, para 7.101 footnote 755

[119] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 31(1)

Supporting the third situation, Pauwelyn stated that there is no presumption that the WTO law should always prevail in cases of conflict with non-WTO law. He argued that international law can be excluded only "as a result of contracting out by the treaty or a general conflict clause in favour of the treaty. However, such contracting out or conflict clause does not concern the potentially applicable law in settling disputes as much as which of several potentially applicable law is to prevail."[120] Pauwelyn wants to say that the WTO system is part of the public international law. It did not contract out of its ambit *in toto*, thus, despite the obligation to address and possibly apply WTO rules in certain situations, there is nothing in the WTO law that precludes the WTO judicial bodies from addressing and applying non-WTO law in WTO disputes. As a part of the wider corpus of public international law, the DSU does not have to mention or confirm explicitly that WTO judicial bodies have to apply relevant rules of international law norms in WTO disputes. This confirmation occurs automatically as a consequence of being part of public international law.[121] Restricting the applicable law in WTO disputes to WTO law would inevitably, as Pauwelyn argues, creates "small, isolated pockets of international law, delinked from other branches of the wider corpus of international law. It goes against the unity of international law as well as the principle of *pacta sunt servanda.*"[122]

This argument cannot be accepted as well since neither the language of article 7, nor any other DSU provision supports it. Although the DSU exists in the wider corpus of international law, its basic function is to achieve the satisfactory settlement of trade disputes. The settlement should be reached in accordance with the rights and obligations of the WTO member states stipulated under the DSU and the WTO covered agreements,[123] rather than with their rights and obligations outside the WTO agreement. Article 7 shows clearly that the WTO Panels have to examine claims and defences in accordance with the WTO covered agreements. If the DSU intended to allow the panels to use non-WTO law, then it would have reflected such intention in the wording of article 7. For instance, the text of article 7(1) would be drafted to include the

[120] Joost Pauwelyn, 'The Role of Public international Law in the WTO: How Far Can We GO?' (2001) 95(3) The American Journal of International law 535, 564. **See also**, Lorand Alexander Bartels, 'Applicable Law in WTO Dispute Settlement Proceedings' (2001) 35(3) Journal of World Trade 499, 507-509

[121] Joost Pauwelyn, 'The Role of Public international Law in the WTO: How Far Can We GO?' (2001) 95(3) The American Journal of International law 535, 561-562

[122] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 461

[123] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 3(4)

phrase (other agreement(s) cited by the parties to the dispute) beside the existing phrase "name of the covered agreement(s)."

Additionally, Pauwelyn seems to have overlooked an important fact related to the freedom of states to be subject to international law provisions. The dissertation showed in chapter 4 that the international law does not have a central legislator drafting its rules nor an executive authority with power to enforce the law. States are the creators and at the same time the subjects of international law. Thus, states are free at any time to agree on creating "small pockets" in terms of specialized substantive rules, allowing them to prevail over international law norms, except the *jus cogens* norms.

Finally, the *Korea - Government Procurement* case does not support the view of the proponents considering that non-WTO law is applicable law according to article 7. Rather, it supports the fact that non-WTO law is used for interpretative purposes. International law can be used only in interpreting WTO norms to clarify the meaning of the provisions of WTO covered agreements as mentioned in article 3(2) of the DSU. The usage of international law in treaty interpretation does not mean that it is part of the applicable law in WTO disputes.

In essence, the view that non-WTO law is part of the applicable law in WTO disputes based on the terms of reference of panels stipulated in article 7 of the DSU is untenable.

#### 5.4.3.3 Article 11 of the DSU

Article 11 of the DSU specifies the functions of the WTO panels as follows:

1- Assist the DSB in discharging its responsibilities under the DSU and the WTO covered agreements.

2- Carry out an objective assessment of the matter before it and the facts of the case.

3- Examine the applicability and conformity of the matter and facts with the relevant covered agreements.

4- Make other findings that will assist the DSB in making recommendations or rulings as provided in the covered agreements.

From the text of article 11, it is clear that the panels have to apply the law in the WTO covered agreements only. The article does not mention that the panels, when carrying their objective

assessment of the matter and the facts of a case, apply non-WTO law. Again, as argued above in article 7, if the DSU intended to allow the panels to use non-WTO law, then it would have reflected such intention in the wording of article 11. For instance, the text of article 11 would be drafted to allow the panels to make the objective assessment according to other sources of international law, in addition to the already existing phrase "covered agreements."

However, few scholars argue that article 11 mandates the WTO adjudicating bodies to use non-WTO law as applicable law in WTO disputes. The term "objective assessment of the matter" used in the article contains "implied powers" that would be construed as an authorization to the WTO adjudicating bodies to decide all aspects of a dispute even those involving questions of public international law. This is necessary to avoid piecemeal decision-making which leaves relevant questions of law in a dispute undecided. It also asserts that WTO law is not a closed legal circuit but rather a part of the larger corpus of public international law.[124] Pauwelyn supported this view, where he argued that this article obliges the WTO panel to assess the applicability of WTO law objectively according to the rules of conflict in general international law. The panel may find that invoking international law, as a defence, renders the WTO provisions unviolated. Therefore, failure to consider international law would preclude "the objective assessment of the matter" and the applicability of the relevant covered agreements.[125]

Such arguments are erroneous because article 11 has to be read together with article 7 that sets out the mandate of the WTO panel. So, the panel has to perform its functions, as mentioned in article 11, within its mandate that limits the applicable law to WTO covered agreements. Also, reading the phrase "other findings" in relation to the phrase preceding it, does not support such arguments. The phrase "other findings" is preceded by "… the applicability of and conformity with the relevant agreement and make such other findings …" This means that the panel has to determine the applicability of the WTO provisions to the matter before it, as part of the normal judicial reasoning. The judicial reasoning examines the applicability of the law to the facts, i.e., the panel shall explore whether the WTO provision applies on the matter in question rather than exploring whether such matter conforms with non-WTO law or otherwise. So, the panel does not apply non-WTO law in its examination.

[124] Thomas J. Schoenbaum, 'WTO Dispute Settlement: Praise and Suggestions for Reform' (1998) 47(3) International and Comparative law Quarterly 647, 652-653
[125] Joost Pauwelyn, 'The Role of Public international Law in the WTO: How Far Can We GO?' (2001) 95(3) The American Journal of International law 535, 562

From the previous analysis of the WTO normative framework, it appears that it cannot provide a solution to the conflict between pharmaceutical patents in TRIPS and human right to health. It is highly unlikely that human rights law could be taken into account within the WTO system. The WTO dispute settlement system has limited jurisdiction *ratione materiae*, where it is restricted to claims brought pursuant to the WTO covered agreements. Also, the combined reading of the DSU articles, invoked in the arguments about the applicable law in WTO disputes, shows that the respondent cannot raise a defence against claims of WTO law violation relying only on human rights law. Such defence shall not be accepted since human rights law is not part of the applicable law in WTO dispute settlement system. Non-WTO law can be invoked only when interpreting the WTO covered agreements provisions or when it is referred to in procedural matters. Applying non-WTO law, except in these two instances, shall entail modifying the existing obligations of WTO member states which is restricted to those found in the WTO covered agreements. If such modification occurred, it would undermine the predictability and security of the WTO system.

It should be stressed again that the usage of international law in interpretation does not mean that it is part of the applicable law in WTO disputes. The WTO adjudicating bodies use non-WTO law only to clarify the meaning of the WTO covered agreements' provisions. They are not allowed to add or diminish the rights and obligations of WTO member states as stipulated under articles 3(2) and 19(1) of the DSU. This conforms with the principle stating that a judicial body does not make a new law but interprets and applies only the existing law. Only the legislative body in the WTO, namely the WTO General Council or the Ministerial Conference, has the exclusive authority to add or diminish the rights and obligations under the WTO covered agreements, and to issue authoritative interpretations binding on all WTO member states.

Gabrielle Marceau emphasized this finding, where she elucidated that allegations and arguments relating to human rights are not considered in the WTO dispute settlement system. She added that the WTO adjudicating bodies cannot apply or enforce other treaties or customs than WTO covered agreements. They cannot also determine the legal consequences of rights and obligations of WTO member states, except according to WTO law. Non-WTO law, including human rights, could be invoked when necessary for the interpretation of WTO law. WTO members, as she suggested, did not grant WTO remedies for the enforcement of rights and obligations in any treaty in international law, other than WTO covered agreements. However, WTO members who violated their human rights obligations may be liable, but their

responsibility cannot be enforced via the WTO adjudicating bodies. As such, Marceau proposed that WTO law must be interpreted consistently with public international law, *inter alia*, human rights law. The principle of interpretation in good faith of WTO provisions should lead to a reading and application of WTO norms in consistency with human rights norms.[126]

The previous three approaches regarding the applicable law in WTO disputes revolve around whether the WTO dispute settlement system should or should not be applying non-WTO law. None of them defined clearly what is WTO law. They did not provide a specific rule to identify the legal norms of the WTO in order to observe and evaluate the actual practice of the WTO dispute settlement system regarding human rights law.

As illustrated above, the lack of an explicit provision in the WTO DSU regarding the sources of applicable law is a subject of continuous controversy. Both the DSU and the WTO agreement do not contain a provision similar to article 38(1) of the Statute of the ICJ with its explicit catalogue of applicable sources of law.[127] However, despite the lack of an explicit equivalent to that article, its terms could still be brought into WTO law via article 3(2) of the WTO DSU. The article obliges the WTO dispute settlement system to clarify the WTO provisions "in accordance with customary rules of interpretation of public international law." Thus, all sources enumerated in article 38(1) of the ICJ could be considered potential sources of law that could be utilized when interpreting WTO provisions. This leaves a wide scope of discretion to the WTO adjudicating bodies, in the interpretation process, when considering WTO disputes.

With this sole reference to international law, the WTO case law may provide more indication on whether the WTO adjudicating bodies, in their interpretation practice, have taken into account human right to health or otherwise. Could the WTO case law be counted as applicable law in WTO disputes settlement?

In the next section, Hart's secondary rule of recognition will be utilized to argue that the jurisprudence of the WTO dispute settlement system is counted as applicable law in WTO disputes. In other words, the WTO law includes the actual and rhetorical practice of the WTO adjudicating bodies when they use international law in interpretation.

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[126] Gabrielle Marceua, 'WTO Dispute Settlement and Human Rights' (2002) 13(4) European Journal of International Law 753

[127] Statute of the International Court of Justice (adopted 26 June 1945, entered into force 24 October 1945) 3 Bevans 1179, 59 Stat 1031, TS 993 (ICJ) art 38(1). **See also**, Anja Lindroos and Michael Mehling, 'Dispelling the Chimera of Self-Contained Regimes International Law and the WTO' (2006) 16(5) The European Journal of International Law 857, 874

### 5.5 Defining WTO Law

The purpose of this section is to define WTO law before exploring whether human rights law could be accommodated within the WTO system. The dissertation shall use Herbert Hart's theory of the rule of recognition to define WTO law since there is no agreement on a clear definition of what constitutes WTO law.

Hart illustrated that the notion of every definition carries its exclusion. He stated that "sometimes a definition of a word can supply a map at one time, and at the same time it may make explicit the latent principle which guides our use of the word, and may exhibit relationships between the type of phenomena to which we apply the word and other phenomena."[128] Therefore, defining WTO law shall supply a map to realize what can count as WTO law and what does not constitute WTO law.

Hart focused on what the judiciary or legal officials in any legal system do, rather than proposing a definition of law as a system of orders backed by threats, or focusing on how the law could be derived from moral orders or dogmatic definitions.[129] His theory relied on the secondary rules of recognition which exist as a factual matter in any domestic legal system. The secondary rules of recognition are used by the judiciary in their own practice to identify what is valid and applicable as a legal rule and what is not.[130] Hart's theory has to be emphasized to build on its concept in determining what constitutes WTO law.

According to Hart, the foundation of any fully developed legal system are primary rules of obligations, some of which are in form of orders backed by threats, and secondary rules of recognition. The latter are the basic and ultimate norms of the legal system. They define the common identifying test for legal validity in any legal system, i.e., what counts and what does not count as a law. Hart stated that "to say that a given rule is valid is to recognize it as passing all the tests provided by the rule of recognition," i.e., "it satisfies all the criteria provided by the rule of recognition."[131]

Hart asserted that the secondary rule of recognition is an empirical observable fact that is recognized in the practice of judiciary or the practice of judicial officials of the legal system.

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[128] H. L. A. Hart, *The Concept of Law* (3rd edn, Oxford University Press 2012) 14
[129] Ibid, 15. **See also**, Jason A. Beckett, 'The End of Customary International Law? A Purposive Analysis of Structural Indeterminacy' (PhD thesis, University of Glasgow 2005) 24 < https://core.ac.uk/download/pdf/40081051.pdf> accessed 15 July 2020
[130] H. L. A. Hart, *The Concept of Law* (3rd edn, Oxford University Press 2012) 103, 117
[131] Ibid, 103, 107. **See also**, Stephen V. Carey, 'What is the Rule of Recognition in the United States?' (2009) 157 University of Pennsylvania Law Review 1161, 1165-1168

Since it is the practice of judiciary which could differ from one legal system to another, it does not have a specific content. In other words, the content of the secondary rules of recognition could vary from one system to another. However, as an idea, it is found in every judicial system.[132] As such, the rule of recognition is generic and not specific.

Hart postulates two issues in defining the rule of recognition as the practice of the judiciary. The first is that the rule of recognition, unlike other rules in the legal systems, is always a valid rule since there is "no rule providing criteria for the assessment of its own legal validity."[133] The second is that the rule of recognition is not valid until it is accepted by judiciary.[134]

Hart opines that the internal point of view is inevitable to understand the content of the rule of recognition which is the foundation of any legal system.[135] As stated by Coleman, the internal point of view is the committed point of view which makes those who apply the law accept certain rules as reason-giving. Thus, officials are committed to the secondary rules of obligation because of the internal point of view which makes them apply such rules as action-guiding rules, rather than due to the sanctions imposed by such rules in case of non-compliance.[136] On the contrary, the external point of view, as Hart opined, is limited in understanding any legal system because it is not directed to judicial officials, who only apply the internal point of view, but rather directed to the subjects of the legal system (citizens) who are responsible for obeying the law.[137] An example of secondary rules of recognition is case precedents which are applied by legal officials as a valid law. The case precedents are not subject to an external validation due to the internal point of view that makes the legal officials consider that the past decisions inform the current ones.[138] On the contrary, individuals would view the application of legal officials to case precedents as a response to a rule that the legal officials recognize. They would not view such rule as one that is applied to them because they do not have that internal point of view to the rule of recognition.

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[132] H. L. A. Hart, *The Concept of Law* (3rd edn, Oxford University Press 2012) 98, 99, 108
[133] Ibid, 107
[134] Ibid, 103-105
[135] Ibid, 86-90
[136] Ibid. **See also**, Jules Leslie Coleman, 'Incorporationism, Conventionality, and the Practical Difference' (1998) 4 Legal Theory Journal 381, 391
[137] Jason A. Beckett, 'The End of Customary International Law? A Purposive Analysis of Structural Indeterminacy' (PhD thesis, University of Glasgow 2005) 26-27 < https://core.ac.uk/download/pdf/40081051.pdf> accessed 15 July 2020. **See also**, H. L. A. Hart, *The Concept of Law* (3rd edn, Oxford University Press 2012) 86-87
[138] Julie Dickson, 'Is the Rule of Recognition Really a Conventional Rule' (2007) 27(3) Oxford Journal of Legal Studies 373, 393

In essence, according to Hart, any rule is considered to be valid and applied in any legal system due to the acceptance by the legal officials of the rule of recognition as the rule which identifies the validity of law. The rule of recognition itself, from an internal point of view, is not subject to external validation.

Consequently, the judgments of the legal officials have greater authority than other rules due to the rule of recognition located in their practices. If the judicial officials accept that case precedents are binding due to the rule of recognition, then there is a normative aspect to their acceptance of the internal point of view. Thus, Hart contends that the "judicial officials have an obligation to follow and criticize deviations from the rule of recognition as the ultimate rule that determines other rules as valid law."[139]

If Hart did not assume that the rule of recognition is the ultimate rule with no external validation, then it would be difficult to determine its content. In other words, Hart contends that the rule of recognition is a self-referential matter of fact, where no rule could provide criteria for assessing its validity. This is based on the internal point of view of the legal system which is contingent upon the rule of recognition itself.[140] The law, though, would become a law because of an "exogenous force or agent," i.e., "the law is the law because it is the law."[141] To clarify that the validity of the rule of recognition "is assumed but cannot be demonstrated," Hart gave the example of the standard meter bar in Paris. Worldwide, it is assumed that it is "the ultimate test of correctness of all measurements in meters." This is an assumed matter without demonstration that it is correct *per se*.[142]

In contrast, John Austin's method for defining law was different. He attempted to find a definition of law that would include all the things that he believed are law and exclude others that he considered not law.[143] He defined law as the "rule laid down for the guidance of an intelligent being by an intelligent being having power over him."[144] This definition implies that the sovereign, as the supreme authority, is neither bound or obliged by any command, nor is he

[139] H. L. A. Hart, *The Concept of Law* (3rd edn, Oxford University Press 2012) 94-95. **See also**, Ronnie R. Yearwood, *The Interaction between World Trade Organization (WTO) Law and External International Law: The Constrained Openness of WTO Law* (Routledge London 2012) 38-39
[140] H. L. A. Hart, *The Concept of Law* (3rd edn, Oxford University Press 2012) 104, 107
[141] Ronnie R. Yearwood, *The Interaction between World Trade Organization (WTO) Law and External International Law: The Constrained Openness of WTO Law* (Routledge London 2012) 39
[142] H. L. A. Hart, *The Concept of Law* (3rd edn, Oxford University Press 2012) 104, 109
[143] John Austin, *The Province of Jurisprudence Determined* (Wilfrid E. Rumble edn, Cambridge University Press 1995) 18-24
[144] Ibid, 10

subject to any authority. People either comply with the commands of the sovereign or not, where non-compliance leads to sanctions.[145] As such, the law in Austin's view is a habit of disobedience owed to a sovereign.

Austin's method of defining the law cannot be transposable to international law since the latter lacks any single sovereign or centralized legislator to enforce it. The creators and main subjects of international law are the states themselves. There is no central adjudicator to resolve potential conflicts arising from the different sub-systems of international law. Thus, Austin's definition of law as a command imposed by a single sovereign cannot be relied upon in international law, otherwise international law would not be a law. That is why the dissertation adopted Hart's concept of law, rather than Austin's method, in defining WTO law. Noticeably, Hart did not intend, as he illustrated in his book *The Concept of Law*, to suggest a definition of law, but rather, to identify law from the practice of judiciary.

It could be argued that Hart's definition of law as the practice of judicial officials of a centralized judiciary is not suitable for application in international law. Unlike domestic law, international law is fragmented and lacks a centralized judicial system. Adopting Hart's definition of law, then, means that the international law could not be a proper legal system like the domestic law. This would be the same situation that occurs according to Austin's definition of law which bars international law as a law because it lacks a single sovereign similar to domestic law.

Nevertheless, this does not prevent the usage of Hart's theory to define WTO law for 2 reasons;

Firstly, the WTO system has a centralized judicial system represented by the WTO dispute settlement system. The dissertation elucidated previously that this system has a sophisticated judicial system with a standing Appellate Body to hear appeals from the panels' reports. It is a judicial system that builds a consistent WTO case law. It has a compulsory and exclusive jurisdiction with a robust enforcement mechanism. As such, it is identical to the centralized judicial systems for which Hart formed the secondary rule of recognition to explain. Therefore, Hart's rule of recognition can be safely used to identify WTO law.

Secondly, even if it is argued that Hart's definition of law as the practice of a centralized judiciary is not applicable to WTO law since it is part of the wider corpus of international law and not a self-contained regime, the rule of recognition *per se* is still applicable. The rule of recognition in itself is a method for defining law that can also be used to define international

[145] Ibid, 194-195

law regardless of its fragmented nature and lack of any centralized judicial system. In this case, it serves to identify international law based on the concept viewing the rule of recognition as a "schematic representation of reality,"[146] i.e., a matter of fact, regardless of restricting it, as Hart did, to the practice of a centralized judiciary.[147] In this case, the dissertation can transpose from Hart's theory, only the concept of the secondary rule of recognition, as a common identification in any legal system regardless of whether it is centralized or not, and use it in defining the WTO law as the practice of judiciary.

Ultimately, the secondary rule of recognition in WTO law is recognized in the practice of the WTO adjudicating bodies. Thus, the WTO law could be defined as the actual and rhetorical practice of the WTO adjudicating bodies when they use international law in interpreting WTO provisions. This shall be explored in the next section, more specifically the practice of the WTO adjudicating bodies when they use the rules of interpretation stipulated in articles 31 and 32 of the VCLT in interpreting WTO provisions.

### 5.6 Interpretation of WTO Law

The WTO jurisprudence considered the VCLT, specifically articles 31 and 32, as a codification of customary rules of interpretation of public international law. Several WTO case law emphasized this understanding. In *US - Gasoline*, *Japan - Taxes on Alcoholic Beverages*, *US - Carbon* Steel cases, the WTO Appellate Body stated that the interpretative issues arising in WTO disputes have to be settled through the application of customary rules of interpretation of public international law. It is well settled in WTO jurisprudence that the principles codified in articles 31 and 32 of the VCLT are such customary rules. In other words, articles 31 and 32 of the VCLT have "attained the status of rules of customary or general international law." As such, the Appellate Body is obliged by virtue of article 3(2) to apply such rules when seeking to clarify the provisions of the WTO covered agreements. "That direction reflects a measure of recognition that the WTO Agreement is not to be read in clinical isolation from public international law."[148] The same understanding is recognized by the WTO Appellate Body in *EC*

[146] Maarten Bos, 'Will and Order in the Nation-State System Observations on Positivism and Positive International Law' (1982) 29(1) Netherlands International Law Review 3, 8
[147] Jason A. Beckett, 'The End of Customary International Law? A Purposive Analysis of Structural Indeterminacy' (PhD thesis, University of Glasgow 2005) < https://core.ac.uk/download/pdf/40081051.pdf> accessed 15 July 2020
[148] WTO Appellate Body Report, *United States - Standards for Reformulated and Conventional Gasoline* (adopted 20 May 1996) WTO Doc WT/DS2/AB/R, 17. **See also**, WTO Appellate Body Report, *Japan - Taxes on Alcoholic Beverages* (adopted 1 November 1996) WTO Doc WT/DS8/AB/R, WT/DS10/AB/R,

- *Hormones* case, where the Appellate Body stated that nothing should relieve it from the duty of applying the customary rules of treaty interpretation of public international law when reading the provisions of the SPS Agreement.[149] This also applies to *Brazil - Measures Affecting Desiccated Coconut* case, where the Appellate Body stated that the WTO panel had properly applied the customary rules of interpretation of public international law, as set out in articles 31 and 32 of the VCLT, on the disputed matter.[150] The ICJ had also recognized, in several cases, article 31 of the VCLT, as a reflection of customary rules of interpretation of public international law.[151]

These cases impose an obligation on the WTO adjudicating bodies to interpret the WTO covered agreements in future WTO disputes in a way that takes into account other international treaties including human rights.[152] However, it has to be noted that such interpretation should not add or diminish the rights and obligations of WTO member states under the WTO covered agreements.[153] Certainly invoking international law *in toto* would change the rights and obligations under the WTO covered agreements. Thus, the WTO adjudicating bodies, while recognizing and applying the customary rules of interpretation, should be cautious when taking into account non-WTO law in the interpretation process of the WTO covered agreements.

Before addressing the rules of interpretation in the VCLT, it is worth clarifying in brief the concept of interpretation. Treaty interpretation is the process used to construe the legal meaning of a treaty term from a number of possible meanings. To achieve that purpose, the interpreter searches for the ordinary meaning of the treaty term in its context, in light of the object and

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WT/DS11/AB/R, 10-11. **See also**, WTO Appellate Body Report, *United States - Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany* (adopted 19 December 2002) WTO Doc WT/DS213/AB/R, para 61. **See also**, WTO Panel Report, *United States - Measures Affecting the Cross-Border Supply of Gambling and Betting Services* (adopted 20 April 2005) WTO Doc WT/DS285/R, paras 6.9, 6.10 (which reflects the same wording of the *US-Gasoline* case)

[149] WTO Appellate Body Report, *European Communities - Measures Concerning Meat and Meat Products (Hormones)* (adopted 13 February 1998) WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, para 124

[150] WTO Appellate Body Report, *Brazil - Measures Affecting Desiccated Coconut* (adopted 20 March 1997) WTO Doc WT/DS22/AB/R, 7

[151] *Territorial Dispute (Libyan Arab Jamahiriya/Chad)* (Judgement) [1994] ICJ Rep 6, para 41. **See also**, *Arbitral Award of 31 July 1989 (Guinea-Bissau/Senegal)* (Judgement) [1991] ICJ Rep 53, para 48. **See also**, *Land, Island and Maritime Frontier Dispute (EL Salvador/Honduras: Nicaragua Intervening)* (Judgment) [1992] ICJ Rep 350, paras 373, 380. **See also**, *Maritime Delimitation and Territorial Questions Between Qatar and Bahrain (Qatar/Bahrain)* (Judgement) [1995] ICJ Rep 6, para 33. **See also**, *Legality of the Threat or Use of Nuclear Weapons* (Advisory Opinion) [1996] ICJ Rep 226, paras 19-21

[152] Jiaxiang Hu, 'The Role of International Law in the Development of WTO Law' (2004) 7(1) Journal of International Economic Law 143, 144

[153] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) arts 3(2), 19(2)

purpose of the whole treaty.[154] He should not surpass the scope of the possible meanings of the term, otherwise the interpretation would change the rights and obligations of parties to the treaty. However, the interpreter has to also take into consideration the intention of the treaty parties when implementing the treaty. Such intention could be expressed from the subsequent agreements or subsequent state practice regarding the interpretation of the treaty, or the application of its provisions.[155] It has to be noted that when the WTO adjudicating bodies interpret WTO provisions, the interpretation is binding on the parties to the dispute only. Authoritative interpretations that bind all WTO member states are assigned only to the Ministerial Conference and the General Council by virtue of article IX (2) of the WTO Agreement.

The rules of interpretation in the VCLT, namely articles 31 and 32, contain various principles of interpretation which facilitate the duty of treaty interpreters giving them broad open-ended choices of interpretation. The VCLT classifies the principles into general and supplementary rules of interpretation. The first occupied an important position which marginalised the position of the second. The general rules of interpretation include the textual and contextual interpretations, the teleological interpretation which values the objectives and purposes of a treaty as a whole, and the evolutionary interpretation which refers to a broad range of rules of international law changing from time to time. Meanwhile, the supplementary rules of interpretation include the subjective interpretation which refers to the parties' negotiations and the preparatory work preceding the conclusion of a treaty.[156] Together, the general and supplementary rules of interpretation in the VCLT are sufficient and flexible enough to encompass most interpretive problems. This was asserted by the ILC when it stated that the VCLT articles regarding the interpretation of treaties covers all methods of interpretation, where

[154] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 110. **See also**, Shai Dothan, 'The Three Traditional Approaches to Treaty Interpretation: A Current Application to the European Court of Human Right' (2019) 42(765) Fordham international law Journal 765, 767. **See also**, Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 31(1)

[155] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 31(3)

[156] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 116-134. **See also**, Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 194-208. **See also**, Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) arts 31, 32

"in fact it is hard to think of any approach to interpretation that would be excluded from articles 31 and 32."[157]

### 5.6.1 Textual and Teleological Interpretations

The textual interpretation is stipulated in article 31(1) of the VCLT. It states that "a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose." This principle is considered "the pivot of the traditional doctrine of interpretation."[158]

According to the textual interpretation, the intentions of the parties to a treaty are articulated in its wording. The wording should not be construed in a way that diverge from the ordinary meaning.[159] The requirement of interpretation in good faith pursues the rule of *pacta sunt servanda* stipulated in article 26 of the VCLT, where a treaty in force is binding on its parties who have to perform it in good faith.

The WTO adjudicating bodies applied the textual interpretation in several WTO cases. In *Japan - Taxes on Alcoholic Beverages* case, the WTO Appellate Body asserted that "article 31 of the VCLT provides that the words of the treaty form the foundation for the interpretive process."[160] Also, in *EC - Hormones* case, the Appellate Body manifested that the primary rule in treaty interpretation is to read and interpret the actually used words and not the words which "the interpreter may feel should have been used."[161] The purpose of the textual interpretation, as such, is to "ascertain the common intentions of the parties."[162] These cases seem like a clear support for textual interpretation.

However, it is crucial when applying the textual approach to discern the overall objectives and purposes of the treaty. The interpreter has to interpret the treaty with reference to its leading

[157] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 427
[158] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 117
[159] Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 194
[160] WTO Appellate Body Report, *Japan – Taxes on Alcoholic Beverages* (adopted 1 November 1996) WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, 11
[161] WTO Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)* (adopted 13 February 1998) WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, para 181
[162] WTO Appellate Body Report, *European Communities - Customs Classification of Certain Computer Equipment* (adopted 22 June 1998) WTO Doc WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R, para 84

concept that is manifested in its objects and purposes, for example the maintenance of public interest, or the promotion of human rights. This is known as the teleological interpretation.[163] It goes beyond the ordinary meaning of the text, as done under the textual interpretation, and searches for the objects and purposes of the treaty as a whole in addition to that of a specific provision.[164]

Sir Ian Sinclair noted that the textual interpretation should be consistent with the teleological interpretation. He opined that the textual interpretation should be given the primary role, and the teleological one should be considered as a supplementary process in the application of treaty interpretation. However, if the textual interpretation resulted in an inconsistent or antithetical meaning with the teleological objectives of the treaty, it should not be applied.[165] Interestingly, the VCLT reflects an evolutionary perspective towards interpretation by combining both the textual and teleological approaches under the general rule of treaty interpretation.

The teleological interpretation has been utilized in the WTO jurisprudence in several cases. In the *US - Shrimp* case, the WTO Appellate Body interpreted the text of a GATT provision in its context considering first the object and purpose of that provision and then the objects and purposes of the whole GATT agreement.[166] Also, in *Japan - Taxes on Alcoholic Beverages* case, the WTO Appellate Body asserted that the objects and purposes of a treaty should be used to determine the meaning of the "terms of the treaty" together with the ordinary meaning given to the wording of the treaty.[167] Further, in *European Economic Community - Regulations on Imports of Parts and Components* case, the WTO panel interpreted the phrase "measures necessary to secure compliance with rules and regulations" which is stipulated in article XX(d) of the GATT in a way that considers the wording of the article in light of the objectives and purposes of the GATT.[168] This also applies to other WTO cases including *US – Restrictions on Imported Sugar*[169] and *European Economic Community – Restrictions on Imports of Desert*

[163] Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 194-195
[164] Michael Lennard, 'Navigating by the Stars: Interpreting the WTO Agreements' (2002) 5(1) Journal of International Economic Law 17, 27-28
[165] Ian Sinclair, *The Vienna Convention on the Law of Treaties* (2nd edn, Manchester University Press 1984) 121, 130
[166] WTO Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products* (adopted 6 November 1998) WTO Doc WT/DS58/AB/R, paras 116 -117
[167] WTO Appellate Body Report, *Japan – Taxes on Alcoholic Beverages* (adopted 1 November 1996) WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, 12
[168] GATT Panel Report, *European Economic Community – Regulation on Imports of Parts and Components* (adopted 16 May 1990) GATT Doc L/6657-37S/132, paras 5.12- 5.18
[169] GATT Panel Report, *United States – Restrictions on Imports of Sugar* (adopted 22 June 1989) GATT Doc L/6514-36S/331, para 5.2

*Apples.*[170] In all these cases, the WTO adjudicating bodies referred to and applied the textual interpretation in consistency with the teleological interpretation as stipulated in article 31(1) of the VCLT.

On the contrary, in *Canada – Pharmaceutical Patents* case,[171] the dissertation showed in chapter 2 that the WTO panel had adopted a narrow definition to the limited exceptions provided by article 30 when examining the stockpiling exception. It favoured only the interests of the patent holder allowing them to prevail over public health expectations. It did not take into consideration the objectives and principles of the TRIPS agreement stipulated in articles 7 and 8. Those articles provide for adoption of measures to protect public health and achieve the mutual advantages of producers and consumers of pharmaceutical products.

The interpretation of the TRIPS provisions should follow the same approach pursued in the interpretation of other WTO agreements' provisions. The TRIPS provisions have to be interpreted not only according to the ordinary meaning given to their terms, but also in light of their objectives and principles stated in articles 7 and 8 of the TRIPS. The TRIPS objectives and purposes infer that they tried to strike a balance between the economic goals of pharmaceutical patent protection and the social goals of health protection.

This approach was affirmed by the Doha Declaration which stated that the TRIPS provisions should be "read in the light of the object and purpose of the agreement as expressed, in particular, in its objectives and principle."[172] The meaning of the phrase "in particular, in its objectives and principles" infers that when interpreting the text of a TRIPS provision, the interpretation should encompass not only the object and purpose of the provision in its context, but also the overall objectives and principles of the TRIPS agreement.

The approach relying on teleological interpretation to justify taking into account human rights law in WTO interpretation may open a room for invoking the right to access to medicines in TRIPS interpretation. It also connects the TRIPS, as a WTO agreement, to the wider corpus of public international law. Nevertheless, given the reluctance of the US to ratify the ICESCR,[173]

[170] GATT Panel Report, *European Economic Community - Restrictions on Imports of Desert Apples - Complaint by Chile* (adopted 22 June 1989) GATT Doc L/6491-36S/93, para 12.13
[171] WTO Panel Report, *Canada - Patent Protection of Pharmaceutical Products* (adopted 7 April 2000) WTO Doc WT/DS114/R
[172] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration) para 5(a)
[173] 'International Covenant on Economic, Social and Cultural Rights' (UN Treaty Collection, 12 May 2021) < https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-3&chapter=4&clang=_en> accessed 12 May 2021

any WTO decision invoking human right to health in the interpretation process would likely to meet severe criticism from the US.

The problem in TRIPS is that there is a lack of guidance on implementation of the balance between the robust patent protection standards provided by the substantive provisions of the TRIPS, and the public interests in the accessibility to essential medicines. This situation leads to interpretations that do not take into consideration the principles of the TRIPS. In other words, the substantive provisions of pharmaceutical patents in TRIPS agreement often discourage the WTO adjudicating bodies from taking into consideration, the human right to health in interpretation.

### 5.6.2 Contextual Interpretation

The general rule of treaty interpretation in the VCLT addresses the usage of contextual interpretation in article 31(1)(2). The context of the treaty, includes not only the ordinary meaning of its terms in their context, but also: "a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty; b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty."

The ILC explained that for a document to constitute part of the contextual interpretation, it has to be made in connection with the conclusion of the treaty and accepted by all treaty parties in a way that express their intention explicitly to consider such document an integral part of the treaty. Moreover, the ILC mentioned that these documents should not be treated for the purpose of treaty interpretation as a "mere evidence to which recourse may be had for the purpose of resolving an ambiguity or obscurity, but as part of the context for the purpose of arriving at the ordinary meaning of the terms of the treaty."[174]

The WTO jurisprudence shows that these conditions are taken into consideration when deciding whether a certain document could be used in contextual interpretation or otherwise. Several WTO cases mentioned that all parties to the treaty in dispute should be parties to the other

[174] UN General Assembly, 'Yearbook of the International Law Commission 1966 Vol II: Documents of the Second Part of the Seventeenth Session and of the Eighteenth Session Including the Reports of the Commission to the General Assembly' (1967) UN Doc A/CN. 4/SER.A/1966/Add. 1, 221. **See also**, UN General Assembly, 'Yearbook of the International Law Commission 1964 Vol I: Summary Records of the Sixteenth Session' (1965) UN Doc A/CN.4/SER.A/1964, 125

agreement or accept the other instrument in order to be relied upon in contextual interpretation. It is not sufficient that such agreement or instrument is made in connection with the conclusion of the treaty in question.[175] Also, the agreement or instrument has to be "concerned with the substance of the treaty in dispute and clarify certain concepts in the treaty or limit its field of application. It must be equally drawn up on the occasion of the conclusion of the treaty."[176] Therefore, explanatory statements and preparatory work of an agreement do not qualify as context for the purpose of treaty interpretation.[177]

### 5.6.3 Subjective Interpretation

The subjective interpretation primarily considers the actual intentions of the treaty parties which are expressed in the negotiation process and the circumstances surrounding the treaty conclusion. It refers to the whole course of *travaux préparatoires* (negotiations and preparatory work) which lead to the conclusion of the treaty. It seeks to examine the actual intention of the parties at the time of concluding its final text.[178]

Subjective interpretation is considered a supplementary means of interpretation. Interpreters resort to it only if using the general rule of interpretation stipulated in article 31 of the VCLT renders the meaning of a treaty provision "ambiguous or obscure; or leads to a result which is manifestly absurd or unreasonable."[179]

The subjective interpretation was consistently supported by the theory stating that the international law is based ultimately on the will of states. Sir Hersch Lauterpacht, a prominent

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[175] WTO Panel Report, *European Communities - Customs Classification of Frozen Boneless Chicken Cuts* (adopted 27 September 2005) WTO Doc WT/DS269/R, para 7.153. **See also**, WTO Panel Report, *United States – Section 110(5) of US Copyright Act* (adopted 27 July 2000) WTO Doc WT/DS160/R, para 6.45

[176] WTO Panel Report, *European Communities - Customs Classification of Frozen Boneless Chicken Cuts* (adopted 27 September 2005) WTO Doc WT/DS269/R, para 7.154. **See also**, WTO Panel Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services* (adopted 20 April 2005) WTO Doc WT/DS285/R, para 6.76. **See also**, WTO Panel Report, *United States – Section 110(5) of US Copyright Act* (adopted 27 July 2000) WTO Doc WT/DS160/R, para 6.45

[177] WTO Panel Report, *United States – Section 110(5) of US Copyright Act* (adopted 27 July 2000) WTO Doc WT/DS160/R, para 6.46. **See also**, WTO Appellate Body Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services* (adopted 20 April 2005) WTO Doc WT/DS285/AB/R

[178] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 132. **See also**, Francis G. Jacobs, 'Varieties of Approach to Treaty Interpretation: With Special Reference to the Draft Convention on the Law of Treaties Before the Vienna Diplomatic Conference' (1969) 18(2) The International and Comparative Law Quarterly 318, 319. **See also**, Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 32

[179] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) art 32

supporter of the subjective interpretation, stressed particularly the recourse to the *travaux préparatoires* of the treaty as an effective way to ascertain the intentions of the parties. However, it is argued that resorting to the *travaux préparatoires* of a treaty may give rise to controversy since the will of the parties in the negotiation process may contradict with the treaty terms. The parties to a treaty will only agree to an interpretation considering only the actual wordings of the treaty in question. Even if the parties agreed to give the *travaux préparatoires* effect before concluding the treaty, unforeseen matters not discussed in the preparatory works may appear afterwards. Thus, it shall be necessary to shift to the textual interpretation to express the parties' intentions. Furthermore, in many cases, the records of treaty negotiations are misleading or incomplete. This entails a considerable discretion regarding the value and worthiness of negotiations in treaty interpretation.[180]

For all these difficulties, the VCLT considered that the textual interpretation is the starting point of the interpretation process to express the intentions of the parties to a treaty. The textual interpretation is the general rule of interpretation, and the subjective interpretation is a supplementary one as the VCLT mentioned.

The rationale adopted by the VCLT maintains the stability and certainty of treaty relations that "must remain the overriding concern of international law." Also, such rationale supports the rule of law and the well-known legal principle of *pacta Sunt servanda*.[181] This was asserted by the ILC, where it gave primacy to the treaty text in interpretation and placed the *travaux préparatoires* in a secondary level.[182]

The WTO jurisprudence clarifies that it is not mandatory to use the supplementary material in treaty interpretation. It can be used, subsequent to the application of article 31 of the VCLT, as an exception in certain circumstances provided that the conditions stipulated under article 32 of the VCLT are fulfilled.[183]

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[180] Francis G. Jacobs, 'Varieties of Approach to Treaty Interpretation: With Special Reference to the Draft Convention on the Law of Treaties Before the Vienna Diplomatic Conference' (1969) 18(2) The International and Comparative Law Quarterly 318, 321-322, 338-339

[181] Ibid, 339

[182] UN General Assembly, 'Yearbook of the International Law Commission 1966 Vol I Part II: Summary Records of the Eighteenth Session' (1967) UN Doc A/CN. 4/SER.A/1966, 203

[183] WTO Panel Report, *Japan – Taxes on Alcoholic Beverages* (adopted 1 November 1996) WTO Doc WT/DS8/R, WT/DS10/R, WT/DS11/R, para 87. **See also**, WTO Appellate Body Report, *Canada - Measures Affecting the Importation of Milk and the Exportation of Dairy Products* (adopted 27 October 1999) WTO Doc WT/DS103/AB/R, WT/DS113/AB/R, para 82

The supplementary means of interpretation are not defined in article 32 of the VCLT in an exhaustive manner. Therefore, "an interpreter has a certain flexibility in considering relevant supplementary means in a given case so as to assist in ascertaining the common intentions of the parties."[184]

The WTO jurisprudence indicated that the WTO adjudicating bodies had resorted to the subjective interpretation in several WTO cases. However, they used such interpretation to confirm the meaning reached according to the rules of interpretation in article 31 of the VCLT. In *Canada - Certain Measures Concerning Periodicals* case, the WTO Appellate Body referred to the *travaux préparatoires* as a supplementary means of interpretation.[185] In *European Communities - Measures Affecting Importation of Certain poultry Products* case, the WTO Appellate Body referred to the circumstances of concluding the Agreement of Oilseed as a supplementary means of interpretation.[186] In *US - Gambling* case, the WTO panel referred to the use of the supplementary means of interpretation, *inter alia*, the negotiating history of the treaty, to confirm the meaning prescribed in article 31 of the VCLT.[187] Finally, in *US - Shrimp* case, the negotiating history was referred to in order to confirm the interpretation of the chapeau of article 20 of the GATT.[188]

Nevertheless, the WTO Appellate Body adopted a restrictive approach to the *travaux préparatoires*. In *US - Stainless Steel (Mexico)* case, for example, the Appellate Body excluded the negotiating proposals referred to by the US because they reflected the positions of only some of the negotiating parties. They did not represent the common intentions of the treaty parties.[189] In the same case, the WTO Appellate Body excluded the panel reports referred to by the US on the grounds that they examined the Anti-Dumping issue under the provisions of the Tokyo Round Anti-Dumping Code. The Appellate Body noted that the Tokyo Round is not relevant and had been terminated by the Uruguay Round of Multilateral Trade Negotiations which

[184] WTO Appellate Body Report, *European Communities - Customs Classification of Frozen Boneless Chicken Cuts* (adopted 27 September 2005) WTO Doc WT/DS269/AB/R, WT/DS286/AB/R, para 283
[185] WTO Appellate Body Report, *Canada - Certain Measures Concerning Periodicals* (adopted 30 July 1997) WTO Doc WT/DS31/AB/R, 33-35
[186] WTO Appellate Body Report, *European Communities - Measures Affecting Importation of Certain poultry Products* (adopted 23 July 1998) WTO Doc WT/DS69/AB/R, para 83
[187] WTO Panel Report, *United States - Measures Affecting the Cross-Border Supply of Gambling and Betting Services* (adopted 20 April 2005) WTO Doc WT/DS285/R, paras 6.47-6.48
[188] WTO Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products* (adopted 6 November 1998) WTO Doc WT/DS58/AB/R, para 157
[189] WTO Appellate Body Report, *United States - Final Anti-Dumping Measures on Stainless Steel from Mexico* (adopted 20 May 2008) WTO Doc WT/DS344/AB/R, para 130

concluded the WTO Anti-Dumping Agreement.[190] The Appellate body ignored the fact that the GATT parties negotiated more detailed codes of Anti-Dumping before the Uruguay Round, like, the Agreement on Anti-Dumping Practices that resulted from Kennedy Round in 1967, and the Anti-Dumping Code resulting from the Tokyo Round in 1980.[191] Certainly the WTO member states in the Uruguay Round had built up on what they had achieved in their previous negotiations regarding the Anti-Dumping issue.

The WTO Appellate Body's restrictive approach to the *travaux préparatoires* was criticized by several jurists arguing that the approach was not universally pursued in international economic organizations. The practice of the International Monetary Fund (IMF), for example, shows that the "*travaux préparatoires* are almost always examined when interpretation is undertaken."[192] In the field of investment arbitration, the IMF stated that recourse to supplementary means should be performed without observing the inhibitions of article 31 of the VCLT. The recourse to *travaux préparatoires* would enforce the common intentions of the parties, thus affirming the principle of states sovereignty.[193]

In fact, the restrictive approach to the *travaux préparatoires* curbs the common intention of the treaty parties since it focuses only on the text. Thus, the WTO adjudicating bodies should pursue a liberal approach in that regard by considering the *travaux préparatoires* of the treaty either to ensure the meaning resulting from applying the interpretation rules in article 31 of the VCLT, or to determine the meaning when such interpretation rules leave the meaning ambiguous or absurd.

The WTO jurisprudence illustrated that several documents could be invoked as supplementary means in the interpretation process. Examples include the state practice, its legislations and court decisions, the historical background surrounding the negotiations of a treaty, GATT disciplines in a specific matter, and the relevant dispute settlement proceedings which was decided according to those disciplines.[194] The WTO Appellate Body asserted that to be

[190] Ibid, para 132
[191] 'Technical Information on Anti-Dumping' (WTO) < https://www.wto.org/english/tratop_e/adp_e/adp_info_e.htm > accessed 11 February 2021
[192] Joseph Gold, *Interpretation: The IMF and International Law* (Kluwer Law International The Hague 1996) 184
[193] J. Romesh Weeramantry, *Treaty Interpretation in Investment Arbitration* (Oxford university Press UK 2012) 101
[194] WTO Appellate Body Report, *European Communities - Customs Classification of Certain Computer Equipment* (adopted 22 June 1998) WTO Doc WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R, paras 86, 92-94. **See also**, WTO Appellate Body Report, *European Communities - Customs Classification of Frozen Boneless Chicken Cuts* (adopted 27 September 2005) WTO Doc WT/DS269/AB/R, WT/DS286/AB/R, para

considered as circumstances surrounding treaty conclusion within the meaning of article 32 of the VCLT, the certain act, event, or instrument has to be relevant to those circumstances. The relevance of the circumstances for interpretation "should be determined on the basis of objective factors and not subjective intent." The objective factors include "the type of event, document or instrument and its legal nature; temporal relation of the circumstances to the conclusion of the treaty; … subject matter of the document, instrument or event in relation to the treaty provision to be interpreted; and whether or how it was used or influenced the negotiations of the treaty."[195]

Consequently, the *travaux préparatoires* enshrined in article 32 of the VCLT could include, for example, the negotiations of different multilateral trade negotiations, particularly the Uruguay round. The interpretation, thus, should take into consideration the perspectives of the developing countries in the WTO negotiation process regarding a more flexible pharmaceutical patent system that maintains the price level of essential medicines rendering them accessible and affordable to all people. The dissertation showed in chapter 2, the struggle between the developing and developed countries in the WTO negotiations regarding the pharmaceutical patent system. It illustrated the pressure that was put on the developing countries in the negotiations to force them to accept the TRIPS provisions in their current form.

However, the WTO Appellate Body did not mention or even allude to the abuse or imbalance in the negotiation powers between states, and the complexity of the negotiation process which could be included in the *travaux préparatoires* for the purpose of subjective interpretation. This disregard may impact the treaty interpretation and the intentions of the WTO states parties.

In essence, recourse to the subjective interpretation can be relevant to the TRIPS interpretation when aiming to interpret its social and economic impacts or its public health implications. The negotiating history of the TRIPS agreement manifests the attempts to push the antithetical interests of the negotiating states into one multilateral agreement. The TRIPS negotiating history, thus, has to be referred to in the interpretation process in order to confirm the meaning of the term needed to be interpreted, or to determine such term if it is ambiguous or absurd

309. **See also**, WTO Panel Report, *United States - Measures Affecting the Cross-Border Supply of Gambling and Betting Services* (adopted 20 April 2005) WTO Doc WT/DS285/R, para 6.113. **See also**, WTO Appellate Body Report, *United States - Measures Affecting Trade in Large Civil Aircraft – Second Complaint* (adopted 23 March 2012) WTO Doc WT/DS353/AB/R, para 562. **See also**, WTO Appellate Body Report, *United States - Definitive Anti-Dumping and Countervailing Duties on Certain Products from China* (adopted 25 March 2011) WTO Doc WT/DS379/AB/R, para 579

[195] WTO Appellate Body Report, *European Communities - Customs Classification of Frozen Boneless Chicken Cuts* (adopted 27 September 2005) WTO Doc WT/DS269/AB/R, WT/DS286/AB/R, paras 290-291

according to article 31 of the VCLT. This would be similar to the WTO jurisprudence in this regard.

### 5.6.4 Evolutionary or Dynamic Interpretation (Non-Contextual Materials)

The evolutionary or dynamic interpretation is an important doctrine of treaty interpretation in public international law. It provides for an interpretation of treaty provisions that takes into consideration a very broad range of agreements, instruments, and state practice not only existing at the time of conclusion of the treaty but also at the time of its interpretation.[196] As the international law is in a continuous change responding to the global variables, the treaties will not always remain static. Thus, the evolutionary interpretation would render the interpretation consistent with the development of the wider corpus of international law.

Campbell Mclachlan explained that international law is a normative system that changes and develops continuously, and lacks a specific legislature or a hierarchy of norms. It depends only on states consent to abide by treaties provisions. The normative content of the international law is derived from a wide range of sources that operate without any order of relative priority between them as the dissertation showed in chapter 4. Therefore, the evolutionary interpretation is consistent with such dynamic nature. Mclachlan demonstrated that the evolutionary method of interpretation allows the harmonization of international law rules because it permits the application of the conflicting rules invoked in the dispute rather than applying one norm and excluding the other. The latter results from utilizing the conflict resolution techniques, *inter alia*, the *lex specialis* and the *lex posterior* principles.[197]

Joost Pauwelyn argued that the evolutionary method of interpretation should be applied when interpreting the WTO agreements. Unlike the old GATT rules of 1947 which focus mainly on the idea of balancing trade concessions, the obligations of most of the WTO agreements, including the TRIPS, are of a regulatory nature. They set out general standards and conditions for states' conduct which bind them due to their inherent and indefinite juridical force. The WTO agreements are increasingly becoming law-making instruments that use broad and unspecified terms like "public health and nutrition," "public interests," "*ordre public*," and

[196] Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 198-199
[197] Campbell Mclachlan, 'The Principle of Systemic Integration and Article 31/3(c)' (2005) 54(2) International and Comparative law Quarterly 279, 282-286

"morality." The WTO members wanted such terms to evolve with the society and international law. Their meanings would be left for continuous discussion and variations according to the context and time. As such, utilizing the evolutionary interpretation in interpreting WTO provisions seems necessary and logical.[198] From another aspect, the VCLT stated in article 31(1) that treaties shall be interpreted in light of their objects and purposes. The objects and purposes of regulatory treaties are dynamic in nature and independent from the subjective and temporal intentions of their drafters. Thus, the evolutionary interpretation suits the dynamic and evolving nature of the WTO provisions.[199]

The European Court of Human Rights and the ICJ applied the dynamic interpretation in several cases. In *Tyrer v.UK* case, the ECHR stated that conventions are "living instruments which must be interpreted in the light of the present-day conditions."[200] The ICJ in three subsequent judgements followed the evolutionary interpretation when interpreting the term "territorial status."[201] In *South West Africa* case, the ICJ mentioned that an international instrument has to be interpreted and applied within the framework of the entire legal system prevailing at the time of interpretation."[202] In *Aegean Sea Continental Shelf Case,* the ICJ opined that the term "territorial status" does not have a fixed content due to the subsequent evolution of international law, thus it should be interpreted according to the "rules of international law as they exist today."[203] Finally, in *Gabcikovo-Nagymaros Project* case, the ICJ stated that treaties are not static, but rather they are "open to adapt to emerging norms of international law."[204]

The TRIPS agreement should be interpreted in the same evolutionary manner to invoke the right to health since it contains several open-textured terms. Examples include, "a manner conducive to socio-economic welfare" in article 7, "public health" and "public interest" in article 8, "*ordre public*" and "morality" in article 27(2), and "national emergency" and "extreme urgency" in

[198] Joost Pauwelyn, 'The nature of WTO Obligations' (2002) Jean Monnet Working Paper 1/02, 34 < https://jeanmonnetprogram.org/archive/papers/02/020101.html> accessed 19 February 2020. **See also**, Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS) arts 8, 27
[199] Joost Pauwelyn, 'The nature of WTO Obligations' (2002) Jean Monnet Working Paper 1/02, 35-36 < https://jeanmonnetprogram.org/archive/papers/02/020101.html> accessed 19 February 2020
[200] *Tyrer v The United Kingdom* App No 5856/72 (ECHR, 25 April 1978) para 31
[201] *Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) Notwithstanding Security Council Resolution 276 (1970)* (Advisory Opinion) [1971] ICJ Rep 16. **See also**, *Aegean Sea Continental Shelf Case (Greece v Turkey)* (Judgement) [1978] ICJ Rep 3. **See also**, *Case Concerning the Gabcikovo-Nagymaros Project (Hungary/Slovakia)* (Judgement) [1997] ICJ Rep 7
[202] *Legal Consequences for States of the Continued presence of South Africa in Namibia (South West Africa) Notwithstanding Security Council Resolution 276 (1970)* (Advisory Opinion) [1971] ICJ Rep 16, para 53
[203] *Aegean Sea Continental Shelf Case (Greece v Turkey)* (Judgement) [1978] ICJ Rep 3, paras 77, 80
[204] *Case Concerning the Gabcikovo-Nagymaros Project (Hungary/Slovakia)* (Judgement) [1997] ICJ Rep 7, para 112

article 31. The TRIPS also invites dynamic interpretation since its subject matter is IPRs. Those rights are related to technology, which is changing rapidly with time, thus they require a progressive interpretation which considers the fast pace of technological development.

Article 31(3) of the VCLT provides for an evolutionary interpretation. Its drafting is flexible enough that it allows using agreements, state practice, and any relevant rules of international law in order to facilitate the interpretation of a treaty. The following sub-sections will scrutinize that article and explore how the WTO adjudicating bodies applied it in WTO disputes.

#### 5.6.4.1 Article 31(3)(a)(b)

Article 31(3) of the VCLT stipulates that "there shall be taken into account, together with the context: (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation."

The ILC emphasized that the subsequent agreements and subsequent state practice form an authentic means of interpretation. They are considered an "objective evidence of the understanding of the parties as to the meaning of the treaty."[205] The subsequent agreements and subsequent practice, as the ILC explained, are those which are reached or took place "after the conclusion of the treaty." The ILC noted that "conclusion of the treaty" does not mean its entry into force but rather its text has been established as definite.[206] Further, the ILC emphasized that the subsequent agreements and subsequent practice by the treaty parties may guide an evolutionary interpretation of treaties.[207] Indeed taking into account such instruments in the interpretation process renders the interpretation a dynamic one that responds to the changing nature of international relations. However, the ILC found that the WTO adjudicating bodies typically concentrate on the textual interpretation. They occasionally resorted to evolutionary interpretation or applied the effectiveness principle in order to avoid "reducing the whole clauses or paragraphs of the treaty to redundancy or inutility."[208]

[205] International law Commission, 'First Report on Subsequent Agreements and Subsequent practice in Relation to the Interpretation of Treaties, by Georg Nolte, Special Rapporteur' (19 March 2013) UN Doc A/CN.4/660, para 30
[206] Ibid, paras 85, 116
[207] Ibid, para 64
[208] Ibid, para 11

The Doha Declaration emphasized that the TRIPS agreement should be interpreted and implemented in a manner conducive to support the right of each WTO member to take suitable measures to protect public health and promote access to medicines.[209] It could be argued that the declaration could be invoked in WTO interpretation according to the wording of article 31(3)(a)(b).

However, the Doha Declaration is not considered a binding authoritative interpretation to the TRIPS agreement nor an amendment to any of its provisions as illustrated in chapter 2. Although the declaration was adopted at a Ministerial Conference which has the authority to take decisions and adopt binding interpretations of the TRIPS provisions, it failed to take the three-fourths majority required for a decision to be considered a binding authoritative interpretation of the TRIPS provisions.[210]

The Doha Declaration, though, could be considered a non-binding authoritative interpretation supporting the right of WTO members to promote accessibility to medicines. This understanding was emphasized by Frederick Abbott when he noted that any decision stating a meaning related to the TRIPS agreement "may be considered as a very close approximation of an interpretation and, from a functional standpoint, may be indistinguishable."[211]

Nevertheless, even if the Doha Declaration is considered a non-binding authoritative interpretation, the legal effect of a non-binding authoritative interpretation does not amount to subsequent agreement or subsequent practice within the meaning of article 31(3)(a)(b) of the VCLT. Ehlermann and Ehring emphasized this understanding by stating that the WTO adjudicating bodies could rely on a non-binding authoritative interpretation only as "a mere reference or confirmation of legal findings the panels have developed independently of such

[209] Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration) para 4
[210] Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement) arts IV(1), IX(2). **See also**, Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 307-308
[211] Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 308. **See also**, Frederick M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lightening a Dark Corner at the WTO' (2002) 5 Journal of International Economic Law 469, 492. **See also**, ICTSD - UNCTAD, *Resource Book on TRIPS and Development* (Cambridge University Press New York 2005) 131 < https://unctad.org/en/PublicationsLibrary/ictsd2005d1_en.pdf> accessed 10 March 2020

authoritative interpretations."[212] Therefore, the declaration could not be taken into account when interpreting WTO provisions and, *a fortiori*, it is not part of the applicable law in WTO disputes.

In the understanding of the "subsequent practice" stated in article 31(3)(b), the practice has to be concordant subsequent practice common to all treaty parties rather than a general subsequent practice.[213] The former legal advisor to the UN, Anthony Aust, stated that "however, precise a text appears to be, the way in which it is actually applied by the parties is usually a good indication of what they understand it to mean, provided that the practice is consistent, and is common to or accepted by all parties."[214] The ILC asserted that it suffices that the intention or understanding of every treaty party has been directed to accept the practice, rather than every party must individually have engaged in the practice.[215]

Further, Benedict Chigara opined that the state practice clarifies "what states actually believed they were consenting to in the *milieu* of treaty conclusion." The density of state practice subsequent to the adoption of a treaty solidifies the intention of the treaty parties regarding its implementation since they are not bound by what they had previously signed up for. Since international law is characterized by a fast-moving pace and a rapid response to the variables in international relations, then taking into account the state practice in the interpretation process would reflect the ever-changing moods of states when implementing the treaty. Chigara argued that the recourse to state practice in WTO law interpretation is important because it reflects the specific and special purpose that the WTO regime serve. An immutable benefit of invoking state practice in WTO interpretation is that it would encourage state participation in WTO agreements. It minimises the possibility of denunciation of a WTO agreement by its member states which for any reason, may experience aggravation with the rigid implementation of the WTO system.[216]

The recourse to subsequent practice as a means of interpretation is well-established in the jurisprudence of international tribunals. The ICJ referred to the subsequent practice to arrive at,

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[212] Claus-Dieter Ehlermann and Lothar Ehring, 'The Authoritative Interpretation Under Article Ix:2 of the Agreement Establishing the World Trade Organization: Current Law, Practice and Possible Improvements' (2005) 8(4) Journal of International Economic law 803, 807-808

[213] Ian Sinclair, *The Vienna Convention on the Law of Treaties* (2nd edn, Manchester University Press 1984) 138

[214] Anthony Aust, *Modern Treaty Law and Practice* (Cambridge University Press 2000) 194

[215] UN General Assembly, 'Yearbook of the International Law Commission 1966 Vol II: Documents of the Second Part of the Seventeenth Session and of the Eighteenth Session Including the Reports of the Commission to the General Assembly' (1967) UN Doc A/CN. 4/SER.A/1966/Add. 1, 221-222

[216] Benedict Chigara, 'Treaty-Text Loyalists' Burden with Subsequent State Practice' (2021) 68(1) Netherlands International Law Review 61, 65, 66, 68

or confirm the true meaning when the textual or the contextual interpretation leave the meaning ambiguous. In the *Corfu Channel case*, for example, the ICJ stated that "the subsequent attitude of the parties shows it has not been their intention, by entering into a special agreement, to preclude the court from fixing the amount of the compensation."[217]

The WTO Appellate Body applied the subsequent practice as a means of interpretation when interpreting TRIPS provisions. In *Japan - Taxes on Alcoholic Beverages* case, the WTO Appellate Body stated that the subsequent practice as articulated in article 31(3)(b) has to be recognized as "concordant, common and consistent sequence of acts or pronouncements which is sufficient to establish a discernible pattern implying the agreement of the parties regarding its interpretation."[218] This perspective was reaffirmed in the *US - Gambling* case, where the WTO Appellate Body stated that "in order for a practice within the meaning of article 31/3(b) to be established: a) there must be a common, consistent, discernible pattern of acts or pronouncements; and b) those acts or pronouncements must imply agreement on the interpretation of the relevant provision."[219]

The WTO Appellate Body has applied the subsequent practice in WTO interpretation as stated above. However, unlike the ICJ jurisprudence, it adopted a narrow definition to the subsequent practice rather than a broad one that matches the evolutionary/dynamic interpretation. It strictly applied the exact wording of state practice in article 31(3)(b) ignoring cases of subsequent practice by one or more parties.[220] The ICJ, for example, in the case of *Kasikili/Sedudu Island (Botswana/ Namibia)* did not restrict the subsequent practice to the meaning mentioned in article 31(3)(b) of the VCLT but rather adopted a broader definition. While the ICJ did not consider a report by a technical expert (Eason Report) that had been commissioned by one of the parties a subsequent state practice within the meaning of the VCLT, it referred to the report to support the conclusions that it had reached by other means of interpretation.[221]

[217] *The Corfu Channel Case* (Merits) [1949] ICJ Rep 4, 25
[218] WTO Appellate Body Report, *Japan – Taxes on Alcoholic Beverages* (adopted 1 November 1996) WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, 13
[219] WTO Appellate Body Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services* (adopted 20 April 2005) WTO Doc WT/DS285/AB/R, para 192
[220] International law Commission, 'First Report on Subsequent Agreements and Subsequent practice in Relation to the Interpretation of Treaties, by Georg Nolte, Special Rapporteur' (19 March 2013) UN Doc A/CN.4/660, para 93
[221] *Case Concerning Kasikili/Sedudu Island (Botswana/Namibia)* (Judgement) [1999] ICJ Rep 1045, paras 55, 80

The WTO Appellate Body asserted its narrow view in *EC – Chicken Cuts* case when it disagreed on what the WTO panels stated regarding subsequent state practice. In that case, the WTO panel clearly explained that in order to qualify for a subsequent practice within the meaning of article 31(3)(b), it is not necessary that all WTO parties must have engaged in the practice but rather it would suffice to "show that all parties to the treaty have accepted the relevant practice." The panel added that such acceptance "may be deduced from a party's reaction or lack of reaction to the practice at issue." If it is necessary to show that all the WTO members specifically engaged in a specific practice, then "it is highly unlikely that subsequent practice could ever be proved in the WTO context," considering the large number of WTO member states.[222] While the WTO Appellate Body accepted the panel's view that not each and every WTO party must have engaged in a particular practice, it emphasized that the practice must be adopted by some, rather than one or few WTO states parties in order to establish a "concordant" and "common" practice of a "discernible pattern." The Appellate Body explained that "the purpose of treaty interpretation is to establish the *common intention* of the parties to the treaty." It stated, accordingly, that it would be difficult, for the purpose of WTO interpretation, to consider one or few WTO member states engaging in a particular practice, as a subsequent practice within the meaning of article 31(3)(b) of the VCLT.[223]

Moreover, if the subsequent practice diverges from the interpretation adopted by the WTO Ministerial Council or the General Council, the later one prevails. The WTO Appellate Body in *Japan - Taxes on Alcoholic Beverages* case, stated that the subsequent practice for the purpose of interpretation should not conflict with the exclusive authority of the WTO General Council and the Ministerial Conference to adopt interpretations of WTO agreements. Also, the conclusions and recommendations in WTO panels reports are not binding, except on the parties to a particular case. A panel report does not constitute a subsequent practice that binds other panels with the details and reasoning stated in it.[224] The WTO Appellate Body decision in that case asserts that the panel reports do not constitute an authoritative interpretation binding on all WTO members, thus they are not considered subsequent state practice in WTO interpretation. As illustrated above, only the WTO General Council and the Ministerial Conference have the

[222] WTO Panel Report, *European Communities - Customs Classification of Frozen Boneless Chicken Cuts* (adopted 27 September 2005) WTO Doc WT/DS269/R, para 7.253
[223] WTO Appellate Body Report, *European Communities - Customs Classification of Frozen Boneless Chicken Cuts* (adopted 27 September 2005) WTO Doc WT/DS269/AB/R, WT/DS286/AB/R, paras 259, 265
[224] WTO Appellate Body Report, *Japan – Taxes on Alcoholic Beverages* (adopted 1 November 1996) WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, 13

authority to do so. This is asserted by the WTO DSU itself when it gave rights to WTO member states to seek authoritative interpretation of WTO covered agreements' provisions through WTO decision-making bodies.[225]

The above perspective of the WTO Appellate Body indicates its reluctance to adopt a revolutionary/dynamic interpretation. The internal point of view of the Appellate Body is to give more value in the interpretation process to the text of the WTO agreement since it represents the common intention of the WTO member states. The narrow definition of subsequent state practice adopted by the WTO Appellate Body is unlikely to give room to invoke the right to access to medicines, as a subsequent state practice, in TRIPS interpretation. For example, to consider the act of providing compulsory licences on patented medicines a subsequent state practice, it has to be proved that such act is "concordant, common and consistent sequence of acts" by the WTO members. Also, it should be proved that such act does not conflict with the exclusive authority of the WTO General Council and the Ministerial Conference to consider them subsequent practice within the meaning of article 31(3)(b) of the VCLT. The dissertation concluded in chapter 2, regarding the compulsory licences, that developing countries had largely forgone using that system due to its intricate procedures even after the TRIPS amendment. Accordingly, there is a very little chance that the compulsory licence practice could satisfy the narrow view of subsequent state practice adopted by the WTO Appellate Body.

Notably, the subsequent agreements or practice, within the meaning of article 31(3)(a)(b) of the VCLT, could be taken into account only when the WTO adjudicating bodies need to interpret a WTO provision. They cannot be utilized to invoke non-WTO law, *inter alia*, human rights, when the disputed WTO provisions are clear. Otherwise, the WTO adjudicating bodies would be adding or diminishing the rights and obligations provided in WTO covered agreements when issuing their rulings. This is prohibited by virtue of articles 3(2) and 19(2) of the WTO DSU.

#### 5.6.4.2 Article 31(3)(c)

The VCLT in article 31(3)(c) deals with the doctrine of plurality of relevant rules of international law in treaty interpretation. The article stipulates that "there shall be taken into account, together

[225] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 3(9)

with the context, any relevant rules of international law applicable in the relations between the parties." This provision gives the chance to the treaty interpreter to refer to a broad range of not only agreements, but also customary rules of international law when interpreting treaty provisions.[226]

Article 31(3)(c) expresses the principle of systemic integration and advances the coherence and unity of international law, where treaties should not be interpreted in isolation from general international law.[227] It makes all treaties function "as parts of a coherent and meaningful whole."[228] In other words, the interpretation of one treaty has to be by reference to another one with the purpose of linking separate treaty provisions "as aspects of an overall aggregate of the rights and obligations of the States."[229] As argued by Martti Koskenniemi, article 31(3)(c) of the VCLT, allowing for systemic integration, implements a presumption that parties "refer to general principles of international law for all questions which the treaty does not itself resolve." The parties to a treaty do not intend to act inconsistently with generally recognized principles of international law, or with their previous treaty obligations under international law when setting a new regime.[230] Therefore, this article could be used as a linking device between disparate bodies of international law. It gives the chance to take into consideration non-WTO law in WTO dispute settlement system, thus enabling the recognition of the right to access to medicines within the TRIPS.[231]

The reference to "any relevant rules of international law" means that all sources of international law can be taken into account when interpreting WTO provisions. Thus, article 31(3)(c) encompasses the presumption against conflict embodied in article 31(1) of the VCLT, since

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[226] Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 198

[227] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 413. **See also**, Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 253. **See also**, Gabrielle Marceau, 'WTO Dispute Settlement and Human Rights' (2002) 13(4) European Journal of international Law 753, 779

[228] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 414

[229] Adamantia Rachovista, 'The Principle of Systemic Integration in Human Rights Law' (2017) 66 International and Comparative Law Quarterly 557, 559

[230] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 465

[231]Lisa Forman, 'An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law' (2011) 14(2) The Journal of World Intellectual Property 155, 163

other rules shall be taken into consideration beside the rule of effective interpretation of treaties embodied in article 31(1) of the VCLT. This leads to interpreting the WTO provisions in a manner consistent with the wider corpus of international law. This is supported by the findings reached in chapter 4 regarding a potential, rather than genuine, conflict between pharmaceutical patents in the TRIPS agreement and the right to access to essential medicines in the ICESCR. If the conflict between the TRIPS and ICESCR is genuine, i.e., between mutually exclusive obligations, the presumption against conflict must be seen as rebutted because it runs counter to the principle of effective interpretation embodied in article 31(1) of the VCLT. Harmonising mutually exclusive norms is not possible because it restricts the meaning of one norm with reference to the other, thereby not giving the required effect to the first norm. According to the principle of effective interpretation, every treaty norm has to be given its own meaning.[232]

Article 31(3)(c) of the VCLT has long been marginalized and ignored. It attracted little academic comments and is very occasionally relied upon in judicial practice. Recently, it started to grab the attention of international law jurists.[233] The 2004 report of the ILC study group addressing the evolutionary interpretation stated that "the fact that article 31(3)(c) was rarely cited should not obscure its importance as a rule of treaty interpretation. It is quite essential for promoting harmonization and guaranteeing the unity of the international legal system."[234]

In *Djibouti v France* case, the ICJ took the view that article 31(3)(c) of the VCLT should be regarded as a codification of customary international law and thus applicable to the treaty relations between both countries despite the fact that neither of them is a party to the VCLT.[235] In another case, *Pulp Mills on the river Uruguay (Argentina v. Uruguay)*, the ICJ applied the dynamic interpretation when it stated that the interpretation will take into account, together with the context, any relevant rules of international law applicable in the relations between the parties as stipulated in article 31(3)(c).[236]

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[232] Joost Pauwelyn, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003) 250-253. **See also,** Jennifer Anna Sellin, 'Does One Size Fit All? Patents, the Right to Health and Access to Medicines' (2015) 62 Netherlands International Law Review 445, 457, 460

[233] Duncan French, 'Treaty Interpretation and the Incorporation of Extraneous Legal Rules' (2006) 55(2) The International and Comparative Law Quarterly 281, 300

[234] UN General Assembly, 'Report of the International Law Commission on the Work of its Fifty-Sixth Session' (2004) UN Doc A/59/10, para 349

[235] *Case Concerning Certain Questions of Mutual Assistance in Criminal Matters (Djibouti v France)* (Judgement) [2008] ICJ Rep 177, para 112

[236] *Case Concerning Pulp Mills on the River Uruguay (Argentina v Uruguay)* (Judgment) [2010] ICJ Rep 14, para 65

Article 31(3)(c) would provide room for taking into account human right to health when interpreting the TRIPS provisions. However, some caution is required when utilizing this article in TRIPS interpretation. Two conditions have to be fulfilled for the article to apply.

Firstly, the international law norms have to be relevant as stipulated by the article. They have to have "significant and demonstrable bearing on the matter at hand," i.e., applicable to the facts of the case.[237] In order to be relevant, the WTO Appellate Body stated that the international law rules "must concern the same subject matter as the treaty terms being interpreted."[238] Certainly, the right to access to medicines is relevant for grants of pharmaceutical patents.

Secondly, the international law rules have to be applicable in the relation between the parties. This condition raises several issues that need to be elaborated;

A- As stated above, article 31(3)(c) of the VCLT infers that all sources of international law could be applicable. This includes general principles of international law, customary international law, and applicable agreements. This understanding is recognized in the WTO disputes settlement. The WTO adjudicating bodies apply this article when the term used in a WTO agreement is by its nature general and open-textured. The reference to other sources of international law, thus, would help in clarifying the content of the WTO term. It strengthens the integration of WTO law into the entire body of general international law. For example, in *US – Import prohibition of certain shrimp and shrimp products* case, the WTO Appellate Body interpreted the phrase "exhaustible natural resources," in GATT article XX(g), with reference to the International Environmental Law texts. The Appellate Body stated that "the generic term "natural resources" in article XX(g) is not static in its content or reference but is rather by definition, evolutionary."[239] As such, the phrase "must be read by a treaty interpreter in the light of contemporary concerns of the community of nations about the protection and conservation of the environment."[240] To support its view regarding the evolutionary interpretation of the phrase, the Appellate Body referred to the preamble of the WTO Agreement which manifests the importance and legitimacy of environmental protection as an objective of sustainable

[237] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008) 221
[238] WTO Appellate Body Report, *United States - Definitive Anti-Dumping and Countervailing Duties on Certain Products from China* (adopted 25 March 2011) WTO Doc WT/DS379/AB/R, para 308
[239] WTO Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products* (adopted 6 November 1998) WTO Doc WT/DS58/AB/R, para 130
[240] Ibid, para 129

development.[241] Also, the WTO panel, in the case of *EC – Measures Affecting the Approval and Marketing of Biotech Products*, stated that article 31(3)(c) "seems sufficiently broad to encompasses all generally accepted sources of public international law, that is to say, international treaties, customary international law, and the recognized general principles of law."[242] Further, the WTO panel in *EC – Asbestos* case referred to the ILO Convention concerning Safety in the Use of Asbestos in 1986 to find whether or not the WTO treaties referred to in the dispute, namely the TBT, SPS, and the GATT, took into consideration the health objectives. The panel took into account the international standards for the protection of workers dealing with Asbestos, as mentioned in the Asbestos agreement, when interpreting the provisions of the aforementioned WTO agreements.[243] Finally, the WTO Appellate Body in *US – Anti-Dumping and Countervailing Duties* stipulated that the rules of international law in article 31(3)(c) of the VCLT encompass any rule from any source of international law in article 38(1) of the Statute of the ICJ.[244]

Taking into account all sources of international law in treaty interpretation has a substantial implication when interpreting TRIPS provisions in a way that takes into consideration the right to access to medicines. This right is an integral part and a fundamental element in the realization of human right to health. The dissertation illustrated in chapter 3 that the human right to health is a part of the whole human rights regime and a well-established rule of international law stipulated in the ICESCR. Also, the right to access to life-saving medicines is considered an element in the right to life mentioned in the ICCPR. Further, the right to access to medicines in the context of pandemics, like HIV/AIDS, Malaria, and Tuberculosis, is considered customary international law. Thus, invoking all sources of international law in WTO interpretation opens a wide room for taking into consideration the right to health with all its forms.

It is worth noting in this context that the General Comments of human rights cannot be taken into account, according to article 31(3)(c) of the VCLT, when interpreting WTO provisions unless they reflect a commonly shared understanding of the rights and obligations of a human rights treaty. If there is a disagreement regarding the content of a certain General Comment in

[241] Ibid. **See also**, Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement) preamble
[242] WTO Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (adopted 21 November 2006) WTO Doc WT/DS291/R, WT/DS292/R, WT/DS293/R, para 7.67
[243] WTO Panel Report, *European Communities – Measures Affecting Asbestos and Products Containing Asbestos* (adopted 5 April 2001) WTO Doc WT/DS135/R, paras 8.210, 8.295, 8.298
[244] WTO Appellate Body Report, *United States - Definitive Anti-Dumping and Countervailing Duties on Certain Products from China* (adopted 25 March 2011) WTO Doc WT/DS379/AB/R, para 308

clarifying a specific human rights norm, then it cannot be invoked in the interpretation process. The General Comments, as demonstrated in chapter 3, are not legally binding on states parties to both covenants. They only provide an authoritative interpretation of states obligations under the covenants. As such, they cannot be invoked in WTO interpretation unless they are generally accepted by WTO states parties or when their content constitutes customary international law.[245]

B- Another issue is the meaning of the term "the parties" in article 31(3)(c) of the VCLT. Are they the parties to the dispute or the parties to the treaty?

In fact, the opinion focusing on the parties to the dispute is erroneous. The VCLT in article 2(1)(g) defined the meaning of the term "party" as "a state which has consented to be bound by the treaty." Thus, the party within the context of article 31(3)(c) must be read as referring to the parties to the treaty being interpreted not the parties to the dispute settlement proceeding.[246] This understanding is emphasized by the WTO panel in the case of *EC – Measures Affecting the Approval and Marketing of Biotech Products*. The panel stated that the applicable rules of international law are those ones "applicable in the relations between the states which have consented to be bound by the treaty, which is being interpreted, and for which that treaty is in force." The panel deduced that such understanding leads logically to the view that the rules of international law to be taken into account in interpreting WTO agreements are those which are applicable in the relation between WTO members rather than between the WTO parties to the dispute.[247]

Accordingly, it could be argued that the right to health norms may be referred to in the interpretation of the TRIPS agreement even if both parties to the dispute, or any of them are not party to the treaty containing the right to health obligation. The ICESCR provisions, for instance, establishing the right to health may be utilized in interpreting the TRIPS provisions even if any of the parties to the dispute did not ratify the covenant. This is guided by the object and purpose of the TRIPS agreement which illustrate that the right to health is a common understanding of all WTO member states.

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[245] Hans Morten Haugen, *The Right to Food and the TRIPS Agreement with Particular Emphasis on Developing Countries' Measures for Food production and Distribution* (Martinus Nijhoff Publishers Leiden Netherlands 2007) 310-311

[246] Michael Lennard, 'Navigating by the Stars: Interpreting the WTO Agreements' (2002) 5(1) Journal of International Economic Law 17, 36-37. **See also**, Campbell Mclachlan, 'The Principle of Systemic Integration and Article 31/3(c)' (2005) 54(2) International and Comparative law Quarterly 279, 315

[247] WTO Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (adopted 21 November 2006) WTO Doc WT/DS291/R, WT/DS292/R, WT/DS293/R, para 7.68

However, opinions diverge regarding how many WTO member states should be bound by the non-WTO rule to be used in interpreting WTO obligations. There are three possible opinions in this regard.

Some jurists read the phrase "between the parties" in a narrow way. They argue that all WTO states have to be parties to the non-WTO agreement in order to be taken into account when interpreting the WTO provision in dispute. Although this approach provides a clear rule for invoking international law in interpretation, it produces an illogical outcome. It requires that the non-WTO agreement and the WTO agreement have identical membership. This would reduce the number of non-WTO agreements that could be used to interpret WTO provisions. Only few international agreements, if any, have an identical membership. Even in those agreements with identical membership at a certain time, new members may choose to accede to one treaty and not another. This leads to a paradoxical result regarding WTO with its continuous membership growth. The more WTO membership, the more unlikely it will become for any international agreement to have the same membership.[248] This situation renders the WTO system isolated from general international law, although it is part of the wider corpus of public international law. It would also foster more fragmentation of public international law.

Other scholars have a broader understanding. They opine that the non-WTO agreement utilized in interpretation should bind more than one WTO state party but not necessary all WTO states parties. This opinion is supported by the different usage of the word "parties" in article 31(2)(a) and 31(2)(b) of the VCLT. In the first, the VCLT mentioned "all the parties," while in the latter it mentioned "one or more parties." Thus, the use of "the parties" in article 31(3)(c) infers that the VCLT meant that the international norm utilized in interpretation binds fewer than the whole parties to the treaty being interpreted but more than one. Consequently, the non-WTO agreement to be taken into consideration within the WTO dispute should be binding on more than one WTO member state. The right to access to medicines, either in ICESCR or ICCPR, fulfils this requirement, and could then be taken into account in TRIPS interpretation. However, a counter-argument was derived by the proponents of the first argument stated above.

[248] Campbell Mclachlan, 'The Principle of Systemic Integration and Article 31/3(c)' (2005) 54(2) International and Comparative law Quarterly 279, 314. **See also**, Michael Lennard, 'Navigating by the Stars: Interpreting the WTO Agreements' (2002) 5(1) Journal of International Economic Law 17, 36. **See also**, Gabrielle Marceua, 'A call for Coherence in International Law - Praises for the Prohibition Against "Clinical Isolation" in WTO Dispute Settlement' (1999) 33(5) Journal of World Trade 87, 124. **See also,** International Law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 471

They opined that interpreting a TRIPS obligation by using non-WTO agreements that are not binding on all WTO member states would run contrary to the principle of *pacta tertiis nec nocent nec prosunt*. It makes some WTO states agree to alter their TRIPS obligations without the consent of the other WTO members, thus affecting the rights and obligations of states under the whole multilateral agreements of the WTO.[249] As article 3(2) of the DSU mentioned, the rulings of the WTO adjudicating bodies cannot add to or diminish the rights and obligations provided in the WTO covered agreements.

Responding to that counter-argument, it should be clarified that when an interpreter utilizes non-WTO agreement in WTO interpretation, he shall do so for the purpose of interpreting a WTO provision rather than to enforce the non-WTO provisions or to amend the WTO agreement. Further, the WTO adjudicating bodies' reports are binding only on the parties to the dispute. The dissertation illustrated previously that the Ministerial Conference and the General Council have the exclusive authority to adopt formal interpretations of WTO Agreements that are binding on all WTO members by virtue of article IX (2) of the WTO Agreement. This is further asserted by the purpose of the WTO DSU, which is securing a positive solution to a dispute between WTO parties that is mutually acceptable to them.[250]

The third group of scholars allow the non-WTO norms to be taken into account in the WTO interpretation process when they constitute customary international law rules. Thus, the non-WTO law shall always be applicable in interpreting WTO provisions since the customary international law is binding on all WTO member states. Consequently, the right to access to medicines, in case it is invoked as customary international law, could be applied in TRIPS interpretation regardless of the number of WTO member states that are party to the human right treaty used in the interpretation process. The dissertation illustrated in chapter 3 that only the right to access to medicines in the context of pandemics, rather than medicines in general, constitutes customary international law. As such, the WTO adjudicating bodies could utilize it in TRIPS interpretation. Nonetheless, this view may preclude reference to agreements that are

[249] Michael Lennard, 'Navigating by the Stars: Interpreting the WTO Agreements' (2002) 5(1) Journal of International Economic Law 17, 36-37. **See also**, Gabrielle Marceua, 'A call for Coherence in International Law - Praises for the Prohibition Against "Clinical Isolation" in WTO Dispute Settlement' (1999) 33(5) Journal of World Trade 87, 124-125

[250] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 3(7)

widely accepted in the international community but not widely ratified by WTO member states, and not accepted as a customary international law.[251]

The WTO jurisprudence in this regard is not clear. The WTO panel in *EC - Biotech Products* case read the term "in the relations between the parties" as referring to all WTO members. So, recourse to any non-WTO agreement in WTO interpretation is prohibited unless it binds all WTO member states.[252] However, the panel at the end of this case seems undecided regarding the opinion it adopted first when it stated that "the mere fact that one or more disputing parties are not parties to a convention does not necessarily mean that a convention cannot shed light on the meaning and scope of a treaty term to be interpreted."[253] The WTO panel decision was criticized by the ILC because it makes the WTO agreements isolated islands that do not permit reference to international law in the interpretation process.[254] In a more lenient view, yet still restrictive, the Appellate Body in *EC - Computer Equipment* case, stated that "the prior practice of only one of the parties may be relevant, but it is clearly of more limited value than the practice of all parties."[255]

The WTO Appellate Body in *EC – Large Civil Aircraft* has corrected this restrictive interpretation. It noted that the meaning of the term "parties" in article 31(3)(c) of the VCLT has been the subject of much academic debate. No Appellate Body statement clarifies whether "the parties" refer to "all WTO members or rather to a subset of members." As such, the interpretation of "the parties" should reflect "the common intention" of the WTO member states. While the interpreter has to "exercise caution in drawing from an international agreement to which not all WTO members are party," this should not prevent striving for the principle of systemic integration. The Appellate Body noted that a "delicate balance must be struck between taking due account of an individual WTO member's international obligations and ensuring a consistent and harmonious approach to the interpretation of WTO law among all WTO members."[256] Similar to that wide view of the term "parties," the WTO Appellate Body in *US –*

[251] Campbell Mclachlan, 'The Principle of Systemic Integration and Article 31/3(c)' (2005) 54(2) International and Comparative law Quarterly 279, 314
[252] WTO Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (adopted 21 November 2006) WTO Doc WT/DS291/R, WT/DS292/R, WT/DS293/R, para 7.68
[253] Ibid, para 7.94
[254] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, para 471
[255] WTO Appellate Body Report, *European Communities - Customs Classification of Certain Computer Equipment* (adopted 22 June 1998) WTO Doc WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R, para 93
[256] WTO Appellate Body Report, *European Communities and Certain Member States – Measures Affecting Trade in Large Civil Aircraft* (adopted 1 June 2011) WTO Doc WT/DS316/AB/R, paras 844-845

*Shrimp* case examined a wide plethora of multilateral environmental agreements, including the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and the Convention on Biological Diversity (CBD), to interpret the term "exhaustible natural resources" in article XX(g) of the GATT. The conventions cited in the interpretation do not have in their membership all WTO member states.[257]

According to that wider view, the right to health may be referred to when interpreting TRIPS provisions even if not all WTO members are parties to the human rights agreement establishing the right to health; provided that the human right to health norm is relevant to the dispute and the TRIPS provisions invoked in the dispute are open-textured.

C - The last issue is related to the concept of inter-temporality of interpretation. Proponents of this concept opine that the text of article 31(3)(c) of the VCLT allows interpreting treaty provisions in light of the relevant rules of general international law in force, not only at the time of conclusion of the treaty but also at the time of its interpretation. The inter-temporality concept allows an evolutionary/dynamic interpretation of treaties that responds to the evolution and development of international law and to the contemporary needs in the international community. It facilitates, as such, resorting to public health needs in WTO interpretation.[258] Pauwelyn supported this concept arguing that it was consistent with the living or continuing nature of treaties.[259]

The WTO jurisprudence shows that the WTO adjudicating bodies applied the inter-temporality concept to interpret specific provisions in WTO agreements. In *EC - Chicken Cuts,* the WTO panel interpreted the GATT by reference to the Harmonized Commodity and Coding System concluded in 1983 instead of the Geneva Nomenclature concluded in 1937 and Brussels Tariff Nomenclature concluded in 1959. The panel did not take into account the latter two because they are out of fashion.[260] It stated that the "timing of their conclusion suggests that they might be of limited relevance for the headings contained in the Harmonized Commodity and Coding

[257] WTO Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products* (adopted 6 November 1998) WTO Doc WT/DS58/AB/R, paras 130-134
[258] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012) 129. **See also**, Campbell Mclachlan, 'The Principle of Systemic Integration and Article 31/3(c)' (2005) 54(2) International and Comparative law Quarterly 279, 290-291. **See also**, Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 199
[259] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International law* (Cambridge University press 2003) 264-265
[260] WTO Panel Report, *European Communities - Customs Classification of Frozen Boneless Chicken Cuts* (adopted 27 September 2005) WTO Doc WT/DS269/R, paras 7.197-7.205

System given the changes in trade patterns and technology since their conclusion."[261] However, the panel stressed the fact that the inter-temporality nature is used only to clarify the ordinary meaning of the treaty term. If it did not achieve that goal, then it should not be utilized.[262] Similarly, in the *Shrimp - Turtle case*, the WTO Appellate Body referred to several multilateral environmental agreements to provide an interpretation that suits the evolutionary nature of the term "exhaustible natural resources" in article XX(g) of the GATT. One of those environmental agreements being referred to is the UNCLOS which entered into force in 1994 after the conclusion of the GATT 1947.[263] This shows that the WTO Appellate Body took into account general international law rules in force at the time of interpretation.

The concept of inter-temporality can be utilized to introduce the right to access to medicines when interpreting TRIPS provisions. As such, when the terms used in TRIPS provisions are broad and unspecified terms or evolving terms, there could be room for using the inter-temporality concept in evolutionary interpretation. For example, the terms "public order," "public health," and "morality" in the TRIPS agreement are unspecified terms and their meaning can change from time to another, thus inviting non-WTO law in force at the time of interpreting any of them. It could also be used to invoke future binding rules of human right to health in TRIPS interpretation since it is not necessary that such rules are existing at the time of conclusion of the WTO agreements. However, it has to be noted that when the WTO adjudicating bodies take into account human rights law in interpretation, they are obliged not to add or diminish the rights and obligations of WTO member states under the WTO covered agreements.[264]

In essence, the previous arguments and WTO case law infer that article 31(3)(c) obliges the WTO adjudicating bodies to take into account any relevant rule of international law including human rights law when interpreting WTO provisions. This obligation expresses the principle of systemic integration in international law which promotes the coherence and unity between WTO law, as part of the wider corpus of international law, and other international law norms. It also ensures the presumption against conflict in international law, where the TRIPS provisions

[261] Ibid, para 7.198
[262] Ibid, para 7.205
[263] WTO Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products* (adopted 6 November 1998) WTO Doc WT/DS58/AB/R, para 130. **See also**, UN Convention on the Law of the Sea (adopted 10 December 1982, entered into force 16 November 1994) 1833 UNTS 397 (UNCLOS)
[264] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) arts 3(2), 19(2)

related to pharmaceutical patents are interpreted in light of the human right to health norms in order to avoid genuine conflict between them. In other words, article 31(3)(c) avoids utilizing the conflict resolution techniques which result in applying one norm and excluding the other. However, utilizing article 31(3)(c) in interpretation should not create rights or obligations for third parties without their consent, otherwise the interpretation would be opposing the principle of *pacta tertiis nec nocent nec prosunt* stipulated in the VCLT and the WTO DSU.

To achieve both issues, within the context of TRIPS pharmaceutical patents and accessibility to medicines, the value and weight to be given to the right to health should be considered by the interpreter on a case-by-case basis. At the same time, the interpreter should take into account the right to health when interpreting patents obligations in TRIPS in order to avoid conflict between both rights, since only a potential one is recognized between them, and to ensure greater coherence of international law.

The previous analysis infers that the WTO jurisprudence shows little certainty towards adopting the evolutionary interpretation in WTO interpretation. Still, the WTO adjudicating bodies are reluctant to develop interpretations that "subvert the common intention of the treaty parties."[265] Thus, the more WTO members are bound by human rights to health rules, the more persuasive it will be for the WTO adjudicating bodies to take such rules into account in WTO interpretation. Consequently, the right to access to medicine shall be more persuasive to the WTO adjudicating bodies to be taken into account in WTO interpretation if they considered it as part of the right to life in ICCPR or customary international law rather than part of the right to health under ICESCR. The dissertation demonstrated in chapter 3 that the right to life-saving medicines could enjoy the status of *jus cogens* norms and thus binds all WTO members. It also addressed the right to access to medicines in the context of pandemics as customary international law which binds all states as well. Unfortunately, in praxis, the WTO dispute settlement system does not consider it so.

Ultimately, the interpretation methods in articles 31 and 32 of the VCLT are not decisive regarding taking into consideration human rights law in WTO disputes settlement. The rules of interpretation in the VCLT that were laid down as a guide to interpretation appear to be ambiguous and open to several interpretations. Further, those rules, drafted in 1969, seem ineffective to deal with the fragmentation phenomenon that appeared due to the

[265] WTO Appellate Body Report, *Peru – Additional Duty on Imports of Certain Agricultural Products* (adopted 31 July 2015) WTO Doc WT/DS457/AB/R, para 5.94

institutionalization of the international legal system. Thus, they may no longer provide adequate guidance to the WTO adjudicating bodies on how to deal with the tension between WTO law and other rules of international law, including human rights.[266] The more sophisticated and mature the WTO system gets, the more it becomes apparent that public international law is rudimentary and sometimes outdated.[267] This contradicts the suggestion of the ILC to use treaty interpretation in order to offset the fragmentation of international law by interpreting WTO provisions in the context of international law.[268] The ILC itself concluded at the end of its study on the fragmentation of international law that "in general, the VCLT gives insufficient recognition to special types of treaties and the special rules that might go to interpret and apply them. More work here seems necessary."[269]

Therefore, the usage of the VCLT rules of interpretation in resolving WTO disputes did not achieve the desired systemic integration between the patents system in TRIPS, as a WTO law, and the human rights to health, as part of the international law norms. The practice of the WTO adjudicating bodies when using the VCLT interpretation rules shows that they are primarily advancing trade liberalisation. This represents their internal point of view regarding WTO law. As stated by Margaret Young, the outcome of the interpretation process in WTO disputes is de-contextualized and arbitrary reasoning by the adjudicating bodies.[270] Also, Hiroko Yamane criticized the interpretation approach of the WTO adjudicating bodies stating that it excessively relied on textual interpretation and dictionaries rather than evolutionary interpretation; it failed to examine the whole structure of the treaty being interpreted; and it disregarded the object and purpose of the treaty.[271]

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[266] Joshua Meltzer, 'Interpreting the WTO Agreements – A Commentary on Professor pauwelyn's Approach' (2004) 25(4) Michigan Journal of International law 917, 922-923. **See also,** Caroline Henckels, 'Overcoming Jurisdictional Isolationism at the WTO-FTA Nexus: A Potential Approach for the WTO' (2008) 19(3) European Journal of International Law 571

[267] Ibid. **See also**, Joost Pauwelyn, 'Remarks at the Fourth Annual WTO Conference' in Mads Andenas and Federico Ortino (eds), *WTO Law and Process* (British institute of International and Comparative Law 2005) 494

[268] International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682, paras 170-171

[269] Ibid, para 251

[270] Margaret Young, 'The WTO's Use of Relevant Rules of International Law: An Analysis of the Biotech case' (2007) 56(4) International and Comparative Law Quarterly 907, 922-925

[271] Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011) 207

## 5.7 The WTO Case Law on the Tension Between Pharmaceutical Patents and Access to Medicines

Generally, there is a little WTO case law on the interpretation of patents provisions in TRIPS. In most of those cases, mutually agreed solutions are reached after consultations have been requested.[272] Out of those cases, only two WTO cases, have referred to the right to access to medicines in TRIPS disputes.

In a recent WTO case, *EU - Seizure of Generic Drugs in Transit*, India requested consultations with the European Union and the Netherlands on 11 May 2010 concerning the seizure of generic medicines originating in India but transiting in the Netherlands to third country destinations. India alleged that such measures had a serious adverse impact on the ability of developing WTO member countries to protect public health. Thus, the measures were inconsistent with several TRIPS provisions and with the 30 August 2003 Decision on TRIPS and Public Health. India stated that the TRIPS provisions should be interpreted not only in light of its objectives and principles providing for public health protection, but also in light of article 12(1) of the ICESCR which recognizes the right of all people to the enjoyment of the highest attainable standard of physical and mental health.[273] To date, the case is still in WTO consultations and has not been referred to the panels. However, it appears that the case will be resolved by mutual consent and will not lead to a panel report since India's approach of relying on human right to health as an argument has very little chance to succeed in WTO disputes. It is uncertain whether other WTO member states have taken this approach before.

The other case is *Canada- Pharmaceutical Patents*, where the WTO panel adopted a very restrictive approach to the limited exceptions flexibility stipulated in article 30 of the TRIPS.[274] The dissertation analysed this case in chapter 2 showing that the WTO panel interpreted article 30 in a manner that favoured only the interests of the patent holder allowing them to prevail over the right to access to medicines. It did not take into consideration the objectives and principles of the TRIPS agreement, stipulated in articles 7 and 8, providing for adopting

[272] Notification of Mutually Agreed Solution, *Brazil - Measures Affecting Patent Protection* (19 July 2001) WTO Doc WT/DS199/4, G/L/454, IP/D/23/Add.1. **See also**, Notification of Mutually Agreed Solution, *Argentina - Certain Measures on the Protection of Patents and Test Data* (31 May 2002) WTO Doc WT/DS171/3, WT/DS196/4, IP/D/18/Add.1, IP/D/22/Add.1. **See also**, Notification of Mutually Agreed Solution, *Pakistan - Patent Protection for Pharmaceutical and Agricultural Chemical Products* (7 March 1997) WTO Doc WT/DS36/4, IP/D/2/Add.1

[273] Request for Consultations by India, *European Union and a Member State – Seizure of Generic Drugs in Transit* (19 May 2010) WTO Doc WT/DS408/1, G/L/921, IP/D/28

[274] WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (adopted 7 April 2000) WTO Doc WT/DS114/R

measures necessary to protect public health and achieving the mutual advantage of producers and users. The WTO panel should have departed from the dictionary definition of the term "limited exceptions" and allowed exceptions that are narrowly tailored in order to achieve the principles and objectives laid down in articles 7 and 8 of the TRIPS.[275]

The *Canada - Pharmaceutical Patents* case reflects the internal point of view of the WTO adjudicating bodies to mainly apply the WTO law in order to protect the WTO organization they work for. The dissertation showed above that the qualifications required to become a member of WTO panels or the Appellate Body are possession of experience and knowledge in international trade, policy, and the subject matters of the WTO covered agreements.[276] It is not expected that a member must be trained in human rights law to be selected. Accordingly, it is not strange that the WTO adjudicating bodies, in their practice, tend to utilize the interpretation tools in a manner that expresses their internal point of view which often favours the WTO system. They tend to respect the intentions of the WTO member states which are embodied, as they believe, in the WTO texts. This leads to increased fragmentation of international law and a noticeable inconsistency between human rights law and WTO law.

### 5.8 Conclusion

This chapter showed that neither the conflict resolution techniques, *lex specialis*, *lex posterior*, and *lex superior*, nor the VCLT rules of interpretation appear to provide satisfactory solution to the potential conflict between pharmaceutical patents in TRIPS agreement and the right to access to medicines. They are not capable of addressing the factual hierarchy of WTO law, *inter alia*, TRIPS, which is created by the institutionalization and fragmentation of international law.

The WTO normative framework shows that the substantive rules of international law, *inter alia*, human rights law, do not lend themselves to application in WTO disputes. The WTO dispute settlement system has limited jurisdiction *ratione materiae* allowing only claims of violations of WTO provisions. Further, human rights law cannot be invoked as a defence against claims of WTO law violation since it is not part of the applicable law in WTO disputes settlement. This exemplifies the normative conflict between the substantive rules in human rights law, including

[275] Robert Howse, 'The Canadian Generic Medicines Panel. A Dangerous Precedent in Dangerous Times' (2005) 3(4) World Intellectual Property Journal 493, 496-498

[276] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) arts 8(1), 17(3)

the right to health, and the WTO law. The human rights law can only be applied in the area of procedures, for example the burden of proof, due process, and non-retroactivity, and in the interpretation process to clarify the meaning of WTO provisions with the proviso that such interpretation does not add or diminish the rights and obligations of WTO member states. Otherwise, the WTO adjudicating bodies would be violating the WTO DSU provisions.

The VCLT rules of interpretation express the principle of systemic integration in international law, where it allows interpreting a treaty provision in light of other norms of international law. This principle facilitates the coherence and unity between WTO law, as a part of the wider corpus of international law and not a self-contained regime, and other international law norms including human rights law. The VCLT rules of interpretation could be utilized to resolve the potential conflict between pharmaceutical patents in TRIPS and the right to access to medicines since both rights do not contain mutually exclusive obligations like the one recognized in genuine conflicts. Thus, instead of applying one norm and excluding the other, which is the situation when using the conflict-resolution techniques, the VCLT rules of interpretation allow interpreting the TRIPS provisions related to pharmaceutical patents in light of the right to access to medicines in order to balance both obligations. This is supported by the WTO jurisprudence itself which considered such rules, specifically articles 31 and 32 of the VCLT, a codification of customary rules of interpretation of public international law.

In the interpretation process by the WTO adjudicating bodies, the chapter showed the uncertainty regarding taking into account human rights law in WTO disputes settlement. The WTO adjudicating bodies used the treaty interpretation rules in a highly selective result-oriented way for the purpose of constructing WTO law instead of utilizing it as a tool for achieving the desired systemic integration between the patent system in TRIPS, as a WTO law, and the human rights to health as a part of the international law norms. For example, the WTO adjudicating bodies were reluctant to use the evolutionary/dynamic interpretation that gives much room for taking into consideration the right to health in TRIPS interpretation. They preferred the textual and contextual interpretations that stick to the actual wording of the treaty considering it the real embodiment of the state intention. As such, the practice of the WTO adjudicating bodies when using the VCLT interpretation rules shows that they primarily favour WTO law allowing it to prevail over human rights law. This echoes their internal point of view regarding WTO law as a legal system which advances trade liberalization rather than promoting

human rights values, *inter alia*, the right to access to medicines. It is indicative of the political economy and the institutional identity of the WTO trading system.

The actual and rhetorical practice of the WTO adjudicating bodies when interpreting TRIPS is worrisome. It attempts to curtail the freedom of developing countries to fully utilize the TRIPS flexibilities to provide better accessibility to medicines. Hence, it seems that developing countries are reluctant to rely on human rights law to justify utilizing the flexibilities. This lack of reference to human rights law in WTO system responds to deeper, more profound institutional concerns. It shows that states decided not to set up an international system in which human rights are explicitly provided with superior normative force similar to the WTO system. Further, it indicates that states prefer limiting the role of the WTO adjudicating bodies in interpretation to the "deal inherent in the treaty"[277] which they were set up to enforce. In such an environment, members of the WTO panels or the Appellate Body who choose to resort to other interpretation rules, *inter alia*, evolutionary or teleological interpretations, in order to invoke human rights law into the WTO system risk having their decisions being attacked by developed states. As such, when interpreting WTO provisions, the adjudicating bodies do not invoke the rules of human rights, but only refer to the values inherent in those rights. It is trade, rather than human rights, which is the dominant notion in the WTO system. This leads to intensification of the conflict between patent rights in TRIPS and the right to access to medicines. One of the proposed solutions to the tension, as the dissertation will recommend in the conclusion and recommendation chapter, is to integrate human rights law into the WTO DSU by amending the provisions of the latter to include explicit reference to other international law agreements as an applicable law in the WTO system.

[277] Holger Hestermeyer, 'International Human Rights Law and Dispute Settlement in the World Trade Organization' in Martin Scheinin (ed), *Human Rights Norms in 'Other' International Courts* (Cambridge University Press UK 2019) 199, 225

## Chapter 6: Conclusion and Recommendations

### 6.1 Conclusion

This dissertation has critically examined the tension between pharmaceutical patents in the TRIPS agreement and the right to access to essential medicines as an indispensable component of the right to health as guaranteed by various human rights instruments, *inter alia*, the ICESCR. Although WTO member states are obliged to incorporate provisions in their national legislations that grant patent protection for any invention, *inter alia*, pharmaceuticals, they also have a duty to respect, protect, and fulfil the human right to health. Theoretically, the TRIPS tried to strike a balance between granting patent rights and protecting public health by offering several flexibilities to developing countries to access medicines with affordable prices. However, practically, such flexibilities proved to be more onerous than expected. Trying to remedy the deficiencies of the TRIPS agreement in the area of access to medicines, the WTO adopted several instruments, namely, the Doha Declaration, the 30 August 2003 Decision, and the 6 December 2005 Decision to amend the TRIPS agreement. While the Doha Declaration represents a forward step in achieving the balance between patents and public health, the 2003 and 2005 Decisions watered down the wording of the Doha Declaration due to the intricate, cumbersome, and time-consuming procedures required to grant compulsory licences. As such, they failed to allow health concerns to prevail over the TRIPS obligations. Thus, the right to health in the ICESCR interferes with patents rights in the TRIPS.

When analysing that interference, the dissertation found a potential, rather than genuine, conflict between pharmaceutical patents and the right to health, since they do not contain mutually exclusive obligations. The conflict echoes that between the WTO system and the human rights system which occurred due to the institutionalization of the international legal system. The WTO system is endowed with a robust adjudication and enforcement mechanism which armed the TRIPS agreement with teeth to defend IPRs at the global level, while the human rights system lacks a similar one. This created a *de facto* hierarchy beside and entirely independent of the normative hierarchy in international law. Such *de facto* hierarchy is responsible for placing the human rights regime at a lower level than the WTO system allowing the WTO norms to prevail in different situations of conflict. It seems natural to allow human rights concepts to prevail over pharmaceutical patents in cases of conflicts since the first are fundamental and inalienable rights representing timeless expression of the entitlements of all people, while the second are granted for a limited time. However, there is no evidence that suggests the supremacy

of the right to access to medicines under international law except, as the dissertation argues, for the right to access to life-saving medicines since it reaches the status of *jus cogens* norms, and also the right to access to pandemic medicines as customary international law.

The WTO law is not a self-contained regime, but rather a part of the wider corpus of international law. As a sub-system of international law, the WTO law should not operate in isolation of other international law norms, *inter alia*, human rights. However, the WTO normative framework does not support this fact. The WTO law does not contain human rights obligations; and its dispute settlement system has limited jurisdiction *ratione materiae*, thus it does not have jurisdiction over human rights violation complaints; and human rights law is not part of the applicable law in the WTO dispute settlement system. Therefore, the WTO normative framework has largely failed to take into account human rights law. It furthers more fragmentation of international law rather than advancing its unity and coherence.

Nevertheless, this does not mean that the WTO system has been totally blind to refer to human rights concerns and values. Human rights law can be invoked in the interpretation process to clarify the meaning of WTO covered agreements provisions, or when it is referred to in procedural matters. The WTO DSU, the WTO jurisdiction, and the Doha Declaration oblige the WTO adjudicating bodies to clarify the WTO provisions in accordance with the customary rules of interpretation of public international law which are codified in the VCLT. Consequently, the TRIPS agreement should be interpreted in light of its objectives and principles that support the right to protect public health interests, *inter alia*, the right to access to medicines. This is further supported by the findings reached when analysing the philosophical justifications for patent protection. The dissertation argued that in order to invoke human rights instruments into the patent system, it is crucial to justify patent rights according to both the moral arguments that promote public accessibility to inventions and the economic incentive arguments which induce financial investments and promote technological innovation. This opens room to a liberal use of human rights law in WTO disputes and to achieve the systemic integration between patents system in TRIPS, as a WTO law, and human right to health which is part of the international law norms.

However, the practice of the WTO adjudicating bodies when using the VCLT rules of interpretation shows that they did not refer to human rights as a legal system. They used the treaty interpretation techniques in a highly selective result-oriented way for the purpose of advancing trade liberalisation instead of utilizing it as a tool for achieving the desired systemic

integration between WTO law and human rights law. This represents their internal point of view which favours WTO law allowing it to prevail over human rights. The WTO case law shows that the WTO adjudicating bodies excessively relied on the textual and contextual interpretations that stick to the actual wordings of the WTO agreements. They did not adopt an evolutionary/dynamic interpretation that would offer room for taking into consideration the human right to health in TRIPS interpretation. As Hiroko Yamane wrote, the interpretation of the WTO adjudicating bodies disregarded the object and purpose of the TRIPS agreement. This is an indication of the political economy and the institutional identity of the WTO system which mainly considers trade rather than human rights. This intensifies the conflict between pharmaceutical patents in TRIPS and the right to access to medicines, and curtails developing countries' freedom to fully utilize the flexibilities and the manoeuvring rooms within the TRIPS agreement to address public health needs.

The monopolized system of pharmaceutical patents often restricts the human right to health; thus, it is inevitable to rebalance the patentees' rights (economic objectives) with the public right to access to essential medicines (social/moral objectives). In the following section, this chapter will recommend a number of possibilities which may achieve this balance and solve the potential conflict between the TRIPS agreement and accessibility to medicines, at the core of which lies the conflict between the WTO law and human rights law.

### 6.2 Recommendations

The dissertation recommends several possible solutions to resolve the potential conflict between patents under the TRIPS Agreement and the right to access to medicines. They are as follows:

Firstly, giving effect to the conflict rule in the UN Charter which stipulates that whenever there is a conflict between the UN charter obligations and those in any other international agreement, the first shall prevail.[1] By virtue of the UN Charter, states pledge themselves to take joint and separate actions in cooperation with the UN organization to promote universal respect for and observance of all human rights in a non-discriminatory manner. They should also promote solutions for health-related problems.[2] Since, the right to access to medicines is an essential part of the right to health and states have a duty to respect, protect, and fulfil accessibility to

[1] Charter of the United Nations (adopted 26 June 1945, entered into force 24 October 1945) 1 UNTS XVI preamble, art 103
[2] Ibid, arts 1, 55, 56

medicines; and since states are obliged to ensure that the right to health is given due attention in international treaties and that such treaties do not adversely impact upon the right to health in accordance with the UN Charter and applicable international law;[3] therefore, in case of conflict between pharmaceutical patents and the right to access to medicines, the latter should prevail.

Secondly, establishing a new clause in the Marrakesh Agreement Establishing the World Trade Organization that provides for the supremacy of human rights in the ICESCR in case they conflict with any of the provisions of the WTO covered agreements. Such clause may have the following form "in case of the conflict between a human rights obligation in the ICESCR and the obligations of WTO states parties, the former shall prevail." This solution would correspond to several national constitutions which endow human rights with superior status. Integrating human rights within the ambit of WTO law endows human rights obligations with superior status that allows them to prevail over WTO obligations in case of conflict. This would imply that human right to health, specifically the right to access to essential medicines, would be easily enforced by the WTO dispute settlement bodies.

Thirdly, amending article 30 of the TRIPS by explicitly mentioning that the scope of the limited exceptions to the exclusive rights conferred by a patent includes the duty of WTO member states to safeguard the affordability and accessibility to essential medicines, as a part of their duty to respect, protect, and fulfil the right to health. The amendment could be bound by the condition that there is no alternative measure could be taken to achieve this purpose and subject to a judicial review in order to ensure that such exception is not used in an arbitrary manner and does not unreasonably prejudice the legitimate interests of the patent owner. It could also stipulate that this exception is not limited to domestic policies but also has an international dimension. As illustrated in chapter two, granting this exception does not constitute discrimination against the field of pharmaceutical technology. Differential treatment for pharmaceuticals, in case of the existence of a legitimate health reason, is permissible since the differences between fields of technology require responses tailored to each field. It provides for an interpretation that respects the TRIPS principles in allowing WTO members to adopt measures necessary to protect public health.

[3] UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4, paras 38-39

Furthermore, an authoritative interpretation of article 30 is proposed. This interpretation would recognize the right of WTO member states to make, sell, and export patented public health related products without the consent of the patentee to address public health needs in another country. One of the important exceptions provided by article 30 is the regulatory review exception (Bolar exception) which allows generic manufacturers to use the patented invention to develop information required for governmental marketing approval on generic medicines. Given the very restrictive approach adopted by the WTO adjudicating bodies to article 30 in *Canada – Patent Protection* case, as demonstrated in chapter two, the article falls short of providing legal certainty to developing countries when utilizing the exceptions to manufacture and stockpile patented medicines in order to ensure faster accessibility once the patent term expires. Thus, adopting this proposed authoritative interpretation would facilitates the production and export of patented drugs to countries suffering from health crisis. As such, the authoritative interpretation could contribute to overcome the intricate, cumbersome requirements of the compulsory licence flexibility in the TRIPS.

Fourthly, amending articles 7(1) and 11 of the WTO DSU in order to allow the WTO panels to apply non-WTO law, including human rights law, as applicable law in WTO disputes. Article 7(1) could be amended as follows "panels shall have the following terms of reference … to examine, in the light of the relevant provisions in (name of the covered agreement(s) **and other agreement(s)** cited by the parties to the dispute), the matter referred to the DSB …" Article 11 could be amended as follows "a panel should make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements **and other sources of international law**, and make such other findings as will assist the DSB in making the recommendation …"

Fifthly, providing for a formal institutional linkage between the WTO and human rights organizations. The WTO agreement states that "the General Council shall make appropriate arrangements for effective cooperation with other intergovernmental organizations that have responsibilities related to those of the WTO." Further, it stipulates that "the General Council may make appropriate arrangements for consultation and cooperation with non-governmental organizations concerned with matters related to those of the WTO."[4] Such linkage could give human rights organization some influence within the WTO. An example of such cooperation,

[4] Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement) art v

albeit informal, is the workshop between WTO and WHO on Differential Pricing and Financing of Essential Medicines.[5] The WTO DSU also allows such institutional linkage since it permits WTO panels "the right to seek information and technical advice from any … body which it deems appropriate."[6] Accordingly, the WTO panels, in cases related to pharmaceutical patents and the right to access to medicines, could seek information or advice from the WHO or the CESCR regarding the effect of patents on the right to health.

Sixthly, the WTO adjudicating bodies could provide a solution to the potential conflict between patents and access to medicines by several means. They could adopt the evolutionary/dynamic interpretation, thus, taking into consideration the state practice of WTO member states, especially, developing countries, when safeguarding the accessibility to medicines. In line with what the dissertation argued, the WTO adjudicating bodies could consider the right to access to life-saving medicines *jus cogens* norms similar to the right to life in ICCPR or the right to access to pandemic medicines a customary international law, thus allowing them to prevail over patents obligations in cases of potential conflict. Further, the WTO adjudicating bodies could follow the Court of Justice of the European Union (CJEU) which applied the fundamental human rights as general principles of European law inspired by the European states' constitutions and the international human rights agreements they adopted.[7] The development of the case law of the Treaty Establishing the European Community shows that the treaty did not provide for human rights protection but focused on economic matters only. Similarly, the WTO adjudicating bodies could integrate human rights law, *inter alia*, the right to access to medicines, into the WTO system as general principles of international law. Applying human rights as a hard law rather than considering them as values (soft law), in the interpretation process or in procedural matters, strengthens their position in WTO disputes. It advances unity and coherence in international law and facilitates the relationship between human rights compliance and pharmaceutical patent protection.

[5] WHO and WTO, 'Report of the Workshop on Differential Pricing and Financing of Essential Drugs' (Høsbjør, Norway, 8-11 April 2001) < https://apps.who.int/iris/bitstream/handle/10665/66919/a73725.pdf?sequence=1&isAllowed=y > accessed 10 April 2021

[6] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU) art 13(1)

[7] Case 29/69 *Erich Stauder v City of Ulm* [1969] ECR 419

Seventhly, the manner of which the TRIPS provisions are sometimes interpreted, for example, the *Canada - Pharmaceutical Patents* case,[8] depicts the attempts made to curtail the freedom of WTO member states to take full advantage of the TRIPS flexibilities and other manoeuvring rooms within the TRIPS including its principles and objectives. The flexibilities were interpreted in a manner serving only the interests of pharmaceutical companies without considering the objectives and principles of the TRIPS agreement. This makes developing countries reluctant to use the flexibilities for fear of trade sanctions or being brought in front of the WTO adjudicative system with its robust enforcement mechanism. It is imperative that developing countries should be encouraged to make full use of the TRIPS flexibilities, specifically the compulsory licensing flexibility. The intricate and cumbersome procedures to utilize the compulsory licences flexibility, enshrined in the 6 December 2005 Decision amending the TRIPS, should be diluted to facilitate manufacture of generic drugs. These procedures run counter to the Doha Declaration and to the TRIPS principles and objectives.

Eighthly, a recommendation to resolve the conflict between WTO law and human rights law, proposed by Benedict Chigara, is to establish a WTO agency responsible for approving the social benefit of marketed inventions worldwide. The agency should be vested with powers to impose trade prohibition against any product that does not take into consideration the health needs of states.[9]

Ninthly, pharmaceutical companies should exercise good corporate governance by adopting the human rights guidelines for pharmaceutical companies set by the UN High Commissioner for Human Rights. The guidelines include the responsibility of pharmaceutical companies to adopt a human rights policy statement that expressly recognizes and integrates human right to health in relation to the policies, strategies, projects, and programmes of the companies. Further, the guidelines call for pharmaceutical companies to refrain from any conduct that will or may encourage a state to act in a way that is inconsistent with its human right to health obligations.[10]

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[8] WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (adopted 7 April 2000) WTO Doc WT/DS114/R

[9] Benedict Chigara, 'Social Justice: The Link Between Trade Liberalisation and Sub-Saharan Africa's Potential to Achieve the United Nations Millennium Development Goals by 2015' (2008) 26(1) Netherlands Quarterly of Human Rights 9, 16

[10] Rajat Khosla and Paul Hunt, 'Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines' (Human Rights Centre of University of Essex, December 2012) < http://repository.essex.ac.uk/4425/1/human-rights-guidelines-pharmaceutical-companies-access-medicines.pdf > accessed 5 October 2021

Finally, from the perspective of the policy space granted to the WTO member states under the TRIPS agreement; since the TRIPS did not provide a fixed standard to the patentability criteria leaving each state to opt for the level that best suits its needs, it is better for developing countries to adopt and apply stringent or high threshold of novelty and inventive step. Adopting an absolute novelty criterion allows countries to prevent patenting medicines that already exist in public domain. Thus, patents shall be granted only to new or novel drugs globally rather than drugs that are considered traditional knowledge or constitute prior art in any place worldwide. The prices of such medicines are cheap in comparison to patented medicines rendering them accessible and affordable. Moreover, amending patent laws to include high threshold of inventive step allows states to prevent "evergreening" or strategic patenting which enables pharmaceutical companies to make minor or significant modifications to existing medicines and apply for patents.

As illustrated in chapter two, these practices extend the breadth and duration of the primary patented medicine and delay or block the market entry of the cheaper generics. In other words, adopting a high threshold of inventive step allows states to avoid granting patents on incremental improvements to existing medicines, thus promoting generics competition. A lucid example for this high threshold is the introduction of section 3(d) to the Indian Patent Act to avoid the evergreening process in India. By virtue of this section, the Indian patent office rejected the application filed by Novartis to obtain a patent on the beta crystalline form of "Glivec" medicine because this new form did not demonstrate an improved efficacy from the original patented compound.[11]

Indeed, it would be sensible for developing countries to exclude new forms and uses of the original patented drug from patentability in order to promote access to medicines. The IPRs Commission is of the same opinion, as it stated that most developing countries, especially those without research capabilities, should exclude new uses of known pharmaceuticals from patentability.[12] Further, the High-Level Panel on Access to Health Technologies asserts this recommendation, where it encouraged governments to "adopt legislation to limit excessive patenting that stifles health technology R&D and access." The panel emphasized that secondary

[11] Indian Patents (Amendment) Act No 15 of 2005, sec 3(d). **See also**, *Novartis v Union of India*, High Court of Madras, (2007) 4 MLJ 1153

[12] Commission on Intellectual Property Rights, 'Report of the Commission on Integrating Intellectual Property Rights and Development Policy' (Commission on Intellectual Property Rights, September 2002) 50 < http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 1 May 2019

patenting prolongs exclusivity (evergreening), thus, impedes accessibility to medicines.[13] In relation to the COVID-19 pandemic issue, limiting secondary patenting will help governments to promote accessibility to COVID-19 medicines after the expiration of their patent terms since the modifications of the original COVID medicines will be excluded from patentability.

Furthermore, developing countries should avail themselves of the widest scope of parallel importation and incorporate explicit provisions in their national patent legislations that implement the international exhaustion regime. Parallel importation is an important tool to enable accessibility to affordable medicines in developing countries because there are substantial price differences for pharmaceuticals in different markets. Therefore, parallel importation in domestic laws should not be restricted by, for example, requiring the consent of the patentee before importing the patented product. Otherwise, the parallel importation privilege will be restricted to only those cases where the patentee has given consent, which is an unlikely prospect.

Additionally, the TRIPS agreement does not define in article 30 the scope or nature of the permissible exceptions to the patent rights granted, leaving states with considerable freedom to do so. Consequently, developing countries, especially those with pharmaceutical manufacturing capacities like India and Brazil, should include a Bolar exception within their domestic patent legislations in order to enable the pharmaceutical products of a foreign company to gain regulatory approval and enter the market soon after the expiry of the patent term. Providing for Bolar exception is considered an important mechanism in accelerating the introduction of generic medicines to the market after the expiry of the patent term of the original medicines. This promotes the accessibility to essential medicines for people in developing countries. In this connection, the WTO panel emphasized in *Canada - Pharmaceutical Patents* case that the "Bolar exemption must be an example of the type of exception that was intended to come within Article 30."[14]

[13] UN Secretary-General's High-Level Panel on Access to Medicines, 'Report on Promoting Innovation and Access to Health Technologies' (September 2016) 22-23 < http://www.unsgaccessmeds.org/final-report> accessed 12 December 2019

[14] WTO Panel Report, *Canada - Patent Protection of Pharmaceutical Products* (adopted 7 April 2000) WTO Doc WT/DS114/R, para 4.15

### 6.3 Suggestions for Further Research

FTAs or TRIPS-Plus agreements continue to be crucial in addressing the conflict between pharmaceutical patents in TRIPS and the right to access to medicines. As the dissertation did not focus on such agreements, it is therefore recommended that future research be conducted on such topic to build on the findings of this dissertation. The dissertation briefly explained in chapter 2 that the TRIPS-Plus requirements pose a grave threat to the accessibility to medicines in developing countries and inhibit the marketing of generic medicines. It is worthwhile exploring in detail the patentability standards that such agreements adopt, the challenges they pose on the implementation level, and how the WTO dispute settlement system understand their provisions.

Further, it is worth analysing the human rights guidelines for pharmaceutical companies in relation to accessibility to medicines. Such guidelines made several recommendations to pharmaceutical companies to respect the right of countries to fully use the TRIPS flexibilities to promote accessibility to medicines. It urged public-private partnerships to render medicines affordable and accessible to people in developing countries. More research is needed on such guidelines to explore their effect on mitigating the tension between pharmaceutical patents and accessibility to medicines.

Finally, the dissertation recommends examination of the effectiveness of the Medicines Patent Pool as an approach to enhance generic competition and promote the affordability and accessibility to medicines in developing countries. The principle aims to make the patents available to entities other than the patentees by granting the former licences that authorize them to use the patented inventions. Examples of Medicines Patent Pools include the GlaxoSmithKline and Alnylam Pharmaceuticals patent pool for neglected diseases and the International Drug Purchasing Facility (UNITAID) patent pool for HIV/AIDS. Research in this area may clarify whether such an approach provides balance between the interests of patentees in being compensated for the usage of their patented drugs, and the interest of patients in developing countries in accessing medicines at affordable prices.

**Bibliography**

**Table of Cases**

1- Domestic Cases

Argentina

- Mariela Viceconte v Ministry of Health and Social Welfare, Federal Administrative Court of Appeal of Argentina, Case No 31.777/96 (2 June 1998)

Colombia

- Sandra Clemencia Perez Calderon et al v Ministry of Health, Constitutional Court of Colombia, Case SU-225/1998 (20 May 1998)

Ecuador

- Edgar Carpio Castro Jofre Mendoza et al v Ministry of Health, Constitutional Court of Ecuador, Case No 749-2003-RA (2004)

India

- Francis Coralie Mullin v Union Territory of Delhi, Supreme Court of India, 1981 AIR 746; 1981 SCR (2) 516 (13 January 1981)
- Novartis AG v Union of India, High Court of Madras, (2007) 4 MLJ 1153
- Paschim Banga Khet Mazdoor Samity v State of West Bengal, Supreme Court of India, 1996 SCC (4); 37 JT 1996 (6) 43 (6 May 1996)

South Africa

- Minister of Health et al v. Treatment Action Campaign et al, Constitutional Court of South Africa, [2002] ZACC 15; 2002 (5) SA 721; 2002 (10) BCLR 1033 (5 July 2002)
- Pharmaceutical Manufacturers' Association of South Africa et al v President of the Republic of South Africa et al, Constitutional Court of South Africa, (CCT31/99) [2000] ZACC 1; 2000 (2) SA 674; 2000 (3) BCLR 241 (25 February 2000)

- Pharmaceutical Manufacturers' Association of South Africa et al v President of the Republic of South Africa et al, High Court of South Africa (Transvaal Provincial Division), Case No 4183/98, Notice of Motion (1998)
- Soobramoney v Minister of Health (Kwazulu-Natal), Constitutional Court of South Africa, (CCT32/97) [1997] ZACC 17; 1998 (1) SA 765 (CC); 1997 (12) BCLR 1696 (27 November 1997)

United Kingdom

- Boulton and Watt v Bull (1795) 2 H. Bl. 463, 126 ER 651
- Darcy v Allein (1602) 74 ER 1131
- Liardet v Johnson (1778) 62 ER 1000

USA

- Grant v Raymond, 31 US 218 (1832)
- Henry v A.B. Dick Company, 224 US 1 (1912)
- J. E. M. Ag Supply Inc et al v Pioneer Hi-Bred International Inc, 534 US 124 (2001)
- Motion Picture Patents Company v Universal Film Manufacturing Company, 243 US 502 (1917)
- Roche Products Inc v Bolar Pharmaceutical Co Inc, 733 F2d 858 (Fed Cir 1984)
- Rodriguez Fernandez v Wilkinson, Trial Judgment, 505 F Supp 787 (D Kan 1980), ILDC 2019 (US 1980), 31st December 1980, United States; Kansas; District Court for the District of Kansas

Venezuela

- Cruz del Valle Bermúdez et al v Ministerio de Sanidad y Asistencia Social, Supreme Court of Venezuela, Case No 15.789 Decision No 916 (1999)
- Glenda Lopez et al v Instituto Venezolano de Seguros Sociales, Supreme Court of Venezuela, Constitutional Chamber, Case No 00-1343 (6 April 2001)

2- International Cases

African Commission on Human Rights

- Social and Economic Rights Action Centre and the Centre for Economic and Social Rights v Nigeria, Communication No 155/1996 (African Commission Decision, 27 May 2002) Case Ref ACHPR/COMM/A044/1

Court of Justice of the European Union (CJEU)

- Case 29/69 Erich Stauder v City of Ulm [1969] ECR 419
- Case C-457/10 P AstraZeneca AB and AstraZeneca plc v European Commission [2012] OJ C26/2
- Case C-459/03 Commission of the European Communities v Ireland [2006] ECR I-4657
- Case T-321/05 AstraZeneca AB and AstraZeneca plc v European Commission [2010] ECR II–2805

European Commission

- AstraZeneca (Case COMP/A.37.507/F3) Commission Decision 2006/857/EC [2005] OJ L332/24

European Commission of Human Rights

- Federal Republic of Austria v Government of the Republic of Italy App No 788/60 (Commission Decision, 11 January 1961)

European Court of Human Rights (ECHR)

- Antonio Conceiçao Tavares v France App No 16593/90 (ECHR, 12 September 1991)
- Association of Parents v United Kingdom App No 7154/75 (ECHR, 12 July 1978)
- Neumeister v Austria (article 50) (1974) Series A 17
- Tyrer v The United Kingdom App No 5856/72 (ECHR, 25 April 1978)

GATT

- Canada/European Communities – Article XXVIII Rights (26 October 1990) DS12/R-37S/80
- European Economic Community – Regulation on Imports of Parts and Components (adopted 16 May 1990) GATT Doc L/6657-37S/132
- European Economic Community - Restrictions on Imports of Desert Apples - Complaint by Chile (adopted 22 June 1989) GATT Doc L/6491-36S/93
- Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes (adopted 7 November 1990) GATT Doc DS10/R-37S/200
- United States – Restrictions on Imports of Sugar (adopted 22 June 1989) GATT Doc L/6514-36S/331
- United States – Restrictions on Imports of Tuna (adopted 3 September 1991) GATT Doc DS21/R - 39S/155
- Uruguayan Recourse to Article XXIII (adopted 16 November 1962) GATT Doc L/1923 – 11S/95

Inter-American Court of Human Rights

- Case of the "Street Children" (Villagran-Morales et al) v Guatemala, Merits, IACHR Series C No 63 (19 November 1999)
- Restrictions to the Death Penalty (Arts. 4(2) and 4(4) American Convention on Human Rights), Advisory Opinion OC-3/83, IACHR Series A No 3 (8 September 1983)

International Tribunal for the Law of the Sea (ITLOS)

- The Mox Plant Case (No 10) (Ireland v United Kingdom) Provisional Measures (ITLOS Order, 3 December 2001) ITLOS Reports 2001, 95

Permanent Court of Arbitration (PCA)

- Dispute Concerning Access to Information Under Article 9 of the OSPAR Convention Between Ireland and the United Kingdom of Great Britain and Northern Ireland

(Ireland v United Kingdom of Great Britain and Northern Islands) (PCA Final Award, 2 July 2003) XXIII RIAA 59

- The Mox Plant Case (Ireland v United Kingdom) (PCA Order No 3, 24 June 2003) ICGJ 366, 126 ILR 310

PCIJ/ICJ

- Aegean Sea Continental Shelf Case (Greece v Turkey) (Judgement) [1978] ICJ Rep 3
- Arbitral Award of 31 July 1989 (Guinea-Bissau/Senegal) (Judgement) [1991] ICJ Rep 53
- Barcelona Traction, Light & Power Co (Belgium v Spain) (Second Phase Judgment) [1970] ICJ Rep 3
- Case Concerning Certain Questions of Mutual Assistance in Criminal Matters (Djibouti v France) (Judgement) [2008] ICJ Rep 177
- Case Concerning Kasikili/Sedudu Island (Botswana/Namibia) (Judgement) [1999] ICJ Rep 1045
- Case Concerning Pulp Mills on the River Uruguay (Argentina v Uruguay) (Judgment) [2010] ICJ Rep 14
- Case Concerning Right of Passage Over Indian Territory (Portugal v India) (Merits) 1CJ Rep 1960
- Case Concerning the Gabcikovo-Nagymaros Project (Hungary/Slovakia) (Judgement) [1997] ICJ Rep 7
- Case Concerning United States Diplomatic and Consular Staff in Tehran (United States of America v Iran) (judgment) [1980] ICJ Rep 3
- Case of the S.S. "Wimbledon" (United Kingdom, France, Italy & Japan v Germany (judgment) [1923] PCIJ Rep Series A No 1
- Fisheries Jurisdiction Case (United Kingdom of Great Britain and Northern Ireland v Iceland) (Merits) [1974] ICJ Rep 3

- Jurisdictional Immunities of the State (Germany v Italy: Greece Intervening) (Judgement) [2012] ICJ Rep 99
- Land, Island and Maritime Frontier Dispute (EL Salvador/Honduras: Nicaragua Intervening) (Judgment) [1992] ICJ Rep 350
- Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) Notwithstanding Security Council Resolution 276 (1970) (Advisory Opinion) [1971] ICJ Rep 16
- Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) Notwithstanding Security Council Resolution 276 (1970) (Separate Opinion of Vice-President Ammoun(tr) ) [1971] ICJ Rep 16
- Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory (Advisory Opinion) [2004] ICJ Rep 136
- Legality of the Threat or Use of Nuclear Weapons (Advisory Opinion) [1996] ICJ Rep 226
- Maritime Delimitation and Territorial Questions Between Qatar and Bahrain (Qatar/Bahrain) (Judgement) [1995] ICJ Rep 6
- Military and Paramilitary Activities in and against Nicaragua (Nicaragua v United States of America) (Judgment) [1986] ICJ Rep 14
- North Sea Continental Shelf Case (Federal Republic of Germany v Denmark; Federal Republic of Germany v The Netherlands) (Judgment) [1969] ICJ Rep 3
- Reservations to the Convention on the Prevention and Punishment of the Crime of Genocide (Advisory Opinion) [1951] ICJ Rep 15
- South West Africa Cases (Ethiopia v South Africa; Liberia v South Africa) (Judgment) [1962] ICJ Rep 319
- South West Africa Cases (Ethiopia v South Africa; Liberia v South Africa) (Second Phase Judgment) [1966] ICJ Rep 6
- Territorial Dispute (Libyan Arab Jamahiriya/Chad) (Judgement) [1994] ICJ Rep 6
- The Corfu Channel Case (Merits) [1949] ICJ Rep 4

- United States Diplomatic and Consular Stuff in Tehran (United States of America v Iran) (Judgement) [1980] ICJ Rep 3

WTO

A- Appellate Body Reports

- Brazil - Measures Affecting Desiccated Coconut (adopted 20 March 1997) WTO Doc WT/DS22/AB/R
- Canada - Certain Measures Concerning Periodicals (adopted 30 July 1997) WTO Doc WT/DS31/AB/R
- Canada - Measures Affecting the Importation of Milk and the Exportation of Dairy Products (adopted 27 October 1999) WTO Doc WT/DS103/AB/R, WT/DS113/AB/R
- Chile – Taxes on Alcoholic Beverages (adopted 12 January 2000) WTO Doc WT/DS87/AB/R, WT/DS110/AB/R
- European Communities - Customs Classification of Certain Computer Equipment (adopted 22 June 1998) WTO Doc WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R
- European Communities - Customs Classification of Frozen Boneless Chicken Cuts (adopted 27 September 2005) WTO Doc WT/DS269/AB/R, WT/DS286/AB/R
- European Communities – Measures Affecting Asbestos and Products Containing Asbestos (adopted 5 April 2001) WTO Doc WT/DS135/AB/R
- European Communities - Measures Affecting Importation of Certain poultry Products (adopted 23 July 1998) WTO Doc WT/DS69/AB/R
- European Communities - Measures Concerning Meat and Meat Products (Hormones) (adopted 13 February 1998) WTO Doc WT/DS26/AB/R, WT/DS48/AB/R
- European Communities – Regime for the Importation, Sale and Distribution of Bananas (adopted 25 September 1997) WTO Doc WT/DS27/AB/R
- European Communities – Trade Description of Sardines (adopted 23 October 2002) WTO Doc WT/DS231/AB/R

- European Communities and Certain Member States – Measures Affecting Trade in Large Civil Aircraft (adopted 1 June 2011) WTO Doc WT/DS316/AB/R
- Guatemala - Anti-Dumping Investigation Regarding Portland Cement from Mexico (adopted 25 November 1998) WTO Doc WT/DS60/AB/R
- Japan – Taxes on Alcoholic Beverages (adopted 1 November 1996) WTO Doc WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R
- Korea – Measures Affecting Import of Fresh Chilled and Frozen Beef (adopted 10 January 2001) WTO Doc WT/DS161/AB/R, WT/DS169/AB/R
- Mexico - Tax Measures on Soft Drinks and Other Beverages (adopted 24 March 2006) WTO Doc WT/DS308/AB/R
- Peru – Additional Duty on Imports of Certain Agricultural Products (adopted 31 July 2015) WTO Doc WT/DS457/AB/R
- United States - Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany (adopted 19 December 2002) WTO Doc WT/DS213/AB/R
- United States - Definitive Anti-Dumping and Countervailing Duties on Certain Products from China (adopted 25 March 2011) WTO Doc WT/DS379/AB/R
- United States - Final Anti-Dumping Measures on Stainless Steel from Mexico (adopted 20 May 2008) WTO Doc WT/DS344/AB/R
- United States – Import Prohibition of Certain Shrimp and Shrimp Products (adopted 6 November 1998) WTO Doc WT/DS58/AB/R
- United States – Imposition of Countervailing Duties on Certain Hot-Rolled Lead and Bismuth Carbon Steel Products Originating in the United Kingdom (adopted 7 June 2000) WTO Doc WT/DS138/AB/R
- United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India (adopted 23 May 1997) WTO Doc WT/DS33/AB/R
- United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services (adopted 20 April 2005) WTO Doc WT/DS285/AB/R

- United States - Measures Affecting Trade in Large Civil Aircraft – Second Complaint (adopted 23 March 2012) WTO Doc WT/DS353/AB/R
- United States - Restrictions on Imports of Cotton and Man-Made Fibre Underwear (adopted 25 February 1997) WTO Doc WT/DS24/AB/R
- United States - Standards for Reformulated and Conventional Gasoline (adopted 20 May 1996) WTO Doc WT/DS2/AB/R
- United States – Subsidies on Upland Cotton (adopted 21 March 2005) WTO Doc WT/DS267/AB/R
- United States – Tax Treatment for "Foreign Sales Corporations" (adopted 20 March 2000) WTO Doc WT/DS108/AB/R

B- Panel Reports

- Canada - Patent Protection of Pharmaceutical Products (adopted 7 April 2000) WTO Doc WT/DS114/R
- European Communities - Customs Classification of Frozen Boneless Chicken Cuts (adopted 27 September 2005) WTO Doc WT/DS269/R
- European Communities – Measures Affecting Asbestos and Products Containing Asbestos (adopted 5 April 2001) WTO Doc WT/DS135/R
- European Communities – Measures Affecting the Approval and Marketing of Biotech Products (adopted 21 November 2006) WTO Doc WT/DS291/R, WT/DS292/R, WT/DS293/R
- European Communities – Measures Affecting Trade in Commercial Vessels (adopted 20 June 2005) WTO Doc WT/DS301/R
- European Communities – Regime for the Importation, Sale and Distribution of Bananas (adopted 25 September 1997) WTO Doc WT/DS27/R/ECU
- India – Measures Affecting the Automotive Sector (adopted 5 April 2002) WTO Doc WT/DS146/R, WT/DS175/R
- Indonesia - Certain Measures Affecting the Automobile Industry (adopted 23 July 1998) WTO Doc WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R

- Korea - Measures Affecting Government Procurement (adopted 19 June 2000) WTO Doc WT/DS163/R
- Korea - Measures Affecting Imports of Fresh, Chilled and Frozen Beef (adopted 10 January 2001) WTO Doc WT/DS161/R, WT/DS169/R
- Turkey - Restrictions on Imports of Textile and Clothing Products (adopted 19 November 1999) WTO Doc WT/DS34/R
- United States - Measures Affecting the Cross-Border Supply of Gambling and Betting Services (adopted 20 April 2005) WTO Doc WT/DS285/R
- United States – Section 110(5) of US Copyright Act (adopted 27 July 2000) WTO Doc WT/DS160/R
- United States - Section 301-310 of the Trade Act 1947 (adopted 27 January 2000) WTO Doc WT/DS152/R

C- Other WTO Reports

- European Communities – Measures Concerning Meat and Meat Products (Hormones), Recourse to Arbitration by the European Communities Under Article 22.6 of the DSU (12 July 1999) WTO Doc WT/DS26/ARB
- Notification of Mutually Agreed Solution, Argentina - Certain Measures on the Protection of Patents and Test Data (31 May 2002) WTO Doc WT/DS171/3, WT/DS196/4, IP/D/18/Add.1, IP/D/22/Add.1
- Notification of Mutually Agreed Solution, Brazil - Measures Affecting Patent Protection (19 July 2001) WTO Doc WT/DS199/4, G/L/454, IP/D/23/Add.1
- Notification of Mutually Agreed Solution, Pakistan - Patent Protection for Pharmaceutical and Agricultural Chemical Products (7 March 1997) WTO Doc WT/DS36/4, IP/D/2/Add.1
- Request for Consultations by India, European Union and a Member State – Seizure of Generic Drugs in Transit (19 May 2010) WTO Doc WT/DS408/1, G/L/921, IP/D/28
- Request for the Establishment of a Panel by the United States, Brazil - Measures Affecting Patent Protection (9 January 2001) WTO Doc WT/DS199/3

**Table of Legislation**

1- Domestic Legislation

Brazil

- Brazil Industrial Property Law No 9.279 of 14 May 1996

Canada

- Act to Amend the Patent Act, SC 2001, C 10
- Patent Act, RSC 1985, c P-4
- The Patent Act Amendment Act (Bill C-91), 1992, SC1993, c 2

France

- French patent Act 1791
- French Patent Act 1844
- Ordonnance No 59-250 on 4 February 1959

India

- Indian Patents (Amendment) Act No 15 of 2005

Indonesia

- Law of the Republic of Indonesia No 13 of July 28, 2016 on Patents

South Africa

- Constitution of the Republic of South Africa, 10 December 1996
- Medicines and Related Substances Control Amendment Act, Act No 90 of 1997, amending the Medicines and Related Substances Control Act No 101 of 1965, Republic of South Africa Government Gazette No 18505 (12 December 1997)

UK

- Statute of Monopolies 1623, 21 Jac 1, ch 3
- UK Patents Act 1977 (as amended)

USA

- 19 US Code § 2411, Title III ch 1, 88 Stat 2041 (Section 301 of the Trade Act of 1974)
- 42 US Code § 2181 (2012) Inventions Relating to Atomic Weapons and Filing of Reports
- Patent Act of 1790, Ch 7, 1 Stat 109 (10 April 1790)
- Patent Act of 1793, Ch 11, 1 Stat 318 (21 February 1793)
- Patent Act of 1952, 35 US Code, ch 950, 66 stat 797 (19 July 1952)
- US Constitution

2- International Treaties:

- Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (adopted 17 November 1988, entered into force 16 November 1999) OAS Treaty Series No 69 (Protocol of San Salvador)
- African Charter on Human and Peoples' Rights (adopted 27 June 1981, entered into force 21 October 1986) OAU Doc CAB/LEG/67/3 rev 5, 21 ILM 58, 1520 UNTS 217 (Banjul Charter)
- Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154, 33 ILM 1144 (WTO Agreement)
- Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, 33 ILM 1197 (TRIPS)
- American Convention on Human Rights (adopted 22 November 1969, entered into force 18 July 1978) OAS Treaty Series No 36, 1144 UNTS 123 (Pact of San Jose, Costa Rica)
- Berne Convention for the Protection of Literary and Artistic Works (adopted 9 September 1886, completed at Paris 4 May 1896, revised at Berlin 13 November 1908, completed at Berne 20 March 1914, revised at Rome 2 June 1928, revised at Brussels 26 June 1948, and revised at Stockholm 14 July 1967) 828 UNTS 221

- Charter of the United Nations (adopted 26 June 1945, entered into force 24 October 1945) 1 UNTS XVI
- Convention on the Elimination of All Forms of Discrimination Against Women (adopted 18 December 1979, entered into force 3 September 1981) 1249 UNTS 13 (CEDAW)
- Convention on the Rights of the Child (adopted 20 November 1989, entered into force 2 September 1990) 1577 UNTS 3 (UNCRC)
- Council of Europe, European Social Charter (Revised) (adopted 3 May 1996, entered into force 1 July 1999) ETS 163
- European Patent Convention (adopted 5 October 1973, entered into force 7 October 1977, revised by the Act revising article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000)
- Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (15 April 1994) 1867 UNTS 14, 33 ILM 1143
- General Agreement on Tariffs and Trade (adopted 30 October 1947, entered into force 1 January 1948) 55 UNTS 194 (GATT 1947)
- General Agreement on Tariffs and Trade, Annex 1A of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187, 33 ILM 1153 (GATT 1994)
- International Convention on the Elimination of All Forms of Racial Discrimination (adopted 21 December 1965, entered into force 4 January 1969) 660 UNTS 195 (CERD)
- International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171 (ICCPR)
- International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR)
- North American Free Trade Agreement (signed in US-Canada-Mexico 17 December 1992, entered into force 1 January 1994) 32 ILM 289 and 32 ILM 605 (NAFTA)

- Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, entered into force 7 July 1884) 21 UST 1583, 828 UNTS 305 (Paris Convention)
- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency [2004] OJ L136/1
- Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 Amending Regulation (EC) No 469/2009 Concerning the Supplementary Protection Certificate for Medicinal Products [2019] OJ L153/1
- Statute of the International Court of Justice (adopted 26 June 1945, entered into force 24 October 1945) 3 Bevans 1179, 59 Stat 1031, TS 993 (ICJ)
- TRIPS Agreement (as amended on 23 January 2017)
- UN Convention on the Law of the Sea (adopted 10 December 1982, entered into force 16 November 1994) 1833 UNTS 397 (UNCLOS)
- Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 401, 33 ILM 1226 (DSU)
- Universal Copyright Convention (adopted 6 September 1952 and revised 24 July 1971 including Protocols 1 and 2) 13444 Vol 943 UNTS 178
- Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT)

**Table of International Instruments**

EU

- Council Directive 2001/83/EC of the European Parliament and of the Council 2 December of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use [2001] OJ L311/67

- Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use [2004] OJ L136/34
- Council Directive 87/22/EEC of 22 December 1986 on the Approximation of National Measures Relating to the Placing on the Market of High-Technology Medicinal Products, Particularly Those Derived from Biotechnology [1987] OJ L15/38
- Council Regulation (EEC) No 1768/92 of 18 June 1992 Concerning the Creation of a Supplementary Protection Certificate for Medicinal Products [1992] OJ L182/1
- Council Regulation (EEC) No 2309/93 of 22 July 1993 Laying Down Community Procedures for the Authorization and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Agency for the Evaluation of Medicinal Product [1993] OJ L214/1
- Council Regulation (EC) No 3286/94 of 22 December 1994 Laying Down Community Procedures in the Field of the Common Commercial Policy in Order to Ensure the Exercise of the Community's Rights Under International Trade Rules, in Particular Those Established Under the Auspices of the World Trade Organization [1994] OJ L349/71

UN

- UN Commission on Human Rights, 'Resolution 2001/33: Access to Medication in the Context of Pandemics Such as HIV/AIDS' (23 April 2001) UN Doc E/CN.4/RES/2001/33
- UN Commission on Human Rights, 'Resolution 2002/32: Access to Medication in the Context of Pandemics Such as HIV/AIDS' (22 April 2002) UN Doc E/CN.4/RES/2002/32
- UN Commission on Human Rights, 'Resolution 2003/29: Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria' (22 April 2003) UN Doc E/CN.4/RES/2003/29

- UN Commission on Human Rights, 'Resolution 2004/26: Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria' (16 April 2004) UN Doc E/CN.4/RES/2004/26
- UN Commission on Human Rights, 'Resolution 2005/23: Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria' (15 April 2005) UN Doc E/CN.4/RES/2005/23
- UN Commission on Human Rights, 'Resolution 2004/69: Status of the International Covenants on Human Rights' (21 April 2004) UN Doc E/CN.4/RES/2004/69
- UN General Assembly, 'Resolution 58/179: Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria' (17 March 2004) UN Doc A/RES/58/179
- UN General Assembly, 'Resolution 60/262: Political Declaration on HIV/AIDS' (15 June 2006) UN Doc A/RES/60/262
- UN General Assembly, 'Resolution 63/117: Optional Protocol to the International Covenant on Economic, Social and Cultural Rights' (5 March 2009) UN Doc A/RES/63/117
- UN General Assembly, 'Resolution 65/277: Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV and AIDS' (8 July 2011) UN Doc A/RES/65/277
- UN General Assembly, 'Entry into Force of the Constitution of the World Health Organization' (17 November 1947) UN Doc A/RES/131
- UN Sub-Commission on the Promotion and Protection of Human Rights, 'Resolution 2000/7 on Intellectual Property Rights and Human Rights' (17 August 2000) UN Doc E/CN.4/Sub.2/RES/2000/7
- United Nations Security Council, 'Resolution 1308 (2000) on the Responsibility of the Security Council in the Maintenance of International Peace and Security: HIV/AIDS and International Peace-keeping Operations' (17 July 2000) UN Doc S/RES/1308 (2000)

- Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR)
- UN General Assembly, 'Resolution 55/2: United Nations Millennium Declaration' (18 September 2000) UN Doc A/RES/55/2
- UN General Assembly, 'Resolution S-26/2: Declaration of Commitment on HIV/AIDS' (2 August 2001) UN Doc A/RES/S-26/2
- Human Rights Council, 'Resolution 17/4: Human Rights and Transnational Corporations and Other Business Enterprises' (6 July 2011) UN Doc A/HRC/RES/17/4
- UN Human Rights Council, 'Resolution 6/29: Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (14 December 2007) UN Doc A/HRC/RES/6/29
- Human Rights Council, 'Resolution 8/7: Mandate of the Special Representative of the Secretary General on the Issue of Human Rights and Transnational Corporations and other Business Enterprises' (18 June 2008) UN Doc A/HRC/RES/8/7
- UN Human Rights Council, 'Resolution 12/24: Access to Medicine in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (12 October 2009) UN Doc. A/HRC/RES/12/24

WHO

- World Health Assembly, 'Resolution 53.14: Global Strategy for the Prevention and Control of Non-Communicable Diseases' (22 March 2000) WHA 53.14
- World Health Assembly, 'Resolution 54.11: WHO Medicines Strategy' (21 May 2001) WHA 54.11
- World Health Assembly, 'Resolution 56.30: Global Health-Sector Strategy for HIV/AIDS' (28 May 2003) WHA 56.30
- World Health Assembly, 'Resolution 57.14: Scaling Up Treatment and Care Within a Coordinated and Comprehensive Response to HIV/AIDS' (22 May 2004) WHA 57.14

- World Health Assembly, 'Resolution 59.24: Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action' (27 May 2006) WHA 59.24
- World Health Assembly, 'Resolution 61.21: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property' (24 May 2008) WHA 61.21

WTO

- Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health (concluded 14 November 2001, entered into force 20 November 2001) WT/MIN (01)/DEC/W/2 (Doha Declaration)
- Extension of the Transitional Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products (1 July 2002) WTO Doc IP/C/25 (TRIPS Council Decision of 27 June 2002)
- Extension of the Transitional Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products (6 November 2015) WTO Doc IP/C/73 (TRIPS Council Decision of 6 November 2015)
- Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2 September 2003) WTO Doc WT/L/540 (30 August General Council Decision)
- Working Procedures for Appellate Review (adopted 16 August 2010) WTO Doc WT/AB/WP/6
- WTO TRIPS Council, 'Notification Under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (19 July 2007) WTO Doc IP/N/9/RWA/1
- WTO TRIPS Council, 'Notification Under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (8 October 2007) WTO Doc IP/N/10/CAN/1

- WTO TRIPS Council, 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Communication from the Permanent Mission of Brazil on Behalf of the Delegations of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela' (24 June 2002) WTO Doc IP/C/W/355

Other Instruments

- Declaration of Alma-Ata International Conference on Primary Health Care (6–12 September 1978)
- Vienna Declaration and Programme of Action (12 July 1993) A/CONF.157/23


**Secondary Sources**

**Books**


- Aplin T and Davis J, *Intellectual property Law: Text, Cases and Materials* (2nd edn, Oxford University press 2013)
- Aust A, *Modern Treaty Law and Practice* (Cambridge University Press 2000)
- Austin J, *The Province of Jurisprudence Determined* (Wilfrid E. Rumble edn, Cambridge University Press 1995)
- Australian Law Reform Commission, *Genes and Ingenuity Report: Gene Patenting and Human Health* Methods of medical Treatment' (SOS Printing Group Australia 2004) < https://www.alrc.gov.au/publication/genes-and-ingenuity-gene-patenting-and-human-health-alrc-report-99/ > accessed 27 September 2021
- Bently L and Sherman B, *Intellectual Property Law* (2nd edn, Oxford University Press 2004)
- Bently L and Sherman B, *Intellectual property law* (4th edn, Oxford University Press 2014)
- Bodenhausen GHC, *Guide to the Application of the Paris Convention for the Protection of Industrial Property* (WIPO Publication 1969)

- Braithwaite J and Drahos P, *Global Business Regulations* (Cambridge University Press 2000)
- Brownlie I, *Principles of Public International Law* (6th edn, Oxford University Press 2003)
- Carter BE, Weiner AS and Hollis DB, *International Law* (5th edn, Aspin Publishers 2007)
- Cassese A, *International Law* (2nd edn, Oxford University Press 2005)
- Cassese A, *International Law in a Divided World* (Oxford University Press 1986)
- Chan M, *Ten Years in Public Health 2007-2017* (WHO Publications 2017)
- Chapman A and Russell S, *Core Obligations: Building a Framework for Economic, Social and Cultural* (Intersentia Oxford 2002)
- Coke E, *The Selected Writings and Speeches of Sir Edward Coke*, Vol 1 (Steve Sheppard edn, Liberty Fund Indianapolis 2003)
- Commission on Intellectual Property Rights, Innovation and Public Health, *Public health, Innovation and Intellectual Property Rights* (WHO Geneva 2006)
- Correa CM, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000)
- Correa CM, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed Books 2000)
- Correa CM, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press New York 2007)
- Crawford J, *The International Law Commission's Articles on State Responsibility: Introduction, Text and Commentaries* (Cambridge University Press 2002)
- De Coninck R et al, *Assessing the Economic Impacts of Changing Exemption Provisions During Patent and SPC Protection in Europe* (European Union Publication 2017)

- De Vattel E, *Natural Law and Enlightenment Classics: The Law of Nations, Or, Principles of the Law of Nature, Applied to the Conduct and Affairs of Nations and Sovereigns, With Three Early Essays on the Origin and Nature of Natural Law and on Luxury* (Haakonssen K, Kapossy B and Whatmore R eds, Liberty Fund Indianapolis 2008)
- Donnelly J, *Universal Human Rights in Theory and Practice* (3rd edn, Cornell University Press 2013)
- Drahos P and Braithwaite J, *Information Feudalism: Who Owns the Knowledge Economy* (Earthscan Publications 2002)
- Drahos P, *A Philosophy of Intellectual Property* (Australian National University E-Text 2016)
- Dunoff JL, Ratner SR and Wippman D, *International Law: Norms, Actors, Process: A Problem-Oriented Approach* (2nd edn, Aspin Publishers 2006)
- Dutfield G and Suthersanen U, *Global Intellectual Property Law* (Edward Elgar Publishing Limited UK 2008)
- Dutfield G, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (Ashgate Publishing 2003)
- Dutton HI, *The Patent System and Inventive Activity During the Industrial Revolution 1750-1852* (Manchester University Press 1984)
- European Patent office, *Guidelines for Examination in the European Patent Office* (European patent Office Germany 2021)
- Gervais DJ, *The TRIPS Agreement: Drafting History and Analysis* (2nd edn, Sweet & Maxwell UK 2003)
- Glazier SC, *Patents Strategies for Business* (3rd edn, Law and Business Institute Washington 2003)
- Gold J, *Interpretation: The IMF and International Law* (Kluwer Law International The Hague 1996)

- Goozner M, *The $800 Million Pill: The Truth Behind the Cost of New Drugs* (California University Press 2004)
- Harrison J, *The Human Rights Impact of the World Trade Organization* (Hart publishing 2007)
- Hart HLA, *The Concept of Law* (3rd edn, Oxford University press 2012)
- Haugen HM, *The Right to Food and the TRIPS Agreement with Particular Emphasis on Developing Countries' Measures for Food production and Distribution* (Martinus Nijhoff Publishers Leiden Netherlands 2007)
- Helfer LR and Austin GW, *Human Rights and Intellectual property: Mapping the Global Interface* (Cambridge University Press 2011)
- Hestermeyer H, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2008)
- Humphrey JP, *No Distant Millennium: The International Law of Human Rights* (UNESCO 1989)
- International Council on Human Rights, *Beyond Voluntarism: Human Rights and the Developing International Legal Obligations of Companies* (International Council on Human Rights Policy Switzerland 2002)
- Joseph S, *Blame it on the WTO* (Oxford university Press UK 2013)
- Kalin W and Kunzli J, *The Law of International Human Rights Protection* (2nd edn, Oxford University Press 2019)
- Kapstein EB and Busby JW, *AIDS Drugs for All: Social Movements and Market Transformations* (Cambridge University Press USA 2013)
- Karapapa S and McDonagh L, *Intellectual Property Law* (Oxford University Press 2019)
- Kelsen H, *General Theory of Norms* (Clarendon Press UK 1991)
- Landes WM and Posner RA, *The Economic Structure of Intellectual Property Law* (Harvard University Press 2003)

- Lee JY, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge London 2016)
- Linderfalk U, *On the Interpretation of Treaties: The Modern International Law as Expressed in the 1969 Vienna Convention on the Law of Treaties* (Springer Publishing Netherlands 2007)
- Locke J, *Second Treatise of Government* (Watchmaker Publishing 2011)
- Love P and Lattimore R, *International trade: Free, Fair and Open?* (OECD publications Paris 2009) < https://www.oecd-ilibrary.org/trade/international-trade_9789264060265-en> accessed 13 June 2021
- Lowenfeld AF, *International Economic Law* (2nd edn, Oxford University Press 2008)
- MacLeod C, *Inventing the Industrial Revolution: The English patent System 1660-1800* (Oxford University Press 1988)
- Matthews D, *Globalising Intellectual Property Rights: The TRIPS Agreement* (Routledge London and New York 2002)
- Matthews D, *Intellectual Property, Human Rights and Development: The Role of NGOs and Social Movements* (Edward Elgar UK 2011)
- Mcbeth A, *International Economic Actors and Human Rights* (Routledge Oxford 2009)
- McCarthy JT et al, *McCarthy Desk Encyclopedia of Intellectual Property* (3rd edn, Washington DC 2004)
- McDougal MS, Lasswell HD, and Miller JC, *The Interpretation of International Agreements and World Public Order: Principles of Content and Procedure* (New Haven Press 1994)
- Menell PS et al, *Intellectual Property in the New Technological Age: 2019 Volume I: Perspectives, Trade Secrets & Patents* (Clause 8 Publishing 2019)
- Merges RP, Menell PS and Lemley MA, *Intellectual Property in the New Technological Age* (Aspen Law and Business US 2000)
- Mestre-Ferrandiz J et al, *The R&D Cost of a New Medicine* (Office of Health Economics UK 2012)

- Muzaka V, *The Politics of Intellectual Property Rights and Access to Medicines* (Palgrave Macmillan UK 2011)
- Nozick R and Nagel T, *Anarchy, State, And Utopia* (Basic Books New York 2013)
- Organization for Economic Cooperation and Development (OECD), *OECD Guidelines for Multinational Enterprise* (2011 edn, OECD Publishing)
- Pauwelyn J, *Conflict of Norms in Public International Law*: *How WTO Law Relates to Other Rules of International Law* (Cambridge University Press 2003)
- Reuter P, *Introduction to the Law of Treaties* (Jose Mico & Peter Haggenmacher trs, Routledge UK 2011)
- Ricketson S, *The Berne Convention for the Protection of Literary and Artistic Works:1886 to 1986* (Centre for Commercial Law Studies, Queen Mary Collage, University of London 1987)
- Rubio MG, *Unilateral Measures as a Means of Enforcement of WTO Recommendations and Decisions* (The Hague Academy of Intentional Law 2001)
- Schubert K and McClean D, *Dear Images: Art, Copyright and Culture* (Ridinghouse London 2002)
- Schwartz HF, *Patent Law and Practice* (3rd edn, Federal Judicial Centre Washington DC 2001)
- Sell SK, *Private Power, Private Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press 2003)
- Sherman B and Bently L, *The Making of Modern Intellectual Property Law: The British Experience 1760-1911* (Cambridge University Press 2002)
- Sinclair I, *The Vienna Convention on the Law of Treaties* (2nd edn, Manchester University Press 1984)
- Thornberry P, *International Law and the Rights of Minorities* (Oxford University Press New York 1991)
- Tomuschat C, *Human Rights: Between Idealism and Realism* (2nd edn, Oxford University Press New York 2008)

- Tritton G, *Intellectual Property in Europe* (2nd edn, Sweet and Maxwell London 2002)
- UN, *Human Rights: The International Bill of Human Rights, 40th Anniversary of the Universal Declaration of Human Rights 1948-1988* (UN Department of Public Information Publication 1988) < https://searchlibrary.ohchr.org/record/10494?ln=en> accessed 26 May 2021
- UN Development Program, *Human Development Report 1999* (Oxford University Press New York 1999)
- UN Millennium Development Goal Gap Task Force, *Millennium Development Goal 8: The Global Partnership for Development: Making Rhetoric a Reality* (UN Publication 2012)
- UN Millennium Development Goal Gap Task Force, *Millennium Development Goal 8: Delivering on the Global Partnership for Achieving the Millennium Development Goals* (UN Publication 2008)
- UN Millennium Project, *Prescription for Healthy Development: Increasing Access to Medicines* (Earthscan London 2005)
- UNAIDS, *Courting Rights: Case Studies in Litigating the Human Rights of People Living with HIV* (Canadian HIV/AIDS Legal Network and UNAIDS 2006)
- UNCTAD - ICTSD, *Resource Book on TRIPS and Development* (Cambridge University Press New York 2005)
- Vadi V, *Public Health in International Investment Law and Arbitration* (Routledge London 2013)
- Van Den Bossche P and Zdouc W, *The Law and Policy of the World Trade Organization* (3rd edn, Cambridge University Press 2013)
- Van Hoof G, *Rethinking Sources International Law* (Springer Press 1985)
- Weeramantry JR, *Treaty Interpretation in Investment Arbitration* (Oxford University Press UK 2012)
- WHO Commission on Macroeconomics and Health, *Report on Macroeconomics and Health: Investing in Health for Economic Development* (WHO publications 2001) <

http://www1.worldbank.org/publicsector/pe/PEAMMarch2005/CMHReport.pdf > accessed 12 July 2019

- WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade* (WIPO Publications 2013)
- World Bank, Global Economic Prospects and the Developing countries (Washington D.C. 2001) < https://documents1.worldbank.org/curated/en/285571468337817024/310436360_20050012014722/additional/multi0page.pdf > accessed 22 September 2021
- Xiong P, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Martinus Nijhoff Publishers Leiden Netherlands 2012)
- Yamane H, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Hart Publishing US & Canada 2011)
- Yearwood RR, *The Interaction between World Trade Organization (WTO) Law and External International Law: The Constrained Openness of WTO Law* (Routledge London 2012)

**Edited Books**

- Abbott FM, 'Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (Cambridge University Press UK 2005) 393
- Abbott FM, 'The 'Rule of Reason' and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS' in Thomas Cottier, Joost. Pauwelyn, and Elisabeth Bürgi (eds), *Human Rights and International Trade* (Oxford University Press 2003) 279
- Abbott FM, 'The TRIPS-Legality of Measures Taken to Address Public Health Crises: Responding to USTR-State-Industry Positions That Undermine the WTO' in Daniel L.

M. Kennedy and James D. Southwick (eds), *The Political Economy of International Trade: Essays in Honour of Robert E. Hudec* (Cambridge University Press 2002) 311

- Abbott FM, 'TRIPS and Human Rights: Preliminary Reflections' in Frederick M. Abbott et al (eds), *International Trade and Human Rights: Foundations and Conceptual Issues* (Michigan university Press 2006) 145
- Bale H, 'Patents, Patients and Developing Countries: Access, Innovation and the Political Dimensions of Trade Policy' in Brigitte Granville (ed), *The Economics of Essential Medicines* (Royal Institute of International Affairs 2002) 100
- Brand, 'Article 2- Intellectual Property Conventions' in Peter Tobias Stoll et al (eds), *WTO-Trade Related Aspects of Intellectual Property Rights* (Martinus Nijhoff Publishers 2009) 95
- Bronckers MCEJ, 'The Impact of TRIPS: Intellectual Property Protection in Developing Countries' in Marco C.E.J. Bronckers, *A Cross-Section of WTO Law* (Cameron May Ltd 2001) 185
- Correa CM (ed), *A Guide to Pharmaceutical patents* (South Centre Geneva 2012)
- Correa CM, 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime* (Cambridge University Press UK 2005) 227
- Cullet P, 'Patents and Health in Developing Countries' in John Hatchard and Amanda Perry-Kessaris (eds), *Law and Development: Facing Complexity in the 21st Century* (Cavendish Publishing Limited London 2003) 78
- Dinstein Y, 'The Right to Life, Physical Integrity and Liberty' in Louis Henkin (ed), *The International Bill of Rights: The Covenant on Civil and Political Rights* (Columbia University Press New York 1981) 114
- Drahos P, 'The Universality of Intellectual Property Rights: Origins and Development' in WIPO (ed), *Intellectual Property and Human rights: A Panel Discussion to Commemorate the 50th Anniversary of the Proclamation of the Universal Declaration of Human Rights* (WIPO Geneva 1999) 13

- Drews J, ‘Drug Research: Between Ethical Demands and Economic Constraints’ in Michael A. Santoro and Thomas M. Gorrie (eds), *Ethics and the Pharmaceutical Industry* (Cambridge University Press 2005) 21
- Farnsworth NR, ‘Screening Plants for New Medicines’ in E.O.Wilson and Frances M.Peter (eds), *Biodiversity* (National Academy Press Washington DC 1988) 83
- Fisher WW, ‘Theories of Intellectual Property’ in Stephen R. Munzer (ed), *New Essays in the Legal and Political Theory of Property* (Cambridge University Press 2001) 168
- Hall BH, ‘Patents’ in Steven N. Durlauf and Lawrence E. Blume (eds), *The New Palgrave Dictionary of Economics* (2nd edn, Palgrave Macmillan UK 2008)
- Haugen HM, ‘Why are Intellectual Property Rights Hardly Visible in the United Nations Sustainable Development Goals?’ in Ole-Andreas Rognstad and Inger B. Orstavik (eds), *Intellectual Property and Sustainable Markets* (Edward Elgar UK 2021) 12
- Hestermeyer H, ‘International Human Rights Law and Dispute Settlement in the World Trade Organization’ in Martin Scheinin (ed), *Human Rights Norms in ‘Other’ International Courts* (Cambridge University Press UK 2019) 199
- Humphrey JP, ‘The Universal Declaration of Human Rights: Its History, Impact and Juridical Character’ in Bertram G. Ramcharan (ed), *Human Rights: Thirty Years After the Universal Declaration* (Martinus Nijhoff Publishers 1979) 21
- Jennings R and Watt A (eds), *Oppenheim’s International Law Vol 1 Part 3* (Ninth edition, Pearson Higher Education 1992)
- Karl W, ‘Conflicts Between Treaties’ in Rudolf Bernhardt (ed), *Encyclopedia of Public International Law Vol 7* (North Holland, 1984) 467
- kiss A, ‘The Role of the Universal Declaration of Human Rights in the Development of International Law’ in UN Centre of Human Rights, *Bulletin of Human Rights: Special Issue: Fortieth Anniversary of the Universal Declaration of Human Rights* (UN 1988)

- Klein E, 'The Duty to Protect and to Ensure Human Rights under the International Covenant on Civil and political Rights' in Eckart Klein (ed), *The Duty to protect and to Ensure Human Rights* (BWV Berliner-Wissenschaft 2000) 296

- Marks SP, 'Access to Essential Medicines as a Component of the Right to Health' in Andrew Clapham and Mary Robinson (eds), *Realizing the Right to Health: Swiss Human Rights Book*, Vol 3 (Ruffer & Rub Zurich 2012) 82

- Marsoof A, 'Local Working of Patents: The Perspective of Developing Countries' in Ashish Bharadwaj et al (eds), *Multi-Dimensional Approaches Towards New Technology: Insights on Innovation, Patents and Competition* (Springer Singapore 2018) 315

- Megret F, 'Nature of obligations' in Daniel Moeckli et al (eds), *International Human Rights Law* (2nd edn, Oxford university Press 2010) 96

- Merrill SA and Mazza AM et al(eds), *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* ( The National Academies press 2006) < https://www.nap.edu/catalog/11487/reaping-the-benefits-of-genomic-and-proteomic-research-intellectual-property > accessed 21 April 2019

- Oliveira MA et al, 'Brazilian Intellectual Property Legislation' in Jorge A. Z. Bermudez and Maria Auxiliadora Oliveira (eds), *Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for the Public Health* (WHO/PAHO Collaborating Centre for Pharmaceutical Policies & Oswaldo Cruz Foundation Rio de Janeiro 2004) 151

- Pai Y, 'The Growing Irrelevance of a TRIPS Challenge to India's Patent Law' in Wong-mog Choi (ed), *International Economic Law: The Asia-Pacific Perspectives* (Cambridge Scholars Publishing 2015) 286

- Papadopoulou F, 'TRIPS and Human Rights' in Annette Kur and Marianne Levin (eds), *Intellectual property Rights in a Fair World Trade System. Proposals for Reform of TRIPS* (Edward Elgar UK 2011) 262

- Pauwelyn J, 'Remarks at the Fourth Annual WTO Conference' in Mads Andenas and Federico Ortino (eds), *WTO Law and Process* (British institute of International and Comparative Law 2005) 494

- Riedel E, 'The Human Right to Health: Conceptual Foundations' in Andrew Clapham and Mary Robinson (eds), *Realizing the Right to Health: Swiss Human Rights Book,* Vol 3 (Ruffer and Rub Zurich 2009) 21

- Seuba X, 'Mainstreaming the TRIPS and Human Rights Interactions' in Carlos M. Correa (ed), *Research Handbook of the protection of Intellectual Property Under WTO Rules: Intellectual property in the WTO,* Volume 1 (Edward Elgar Publishing UK 2010) 192

- Shiffrin SV, 'Lockean Arguments for Private Intellectual property' in Stephen R. Munzer (ed), *New Essays in the Legal and Political Theory of Property* (Cambridge University Press 2001) 138

- Siew-Kuan Ng E, 'Global Health and Development: Patents and Public Interest' in Thomas Pogge, Matthew Rimmer, and Kim Rubenstein (eds), *Incentives for Global Public Health* (Cambridge University Press 2010) 101

- Simma B et al (eds), *The Charter of the United Nations: A Commentary*, Vol 1(2nd edn, Oxford University Press 2002)

- Spence M, 'Which Intellectual Property Rights are Trade-Related?' in Francesco Francioni (ed), *Environment, Human Rights and International Trade* (Hart Publishing Oxford 2001)

- Sterckx S, 'The Ethics of Patenting: Uneasy Justifications' in Peter Drahos (ed), *Death of Patents* (Law Text Publishing Limited in association with Queen Mary Intellectual Property Research Institute 2005) 175

- Thierer A and Crews CW (eds), *Copy Fights: The future of Intellectual property in the Information Age* (Cato Institute Washington 2002)

- Trachtman JP, 'Jurisdiction in WTO Dispute Settlement' in Rufus Yerxa and Bruce Wilson (eds), *Key Issues in WTO Dispute Settlement: The First Ten Years* (Cambridge University Press 2005) 132

- Walker S, 'A Human Rights Approach to the WTO's TRIPS Agreement' in Frederick M. Abbott, Christine Kaufmann and Thomas Cottier (eds), *International Trade and*

*Human Rights: Foundations and Conceptual Issues* (Michigan University Press 2006) 171

- Wilson B, 'Social Determinants of Health from a Rights-Based Approach' in Andrew Clapham and Mary Robinson (eds), *Realizing the Right to Health: Swiss Human Rights Book Vol.3* (Ruffer and Rub Zurich 2009) 60

**Encyclopedias**

- Macleod C, 'John Stuart Mill', *Stanford Encyclopedia of Philosophy* (25 August 2016) < https://plato.stanford.edu/entries/mill/ > accessed 20 March 2019
- Stim R, 'Who owns Patent Rights: Employer or Inventor?', *NOLO Legal Encyclopedia* < https://www.nolo.com/legal-encyclopedia/who-owns-patent-rights-employer-inventor.html> accessed 18 September 2021
- Sweet W, 'Jeremy Bentham (1748-1832)', *Internet Encyclopedia of Philosophy* < http://www.iep.utm.edu/bentham/ > accessed 10 March 2019
- Tuckness A, 'Locke's Political Philosophy', *Stanford Encyclopedia of Philosophy* (6 October 2020) < http://plato.stanford.edu/entries/locke-political/> accessed 14 January 2021

**Journal Articles**

- 't Hoen E, 'Report of the Commission on Intellectual Property Rights, Innovation and Public Health: A Call to Governments' (2006) 84(5) Bulletin of the World Trade Organization 421
- 't Hoen E, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha' (2002) 3(1) Chicago Journal of International Law 27
- Abbas MZ, 'Pros and Cons of Compulsory Licensing: An Analysis of Arguments' (2013) 3(3) International Journal of Social Science and Humanity 254

- Abbott FM and Reichmann JH, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 (4) Journal of International Economic Law 921
- Abbott FM, 'Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework' (1989) 22(4) Vanderbilt Journal of Transnational Law 689
- Abbott FM, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lightening a Dark Corner at the WTO' (2002) 5 Journal of International Economic Law 469
- Abbott FM, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) 99 The American Journal of International Law 317
- Abbott FM, 'Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism' (2005) 8(1) Journal of International Economic Law 77
- Ahmadiani S and Nikfar S, 'Challenges of Access to Medicine and the Responsibility of Pharmaceutical Companies: A Legal Perspective' (2016) 24(13) Daru Journal of pharmaceutical Sciences < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855755/> accessed 22 March 2021
- Alston P, 'Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann' (2002) 13(4) European Journal of International Law 815
- Andrieansjah, 'The Impact of COVID-19 on Intellectual Property Legal System Related to Public Health in Connection with TRIPS Flexibilities in Indonesia' (2020) 13(2) Indonesian Law Journal 165
- Arewa O, 'TRIPS and Traditional Knowledge: Local Communities, Local Knowledge and Global Intellectual Property Frameworks' (2006) 10 (2) Marquette Intellectual Property Law Review 154
- Armouti W and Nsour M, 'Test Data Protection: Different Approaches and Implementation in Pharmaceuticals' (2016) 20(2) Marquette Intellectual Property Law Review 267

- Attaran A and Gillespie-White L, 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa' (2001) 286(15) Journal of American Medical Association 1886
- Attaran A, 'How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?' (2004) 23(3) Journal of Health Affairs 155
- Attaran A, 'The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals and Options Under WTO Law' (2002) 12 Fordham Intellectual Property, Media & Entertainment Law Journal 859
- Aufricht H, 'Supersession of Treaties in International Law' (1952) 37(4) Cornell Law Review 655
- Azam MM, 'The Experiences of TRIPS-Compliant Patent Law Reforms in Brazil, India, and South Africa and Lessons for Bangladesh' (2014) 7(2) Akron Intellectual Property Journal 61
- Baker BK, 'Arthritic Flexibilities: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (2004) 14(3) Indiana International and Comparative Law Review 613
- Bartels LA, 'Applicable Law in WTO Dispute Settlement Proceedings' (2001) 35(3) Journal of World Trade 499
- Bartelt S, 'Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health' (2003) 6(2) Journal of World Intellectual Property 283
- Barton JH, 'Research-Tool Patents: Issues for Health in the Developing World' (2002) 80(2) Bulletin of the WHO 121
- Becker LC, 'The Labour Theory of Property Acquisition' (1976) 73(18) The Journal of Philosophy 653
- Bederman DV et al, 'Subjects of International Law' (2003) 35 Studies in Transnational Legal Policy 61

- Bello JH, 'The WTO Dispute Settlement Understanding: Less is More' (1996) 90(3) The American Journal of International law 416
- Berman PS, 'From International Law to Law and Globalization' (2005) 43 Columbia Journal of Transnational Law 485
- Bos M, 'Will and Order in the Nation-State System Observations on Positivism and Positive International Law' (1982) 29(1) Netherlands International Law Review 3
- Burk DL and Lemley MA, 'Is Patent Law Technology-Specific' (2002) 17 Berkeley Technology law Journal 1155
- Cann WA, 'On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply under a Theory of Progressive Global Constitutionalism' (2004) 25(3) Pennsylvania Journal of International Law 755
- Carbone F, 'Employee Inventors and Patent Ownership: Whose Rights are they Anyway' (2021) 13(4) Landslide Magazine - American Bar Association Publications < https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2020-21/march-april/employee-inventors-patent-ownership-whose-rights-are-they-anyway/> accessed 18 September 2021
- Carey SV, 'What is the Rule of Recognition in the United States?' (2009) 157 University of Pennsylvania Law Review 1161
- Champ P and Attaran A, 'Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute' (2002) 27(2) Yale Journal of International Law 365
- Chapman A, 'Approaching Intellectual Property as a Human Right' (2001) 35(3) UNESCO Copyright Bulletin 4
- Charnovitz S, 'What is International Economic Law?' (2011) 14(1) Journal of International Economic law 3
- Chaves GC et al, 'Access to Medicines and Intellectual Property in Brazil: Reflections and Strategies of Civil society' (2008) 5(8) Sur International Journal on Human Rights 163

- Chen LC, 'Protection of Persons (Natural and Juridical)' (1989) 14 Yale Journal of International Law 542
- Chigara B, 'Social Justice: The Link Between Trade Liberalisation and Sub-Saharan Africa's Potential to Achieve the United Nations Millennium Development Goals by 2015' (2008) 26(1) Netherlands Quarterly of Human Rights 9
- Chigara B, 'Treaty-Text Loyalists' Burden with Subsequent State Practice' (2021) 68(1) Netherlands International Law Review 61
- Christov T, 'Liberal Internationalism Revisited: Grotius, Vattel and the International Order of States' (2005) 10(6) The European Legacy 561
- Cohen-Kohler JC et al, 'Canada's Implementation of the Paragraph 6 Decision: Is it Sustainable Public Policy?' (2007) 3(12) Globalization and health Journal < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2180169/> accessed 1 May 2020
- Coleman JL, 'Incorporationism, Conventionality, and the Practical Difference' (1998) 4 Legal Theory Journal 381
- Correa CM, 'Implications of Bilateral Free Trade Agreements on Access to Medicines' (2006) 84(5) WHO Bulletin 399
- Correa CM, 'Ownership of knowledge: The role of patents in pharmaceutical R&D' (2004) 82(10) International Journal of public Health 784
- Correa CM, 'The TRIPS Agreement: How Much Room for Maneuver?' (2001) 2(1) Journal of Human Development 79
- Cottier T, 'TRIPS, the Doha Declaration and Public Health' (2003) 6(2) Journal of World Intellectual Property 385
- Criddle EJ, 'Standing for Human Rights Abroad' (2015) 100(2) Cornell Law Review 269
- Cullet P, 'Patents and Medicines: The Relationship between TRIPS and Human Rights to Health' (2003) 79(1) International Affairs 139
- De Wolf AH, 'Human Rights and the Regulation of Privatized Essential Services' (2013) 60 Netherlands International Law Review 165

- Dibble W, 'Justifying Intellectual Property' [1994] University College London Jurisprudence Review 74
- Dickson J, 'Is the Rule of Recognition Really a Conventional Rule' (2007) 27(3) Oxford Journal of Legal Studies 373
- Diependaele L, Cockbain J and Sterckx S, 'Raising the Barriers to Access to Medicines in the Developing World – The Relentless Push for Data Exclusivity' (2017) 17(1) Developing World Bioethics Journal 11
- Dothan S, 'The Three Traditional Approaches to Treaty Interpretation: A Current Application to the European Court of Human Right' (2019) 42(765) Fordham international law Journal 765
- Downes D, 'How Intellectual Property could be a Tool to Protect Traditional Knowledge' (2000) 25(2) Colombia Journal of Environmental Law 253
- Drahos P, 'BITS and BIPS: Bilateralism in Intellectual property' (2001) 4 The Journal of World Intellectual Property 791
- Drahos P, 'Four Lessons for Developing Countries from Trade Negotiations over Access to Medicines' (2007) 28(1) Liverpool Law Review 11
- Drahos P, 'Intellectual Property and Human Rights' (1999) 3 Intellectual Property Quarterly 349
- Dreyfuss R and Frankel S, 'From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property' (2015) 36(4) Michigan Journal of International Law 557
- Durojaye E, 'Compulsory Licensing and Access to Medicines in post Doha Era: What Hope for Africa?' (2008) 55(1) Netherlands International Law Review 33
- Ehlermann CD and Ehring L, 'The Authoritative Interpretation Under Article Ix:2 of the Agreement Establishing the World Trade Organization: Current Law, Practice and Possible Improvements' (2005) 8(4) Journal of International Economic law 803

- Ehlermann CD, 'Six Years on the Bench of the 'World Trade Court.' Some Personal Experience as Member of the Appellate Body of the World Trade Organization' (2002) 36(4) Journal of World Trade 605
- Ellis J, 'Supporting Innovation in Next-Generation Medicines' (2017) 3 WIPO Magazine 37
- Eppich CK, 'Patenting Dilemma: Drugs for Profit Versus Drugs for Health' (2002) 43(1) Santa Clara Law Review 289
- Falgoust M, 'The Incentives Argument Revisited: A Millean Account of Copyright' (2014) 52(2) The Southern Journal of Philosophy 163
- Fedrico PJ, "Operation of the Patent Act of 1970" (2003) 33(85) Journal of the Patent and Trademark Office Society 33
- Fischer-Lescano A and Teubner G, 'Regime-Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law' (2004) 25(4) Michigan Journal of International Law 999
- Forman L, 'An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law' (2011) 14(2) The Journal of World Intellectual Property 155
- French D, 'Treaty Interpretation and the Incorporation of Extraneous Legal Rules' (2006) 55(2) The International and Comparative Law Quarterly 281
- Gabble R and Kohler JC, 'To Patent or Not to Patent? The Case of Novartis' Cancer Drug Glivec in India' (2014) 10(3) Globalization and Health Journal < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3884017/> accessed 12 December 2020
- Gallus N, 'The Mystery of Pharmaceutical Parallel Trade and Developing Countries' (2004) 7(2) World Intellectual Property journal 169
- Garcia FJ, 'The Global Market and Human Rights: Trading Away the Human Rights Principle' (1999) 25 Brooklyn Journal of International Law 51

- Ghanotakis E, 'How the U.S. Interpretation of Flexibilities Inherent in TRIPS Affects Access to Medicines for Developing Countries' (2004) 7(4) Journal of World Intellectual Property 563
- Gilbert R and Shapiro C, 'Optimal Patent Length and Breadth' (1990) 21(1) Rand Journal of Economics 106
- Gold ER and Lam DK, 'Balancing Trade in Patents: Public Non-Commercial Use and Compulsory Licensing' (2005) 6(1) Journal of World Intellectual Property 5
- Gopakumar KM, 'The WTO Deal on Cheap Drugs: A Critique' (2004) 7(1) Journal of World Intellectual property 99
- Gordon J, 'The Concept of Human Rights: The History and Meaning of its politicization' (1998) 23(3) Brooklyn Journal of International Law 689
- Gupta YK et al, 'The Tamiflu Fiasco and Lessons Learnt' (2015) 47(1) Indian Journal of Pharmacology 11
- Gurgula O & Lee WH, 'COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?' (23 January 2021) Forthcoming in the Journal of generic Medicines < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3771935 > accessed 23 March 2021
- Gurgula O, 'Monopoly v. Openness; Two Sides of IP Coin in the Pharmaceutical Industry' (2017) 20 World Intellectual property Journal 206
- Gurgula O, 'Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?' (2020) 51 International Review of Intellectual Property and Competition Law 1062
- Hafner G, 'Pros and Cons from Fragmentation of International Law' (2004) 25(4) Michigan Journal of International Law 849
- Halewood M, 'Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law' (1997) 35(2) Osgoode Hall Law Journal 243

- Hannum H, 'The Status of the Universal Declaration of Human Rights in National and International Law' (1996) 25(1) Georgia Journal of International and Comparative Law 287
- Hannum H, 'The UDHR in National and International Law' (1998) 3(2) Health and Human Rights Journal 144
- Haugen HM, 'Patent Rights and Human Rights: Exploring their Relationships' (2007) 10(2) World Intellectual Property Journal 97
- Helfer LR, 'Human Rights and Intellectual Property: Conflict or Coexistence?' (2003) 5(1) Minnesota Journal of Law, Science and Technology 47
- Helfer LR, 'Toward a Human Rights Framework for Intellectual Property' (2007) 40 University of California Davis Law Review 971
- Heller MA and Eisenberg RS, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280(5364) Journal of the American Association for the Advancement of Science 698
- Henckels C, 'Overcoming Jurisdictional Isolationism at the WTO-FTA Nexus: A Potential Approach for the WTO' (2008) 19(3) European Journal of International Law 571
- Henkin L, 'Human Rights and State sovereignty' (1996) 25 Georgia Journal of International and Comparative Law 31
- Henkin L, 'The Universal Declaration at 50 and the Challenges of Global Markets' (1999) 25(1) Brooklyn Journal of International Law 17
- Hesse C, 'Enlightenment Epistemology and the Laws of Authorship in Revolutionary France, 1777-1793' (1990) 30 Representations 109
- Hettinger EC, 'Justifying Intellectual property' (1989) 18(1) Philosophy and Public Affairs 31
- Hogerzeil HV et al, 'Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable Through the Courts?' (2006) 368(9532) The Lancet Medical Journal 305

- Holbrook TR, 'Possession in Patent Law' (2006) 59(1) Southern Methodist University Law Review 123
- Hollis A, 'An Efficient Reward System for Pharmaceutical Innovation'(WHO, 6 October 2004) < http://www.who.int/intellectualproperty/news/Submission-Hollis6-Oct.pdf > accessed 13 December 2019
- Holman CM, Minssen T, & Solovy EM, 'Patentability Standards for Follow-On Pharmaceutical Innovation' (2018) 37(3) Biotechnology Law Report 131
- Hovenkamp E, 'Challenges Restraints and the Scope of the Patent' (2016) 4(3) CPI Antitrust Chronicle Journal < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2866630> accessed 12 January 2019
- Howse R, 'From Politics to Technocracy and Back Again: The Fate of the Multilateral Trading Regime' (2002) 96(1) American Journal of International Law 94
- Howse R, 'The Canadian Generic Medicines Panel. A Dangerous Precedent in Dangerous Times' (2005) 3(4) World Intellectual Property Journal 493
- Hu J, 'The Role of International Law in the Development of WTO Law' (2004) 7(1) Journal of International Economic Law 143
- Hughes J, 'The Philosophy of Intellectual Property' (1988) 77 Georgetown Law Journal 287
- Hunt P and Khosla R, 'Are Drug Companies Living Up to Their Human Rights Responsibilities? The Perspective of the Former United Nations Special Rapporteur (2002-2008)' (2010) 7(9) PLOS Medicine Journal
- Hunt P and Khosla R, 'The human right to medicines' (2008) 5(8) Sur International Journal of Human Rights 99
- Jackson JH, 'International Economic Law: Jurisprudence and Contours' (1999) 93 American Society of International Law Proceedings 98

- Jacobs FG, 'Varieties of Approach to Treaty Interpretation: With Special Reference to the Draft Convention on the Law of Treaties Before the Vienna Diplomatic Conference' (1969) 18(2) The International and Comparative Law Quarterly 318
- Jain T, 'Compulsory Licences Under TRIPS and its Obligations for Member Countries' (2009) 8(1) Journal of IPRs of the Institute of Chartered Financial Analysts of India 27
- Jenks CW, 'The Conflict of Law-Making Treaties' (1953) 30 British Yearbook of International Law 401
- Kampf R, 'Patents Versus Patients?' (2002) 40(1) Archiv Des Völkerrechts 90 < https://www.jstor.org/stable/40800024?seq=1#metadata_info_tab_contents> accessed 3 February 2020
- Kastriner LG, 'The Revival of Confidence in the Patent System' (1991) 73(1) Journal of Patents and Trademark Office Society 5
- Kearns AP, 'The Right to Food Exists Via Customary International Law' (1998) 22 Suffolk Transitional Law Review 223
- Kim HC, 'Burden of Proof and the Prima Facie Case: The Evolving History and its Applications in the WTO Jurisprudence' (2007) 6(3) Richmond Journal of Global Law & Business 245
- Kinsella NS, 'Against Intellectual Property' (2001) 15(2) Journal of Libertarian Studies 1
- Kitch EW, 'The Nature and Function of the Patent System' (1977) 20(2) Journal of Law and Economics 265
- Klein DF, 'A Theory for the Application of the Customary International Law of Human Rights by Domestic Courts' (1988) 13(2) Yale Journal of International Law 332
- Kobak JB, Jr, 'The Misuse Defense and Intellectual Property Litigation' (1995) 1 Boston University Journal of Science and Technology Law < http://www.bu.edu/law/journals-archive/scitech/volume1/kobak.pdf> accessed 26 July 2019

- Koch IE, 'Social Rights as Components in the Civil Right to Personal Liberty: Another Possible Step forward in the Integrated Human Rights Approach?' (2002) 20(1) Netherlands Quarterly of Human rights 29
- Koh HH, 'How Is International Human Rights Law Enforced?' (1999) 74(4) Indiana Law Journal 1397
- Koji T, 'Emerging Hierarchy in International Human Rights and Beyond: From the Perspective of Non-Derogable Rights' (2001) 12(5) European Journal of International Law 917
- Kongolo T, 'TRIPS, the Doha Declaration and Public Health' (2003) 6(2) Journal of World Intellectual property 373
- Koskenniemi M and Leino P, 'Fragmentation of International Law? Postmodern Anxieties' (2002) 15(3) Leiden Journal of International Law 553
- Kuyper PJ, 'The Law of GATT as a Special Field of International Law: Ignorance, Further Refinement or Self-Contained System of International Law' (1994) 25 Netherlands Yearbook of International Law 227
- Lamy P, 'The Place of the WTO and its Law in the International Legal Order' (2007) 17(5) The European Journal of International Law 969
- Lamy P, 'Trade-Related Aspects of Intellectual Property Rights: Ten Years Later' (2004) 38(6) Journal of World Trade 923
- Landes WM and Posner RA, 'An Economic Analysis of Copyright Law' (1989) 18 (2) The Journal of Legal Studies 325
- Lanjouw JO and Cockburn IM, 'New Pills for Poor People? Empirical Evidence after GATT' (2001) 29(2) World Development Journal 265
- Lavranos N, 'Regulating Competing Jurisdictions Among International Courts and Tribunals' (2008) 68 Heidelberg Journal of International Law 575
- Leben C, 'The Changing Structure of International Law Revisited' (1997) 8(3) European Journal of International Law 399

- Lee LL, 'Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India' (2008) 23(1) Berkeley Technology Law Journal 281
- Leebron DW, 'Linkages' (2002) 96(1) American Journal of International Law 5
- Leis M, 'Death by Treaty: South Africa's Medicines and Related Substances Amendment Act of 1997 and the Agreement on Trade Related Aspects of Intellectual Property Rights' (2004) 3(1) Journal of International Business and Law 221
- Leisinger KM, 'Corporate Responsibilities for Access to Medicines' (2009) 85 Journal of Business Ethics 3
- Lennard M, 'Navigating by the Stars: Interpreting the WTO Agreements' (2002) 5(1) Journal of International Economic Law 17
- Lindroos A and Mehling M, 'Dispelling the Chimera of Self-Contained Regimes International Law and the WTO' (2006) 16(5) The European Journal of International Law 857
- Lumina C, 'Free Trade or Just Trade? The World Trade Organisation, Human Rights and Development' Pt 2 (2010) 14 African Journal Online <https://repository.up.ac.za/bitstream/handle/2263/16145/Lumina_Free(2010).pdf?sequence=1> accessed 30 May 2019
- Machlup F and Penrose E, 'The Patent Controversy in the Nineteenth Century' (1950) 10(1) Journal of Economic History 1
- MacLeod C et al, 'Evaluating Inventive Activity: The Cost of Nineteenth-Century UK Patents and the Fallibility of Renewal Data' (2003) 3 Economic History Review 537
- Mancilla A, 'A Can of Tomato Juice in the Sea' (2015) 107 Philosophy Now Magazine <https://philosophynow.org/issues/107/A_Can_of_Tomato_Juice_in_the_Sea> accessed 17 February 2019
- Mahncke H, 'Sovereignty and Developing Countries: Current Status and Future Prospects at the WTO' (2009) 22(2) Leiden Journal of International Law 395
- Mansoor F, 'The WTO Versus the ILO and The Case of Child Labour' (2004) 2 Web Journal of Current Legal Issues <

https://www.peacepalacelibrary.nl/ebooks/files/WEBJCLI_MANSOOR_WTO-versus-the-ILO.pdf> accessed 25 March 2020

- Marc P, 'Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?' (2001) 21 New York Law School Journal of International and Comparative Law 109
- Marceau G, 'Conflicts of Norms and Conflicts of Jurisdictions: The Relationship Between the WTO Agreement and MEAs and Other Treaties' (2001) 35(6) Journal of World Trade 1081
- Marceau G, 'WTO Dispute Settlement and Human Rights' (2002) 13(4) European Journal of International Law 753
- Marceua G, 'A call for Coherence in International Law - Praises for the Prohibition Against "Clinical Isolation" in WTO Dispute Settlement' (1999) 33(5) Journal of World Trade 87
- Matthews D, 'TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements' (2005) 27(11) European Intellectual Property Review 420
- Matthews D, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) 7(1) Journal of International Economic Law 73
- May C, 'Why IPRs are a Global Political Issue' (2003) 25(1) European Intellectual Property Review 1
- Mazzoleni R and Nelson RR, 'The Benefits and Costs of Strong patent Protection: A Contribution to the Current Debate' (1998) 27(3) Research policy Journal 273
- Mclachlan C, 'The Principle of Systemic Integration and Article 31/3(c)' (2005) 54(2) International and Comparative law Quarterly 279
- McRae DM, 'The Contribution of International Trade Law to the Development of International Law' (1996) 260 Collected Courses of the Hague Academy of

International Law 99 < https://referenceworks.brillonline.com/entries/the-hague-academy-collected-courses/*A9789041105172_02#A9789041105172_02-106>

- McRae DM, 'The WTO in International Law: Tradition Continued or New Frontier?' (2000) 3(27) Journal of International Economic Law 27
- Meltzer J, 'Interpreting the WTO Agreements – A Commentary on Professor pauwelyn's Approach' (2004) 25(4) Michigan Journal of International law 917
- Menshawy IS, 'Unilateral Acts and Premptory Norms (*Jus Cogens*) in the International Law Commission's Work' (2019) 4(3) Review of Economics and Political Science 182
- Mercurio BC, 'TRIPS, Patents and Access to Life-Saving Drugs in the Developing World' (2004) 8(2) Marquette Intellectual Property Law Review 211
- Merges RP and Nelson RR, 'On the Complex Economics of Patent Scope' (1990) 90(4) Colombia Law Review 839
- Miller ST, 'The Case of Monopolies-Some of its Results and Suggestions' (1907) 6(1) Michigan Law Review 1
- Millum J, 'Are Pharmaceutical Patents Protected by Human Rights?' (2008) 34(11) Journal of Medical Ethics < https://www.researchgate.net/publication/23441979_Are_Pharmaceutical_Patents_Protected_By_Human_Rights> accessed 5 December 2019
- Mitchell AD and Salonidis C, 'David's Sling: Cross-Agreement Retaliation in International Trade Disputes' (2011) 45(2) Journal of World Trade 457
- Moon S, 'Respecting the right to access to medicines: Implications of the UN Guiding Principles on Business and Human Rights for the pharmaceutical industry' (2013) 15(1) Health and Human Rights Journal 32
- Moore AD, 'A Lockean Theory of Intellectual property Revisited' (2012) 49 San Diego Law Review 1069
- Moore AD, 'Intellectual Property, Innovation and Social Progress: The Case Against Incentive Based Arguments' (2003) 26(3) Hamline Law Review 602

- Mus JB, ‘Conflict Between treaties in International Law’ (1998) 45(2) Netherlands International Law Review 208
- Muzaka B, ‘Developing Countries and the Struggle on the Access to Medicines Front: Victories Won and Lost’ (2009) 30(7) Third World Quarterly 1343
- Narula S, ‘The Right to Food: Holding Global Actors Accountable Under International Law’ (2006) 44(3) Columbia Journal of Transnational Law 691
- Nussbaum MC, ‘Capabilities and Human Rights’ (1997) 66(2) Fordham Law Review 273
- OseiTutu IJ, ‘Traditional Knowledge: Is Perpetual Protection a Good Idea?’ (2010) 50(4) Intellectual Property Law Review 697
- Ozawa S et al, ‘Access to Medicines Through Health Systems in Low- and Middle-Income Countries’ (2019) 34 issue supp_3 Health Policy and System Research Journal iii1
- Paas K, ‘Compulsory licensing under the TRIPs Agreement: A Cruel Taunt for Developing Countries?’ (2009) 31(12) European Intellectual Property Review 609
- Palmeter D and Mavroidis PC, ‘The WTO Legal System: Sources of Law’ (1998) 92(3) American Journal of International Law 398
- Park RS, ‘The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients’ (2002) 11(1) Minnesota Journal of Global Trade 125
- Pauwelyn J, ‘Enforcement and Countermeasures in the WTO: Rules are Rules-Toward a More Collective Approach’ (2000) 94(2) American Journal of International Law 335
- Pauwelyn J, ‘The Role of Public international Law in the WTO: How Far Can We GO?’ (2001) 95(3) The American Journal of International law 535
- Penrose E, ‘International Patenting and the Less-Developed Countries’ (1973) 83(331) The Economic Journal 768
- Perehudoff SK, Toebes B, and Hogerzeil H, ‘Essential Medicines in National Constitutions Progress Since 2008’ (2016) 18(1) Health and Human Rights Journal 141

- Petersmann EU, 'From Negative to positive Integration in the WTO: Time for Mainstreaming Human Rights into WTO Law' (2000) 37 Common Market Law Reports 1363
- Petersmann EU, 'Human Rights and International Economic Law in the 21st Century: The Need to Clarify Their Interrelationships' (2001) 4(1) Journal of International Economic Law 3
- Petersmann EU, 'Human Rights and the Law of the World Trade Organization' (2003) 37(2) Journal of World Trade 241
- Petersmann EU, 'Time for a United Nations 'Global Compact' for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration' (2002) 13(3) European Journal of International Law 621
- Pogge T, 'Human Rights and Global Health' (2005) 36 Meta philosophy LLC and Blackwell Publishing Ltd 182
- Pogge T, 'Montreal Statement on the Human Right to Essential Medicines' (2007) 16(1) Cambridge Quarterly of Healthcare Ethics 97
- Prost M, 'Hierarchy and the Sources of International Law: A Critique' (2017) 39 Houston Journal of International Law 285
- Przetacznik F, 'The Right to Life as a Basic Human Right' (1976) 9 Human Rights Journal 585
- Rachovista A, 'The Principle of Systemic Integration in Human Rights Law' (2017) 66 International and Comparative Law Quarterly 557
- Rafiquzzaman R, 'The Optimal Patent Term under Uncertainty' (1987) 5(2) International Journal of Industrial Organization 233
- Ramcharan BG, 'The Legal Status of the International Bill of Human Rights' (1986) 55(4) Nordic Journal of International Law 366
- Ramcharan BG, 'The Right to Life' (1983) 30(3) Netherlands International Law Review 297

- Ratner SR, 'Corporations and Human Rights: A Theory of Legal Responsibility' (2001) 111 Yale Law Journal 443
- Regnier S, 'What is the Value of 'Me-Too' Drugs?' (2013) 16(4) Health Care Management Science Journal 300
- Reichman JH, 'Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection' (1989) 22 Vanderbilt Journal of Transnational Law 747
- Roberts AE, 'Traditional and Modern Approaches to Customary International Law: A Reconciliation' (2001) 95(4) American Journal of International Law 757
- Sands P, 'Turtles and Torturers: The Transformation of International Law' (2001) 33 New York University Journal of International Law and Politics 527
- Schoenbaum TJ, 'WTO Dispute Settlement: Praise and Suggestions for Reform' (1998) 47(3) International and Comparative law Quarterly 647
- Schott JJ, 'Comment on the Doha Ministerial' (2002) 5(1) Journal of International Economic Law 191
- Scotchmer S, 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law" (1991) 5(1) The Journal of Economic Perspectives 29
- Sell SK, 'Intellectual Property as a Trade Issue: From the Paris Convention to GATT' (1989) 13(4) Legal Studies Forum Journal 407
- Sellin JA, 'Does One Size Fit All' Patents, the Right to Health and Access to Medicines' (2015) 62 Netherlands International Law Review 445
- Shanker D, 'The Vienna Convention on the Law of Treaties: The Dispute Settlement System of the WTO and the Doha Declaration on the TRIPS Agreement' (2002) 36(4) Journal of World Trade 721
- Sharma VK et al, 'An Engrossing History of Azidothymidine' (2015) 15(2) Immunology, Endocrine & Metabolic Agents in Medicinal Chemistry Journal < https://www.academia.edu/16198897/engrossing_history_of_azidothymidine > accessed 27 February 2021

- Shelton D, 'Normative Hierarchy in International law' (2006) 100(2) American Journal of International Law 291
- Shelvin C, 'The Difficulties in Finding a Single Theory to Fully Justify Copyright' (2015) 3 North East Law Review 49
- Simma B and Alston P, 'The Sources of Human Rights law: Custom, Jus Cogens and General Principles' (1992) 12 Australian Yearbook of International Law 82
- Simma B and Pulkowski D, 'Of Planets and the Universe: Self-Contained Regimes in International Law' (2006) 17(3) The European Journal of International Law 483
- Simma B, 'Self-Contained Regimes' (1985) 16 Netherlands Yearbook of International Law 111
- Singh A and DasGupta P, 'Pharmaceutical Test Data Protection and Demands for Data-Exclusivity: Issues and Concerns of Developing Countries and India's Position' (2019) 24 Journal of Intellectual Property Rights 69
- Slotboom MM, 'The Exhaustion of Intellectual Property Rights: Different Approaches in EC and WTO' (2003) 6(3) World Intellectual Property Journal 421
- Smith GP, 'Human Rights and Bioethics: Formulating a Universal Right to Health, Health Care or Health Protection?' (2005) 38(5) Vanderbilt Journal of Transnational Law 1295
- Solovy EM and Krishnamurthy PS, 'TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines' (2017) 50(1) George Washington International Law Review 69
- Spelliscy S, 'The proliferation of International Tribunals: A Chink in the Armor' (2001) 40 Colombia Journal of Transnational Law 143
- Sterio M, 'The Evolution of International Law' (2008) 31(2) Boston Collage International and Comparative Law Review 213
- Sykes AO, 'TRIPs, Pharmaceuticals, Developing Countries, and the Doha Solution' (2002) 3(1) Chicago Journal of international Law 47

- Teson F, 'The Kantian Theory of International Law' (1992) 92(1) Columbia Law Review 53
- Trachtman JP, 'The Domain of WTO Dispute Resolution' (1999) 40(2) Harvard International Law Journal 333
- Trispiotis I, 'Socio-Economic Rights: Legally Enforceable or Just Aspirational?' (2010) 8 Opticon 1826 UCL Journal < http://www.ucl.ac.uk/opticon1826/archive/issue8/articles/Article_Laws_-_Ilias__Social_equality__Publish_.pdf > accessed 28 September 2019
- Ur Rehman HA, 'WTO, Compulsory Export Licenses and Indian Patent Law' (2011) 1 Nordic Journal of Commercial Law 1
- Vaitsos C, 'Patents Revisited: Their Function in Developing Countries' (1972) 9(1) The Journal of Development Studies 71
- Van Doorslaer E et al, 'Catastrophic Payments for Health Care in Asia' (2007) 16 Health Economics 1159
- Vandoren P and Van Eeckhaute JC, 'The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making it Work' (2003) 6(6) Journal of World Intellectual Property 779
- Vawda YA and Baker BK, 'Achieving Social Justice in the Human Rights/Intellectual Property Debate: Realizing the Goal of Access to Medicines' (2013) 13 African Human Rights Law Journal 55
- Vázquez CM, 'Trade Sanctions and Human Rights: Past, Present, and Future' (2003) 6(4) Journal of International Economic Law 797
- Vierdag EW, 'The Legal Nature of the Rights Granted by the International Covenant on Economic, Social and Cultural Rights' (1978) 9 Netherlands Yearbook of International Law 69
- Villalpando S, 'The Legal Dimension of the International Community: How Community Interests are Protected in International Law' (2010) 21(2) The European Journal of International Law 387

- Vranes E, 'The Definition of 'Norm Conflict' in International Law and Legal Theory' (2006) 17(2) The European Journal of International Law 395
- Waldock H, 'Human Rights in Contemporary International Law and the Significance of the European Convention' (1965) 11 The British Institute of International and Comparative Law Quarterly Supplementary Publication 1
- Walterscheid EC, 'Early Evolution of the United States Patent Law: Antecedents' Pt 1 (1994) 76(9) Journal of the Patent and Trademark office Society 697
- Walterscheid EC, 'Early Evolution of the United States Patent Law: Antecedents' Pt 4 (1996) 78(2) Journal of the Patent and Trademark Office Society 77
- Walterscheid EC, 'Early Evolution of the United States Patent Law: Antecedents' Pt 2 (1994) 76(11) Journal of the Patent and Trademark Office Society 849
- Weissman R, 'A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rule, and the Remaining WTO Legal Alternatives Available to Third World Countries' (1996) 17 University of Pennsylvania Journal of International Economic Law 1069
- Wirtz VJ et al, 'Access to medications for Cardiovascular Diseases in Low- and Middle-Income Countries' (2016) 133(21) Circulation 2076
- Wojahn PL, 'A Conflict of Rights: Intellectual Property under TRIPS, the Right to Health and AIDS Drugs' (2001-2002) 6(2) UCLA Journal of International Law and Foreign Affairs 463
- Yamin AE, 'Not Just a Tragedy: Access to Medications as a Right Under International Law' (2003) 21(2) Boston University International Law Journal 325
- Yigzaw DA, 'Hierarchy of Norms: The Case for the Primacy of Human Rights Over WTO Law' (2015) 38(1) Suffolk Transnational Law Review 33
- Young KG, 'Freedom, Want, and Economic and Social Rights: Frame and Law' (2009) 24(1) Maryland Journal of International Law 182
- Young M, 'The WTO's Use of Relevant Rules of International Law: An Analysis of the Biotech case' (2007) 56(4) International and Comparative Law Quarterly 907

- Yu PK, 'Reconceptualizing Intellectual property Interests in a Human Rights Framework' (2007) 40 University of California Davis Law Review 1039
- Yu PK, 'Ten Common Questions about Intellectual Property and Human Rights' (2007) 23(4) Georgia State University Law Review 709
- Yu PK, 'TRIPS and its Achilles' Heel' (2011) 18 Journal of Intellectual property Law 479


**Documents and Reports**

ILC


- International law Commission, 'First Report on Subsequent Agreements and Subsequent practice in Relation to the Interpretation of Treaties, by Georg Nolte, Special Rapporteur' (19 March 2013) UN Doc A/CN.4/660
- International Law Commission, 'Preliminary Report by Martti Koskenniemi on the Study of the Function and Scope of the *Lex Specialis* Rule and the Question of Self-Contained Regimes' (4 May 2004) UN Doc ILC(LVI)/SG/FIL/CRD.1/Add.1
- International law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (13 April 2006) UN Doc A/CN.4/L.682
- International Law Commission, 'Report of the Study Group of the International Law Commission on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (18 July 2006) UN Doc A/CN.4/L.702
- International Law Commission, 'Text Adopted by the Commission at its Fifty-Third Session Concerning the Responsibility of States for Internationally Wrongful Acts' (2001)
- International Law Commission, 'The Third Report on State Responsibility by Mr. James Crawford, Special Rapporteur' (15 March 2000) UN Doc A/CN.4/507

UN


- Human Rights Council, ‘Report of the Special Rapporteur Anand Groover on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights Including the Right to Development’ (31 March 2009) UN Doc A/HRC/11/12

- Human Rights Council, ‘Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Promotion and Protection of all Human Rights, Civil, political, Economic, Social and Cultural Rights’ (31 January 2008) UN Doc A/HRC/7/11

- Human Rights Council, ‘Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, John Ruggie: Protect, Respect and Remedy: A Framework for Business and Human Rights’ (7 April 2008) UN Doc A/HRC/8/5

- Human Rights Council, ‘Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, John Ruggie: Guiding Principles on Business and Human Rights: Implementing the United Nations “Protect, Respect and Remedy” Framework’ (21 March 2011) UN Doc A/HRC/17/31

- Office of the High Commissioner for Human Rights, ‘General Comment No 24: Issues Relating to Reservations Made Upon Ratification or Accession to the Covenant or the Optional Protocols Thereto, or in Relation to Declarations Under Article 41 of the Covenant’ (4 November 1994) UN Doc CCPR/C/21/Rev.1/Add.6

- UN Commission on Human Rights, ‘Comments from Governments on the Draft International Declaration on Human Rights, Draft International Covenant on Human Rights and the Question of Implementation’ (27 April 1948) UN Doc E/CN.4/82/Add.4

- UN Commission on Human Rights, ‘Report of the Secretary-General on Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria’ (3 December 2004) UN Doc E/CN.4/2005/38

- UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Addendum Mission to the World Trade Organization' (1 March 2004) UN Doc E/CN.4/2004/49/Add.1
- UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (11 February 2005) UN Doc E/CN.4/2005/51
- UN Commission on Human Rights, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Addendum Mission to Uganda' (19 January 2006) UN Doc E/CN.4/2006/48/Add.2
- UN Commission on Human Rights, 'Report of the Special Rapporteur, Paul Hunt, on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of physical and Mental Health, Submitted in Accordance with Commission Resolution 2002/31' (13 February 2003) UN Doc E/CN.4/2003/58
- UN Commission on Human Rights, 'Report on the Human Rights Situation in the Islamic Republic of Iran by the Special Representative of the Commission, Mr. Reynaldo Galindo Pohi, Appointed Pursuant to Resolution 1986/41' (28 January 1987) UN Doc E/CN.4/1987/23
- UN Commission on Human Rights, 'Report on Non-Discrimination in the Field of Health' (2 March 1989) UN Doc E/CN.4/RES/1989/11
- UN Committee on Economic, Social and Cultural Rights (CESCR), 'General Comment No 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He or She is the Author (Article 15, paragraph 1(c) of the Covenant)' (12 January 2006) UN Doc E/C.12/GC/17
- UN Committee on Economic, Social and Cultural Rights (CESCR), 'Statement of the Committee on the Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: Follow-Up to the Day of General Discussion on Article 15 (1) (c)' (14 December 2001) UN Doc E/C.12/2001/15

- UN Committee on Economic, Social and Cultural Rights, 'General Comment No 3: The Nature of States Parties' Obligations (Article 2, Paragraph 1 of the Covenant)' (14 December 1990) UN Doc E/1991/23
- UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant)' (11 August 2000) UN Doc E/C.12/2000/4
- UN Committee on the Rights of the Child, 'Concluding Observations of the Committee on the Rights of the Child: Côte d'Ivoire' (9 July 2001) UN Doc CRC/C/15/Add.155
- UN General Assembly, '77th Plenary Meeting' (22 December 2003) UN Doc A/58/PV.77
- UN General Assembly, 'Report of the Economic and Social Council on the Protection of Human Rights in Chile' (4 November 1982) UN Doc A/37/564
- UN General Assembly, 'Report of the International Law Commission on the Work of its Seventieth Session' (2018) UN Doc A/73/10
- UN General Assembly, 'Report of the International Law Commission on the Work of its Seventy-First Session' (2019) UN Doc A/74/10
- UN General Assembly, 'Report of the International Law Commission to the General Assembly on the Work of its Fifty-Eighth Session' (2006) UN Doc A/61/10
- UN General Assembly, 'Report of the International Law Commission on the Work of its Fifty-Sixth Session' (2004) UN Doc A/59/10
- UN General Assembly, 'Report of the Secretary-General on Reinvigorating the AIDS Response to Catalyse Sustainable Development and United Nations Reform' (7 April 2017) UN Doc A/71/864
- UN General Assembly, 'Report of the Special Rapporteur Paul Hunt on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (13 September 2006) UN Doc A/61/338
- UN General Assembly, 'The Right to Health: Note by the Secretary-General in the Sixty-Third Session of the General Assembly' (11 August 2008) UN Doc A/63/263

- UN General Assembly, 'Yearbook of the International Law Commission 2001 Vol II Part 2: Report of the Commission to the General Assembly on the Work of its Fifty-Third Session' (2007) UN Doc A/CN.4/SER.A/2001/Add.1(Part 2)
- UN General Assembly, 'Yearbook of the International Law Commission 1950 Vol II: Documents of the Second Session Including the Report of the Commission to the General Assembly' (1957) UN Doc A/CN. 4/SER.A/1950/Add. 1
- UN General Assembly, 'Yearbook of the International Law Commission 1958 Vol II: Documents of the Tenth Session Including the Report of the Commission to the General Assembly' (1958) UN Doc A/CN.4/SER.A/1958/Add.l
- UN General Assembly, 'Yearbook of the International Law Commission 1957 Vol II: Documents of the Ninth Session Including the Report of the Commission to the General Assembly' (1958) UN Doc A/CN.4/SER.A/1957/Add.l
- UN General Assembly, 'Yearbook of the International Law Commission 1964 Vol I: Summary Records of the Sixteenth Session' (1965) UN Doc A/CN.4/SER.A/1964
- UN General Assembly, 'Yearbook of the International Law Commission 1966 Vol II: Documents of the Second Part of the Seventeenth Session and of the Eighteenth Session Including the Reports of the Commission to the General Assembly' (1967) UN Doc A/CN. 4/SER.A/1966/Add. 1
- UN General Assembly, 'Yearbook of the International Law Commission 1966 Vol I Part II: Summary Records of the Eighteenth Session' (1967) UN Doc A/CN. 4/SER.A/1966
- UN Human Rights Committee, 'General Comment No 6: Right to Life (Article 6 of the ICCPR)' (30 April 1982) UN Doc HRI/GEN/1/Rev.1
- UN Sub-Commission on the Promotion and Protection of Human Rights, 'Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights' (27 June 2001) UN Doc E/CN.4/Sub.2/2001/13

- UN Sub-Commission on the Promotion and Protection of Human Rights, 'Report of the Secretary-General on Intellectual Property Rights and Human Rights' (14 June 2001) UN Doc E/CN.4/Sub.2/2001/12
- UN Sub-Commission on the Promotion and Protection of Human Rights, 'Report of the Secretary-General on Intellectual Property Rights and Human Rights. Addendum' (3 July 2001) UN Doc E/CN.4/Sub.2/2001/12/ Add.1
- UN Sub-Commission on the Promotion and Protection of Human Rights, 'Globalization and its Impact on the Full Enjoyment of Human Rights: Preliminary Report Submitted by J. Oloka-Onyango and Deepika Udagama, in Accordance with Sub-Commission Resolution 1999/8' (15 June 2000) UN Doc E/CN.4/Sub.2/2000/13

WHO

- 'Sustainable Development Goals: Goal 3. Target 3.8 (WHO, 2016) < https://apps.who.int/iris/handle/10665/208286 > accessed 11 December 2020
- Hogerzeil HV and Mirza Z, 'The World Medicines Situation 2011: Access to Essential Medicines as Part of the Right To Health' (WHO, 2011) WHO Doc WHO/EMP/MIE/2011.2.10 < http://digicollection.org/hss/documents/s18772en/s18772en.pdf> accessed 17 October 2019
- WHO, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health/ Carlos M. Correa' (June 2002) WHO Doc WHO/EDM/PAR/2002.3

WTO

- Council for TRIPS, 'Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation' (11 July 2002) WTO Doc IP/C/W/363
- Developing Country Group, 'TRIPS and Public Health Paper submitted to the TRIPS Council for the Special Discussion on Intellectual Property and Access to Medicines' (19 June 2001) WTO Doc IP/C/W/296 < https://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm > accessed 17 April 2019

- Sutherland P et al, 'Report of the WTO Consultative Board on the Future of the WTO: Addressing Institutional Challenges in the New Millennium' (2004) < https://www.wto.org/english/thewto_e/10anniv_e/future_wto_e.pdf> accessed 16 January 2020
- WTO Committee on Trade and Environment, 'Cluster on Market Access. Item 8: The Relationship of the TRIPS Agreement to the Development, Access and Transfer of Environmentally-Sound Technologies and Products (EST&PS). Input From India' (29 September 1997) WTO Doc WT/CTE/W/66
- WTO TRPS Council, 'Remarks on Revocation of patents and the TRIPS Agreement by the United States of America' (6 August 1996) WTO Doc IP/C/W/32
- WTO TRIPS Council, Communication from India and South Africa for Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 (2 October 2020) WTO Doc IP/C/W/669
- WTO TRIPS Council, Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic: Communication from the European Union to the Council for TRIPS (18 June 2021) WTO Doc IP/C/W/681
- WTO TRIPS Council, Urgent Trade Policy Responses to the COVID-19 Crises: Intellectual Property: Communication from the European Union to the Council for TRIPS (4 June 2021) WTO Doc IP/C/W/680
- WTO TRIPS Council, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of COVID-19 – Responses to Questions (15 January 2021) WTO Doc IP/C/W/672
- WTO TRIPS Council, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text (25 May 2021) WTO Doc IP/C/W/669/Rev.1

Press Releases

- WTO, 'Members OK Amendment to Make Health Flexibility Permanent' (6 December 2005) Press/426 < https://www.wto.org/english/news_e/pres05_e/pr426_e.htm> accessed 5 March 2020

Other Documents and Reports


- Commission on Intellectual Property Rights, 'Report of the Commission on Integrating Intellectual Property Rights and Development Policy' (Commission on Intellectual Property Rights, September 2002) < http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf>

- European Commission, 'Competition: Commission Fines AstraZeneca €60 Million for Misusing Patent System to Delay Market Entry of Competing Generic Drugs' (15 June 2005) IP/05/737

- European Commission, 'Pharmaceutical Sector Inquiry: Final Report' (8 July 2009) < https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf > accessed 23 September 2021

- European Commission, 'Executive Summary of the Pharmaceutical Sector Inquiry Report' (8 July 2009) < https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf> accessed 23 September 2021.

- International Commission of Jurists, 'Maastricht Guidelines on Violations of Economic, Social and Cultural Rights' (26 January 1997) < http://hrlibrary.umn.edu/instree/Maastrichtguidelines_.html> accessed 13 October 2019

- Japan Patent Office, 'Examination Guidelines for Patent and Utility Model in Japan' (10 March 2020) < https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/index.html> accessed 27 September 2021

- Negotiating Group on TRIPS, Including Trade in Counterfeit Goods, 'Draft Agreement on TRIPS: Communication from the United States' (11 May 1990) MTN.GNG/NG11/W/70

- Negotiating Group on TRIPS, Including Trade in Counterfeit Goods, 'Existence, Scope, and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual property: Note Prepared by the International Bureau of WIPO' (5 May 1988) MTN.GNG/NG11/W/24
- Negotiating Group on TRIPS, Including Trade in Counterfeit Goods, 'Meeting of Negotiating Group of 11, 12, and 14 December 1989' (23 January 1990) MTN.GNG/NG11/17
- Negotiating Group on TRIPS, Including Trade in Counterfeit Goods, 'Secretariat Note on the Meeting of 25 March 1987' (10 April 1987) MTN.GNG/NG11/1
- Negotiating Group on TRIPS, Including Trade in Counterfeit Goods, 'Suggestion by the US for Achieving the Negotiating Objective' (17 October 1988) MTN.GNG/NG11/W/14/Rev.1
- UN Millennium Development Goal, 'Goal 6: Combat HIV/AIDS, Malaria and other Diseases' (UN, 2015) < https://www.un.org/millenniumgoals/aids.shtml> accessed 27 November 2019
- UN Secretary-General's High-Level Panel on Access to Medicines, 'Report on Promoting Innovation and Access to Health Technologies' (September 2016) < http://www.unsgaccessmeds.org/final-report> accessed 12 December 2019
- WTO, 'TRIPS and Pharmaceutical Patents' (September 2006) WTO Fact Sheet < https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf > accessed 13 October 2019


**Conference, Research and Working Papers**


- Abbot FM, 'The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements' (27 December 2011) Quaker UN Office (Geneva) (QUNO), Occasional Paper No 14, April 2004 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1977300> accessed 27 June 2019
- Abbott FM, 'Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO After the Doha Declaration on Public Health' (February 2002) Quaker UN

Office Geneva Occasional Paper No 9 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1977304 > accessed 19 February 2020

- Abbott FM, 'WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries' (2002) UK Commission on Intellectual property Rights Study Paper 2a < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1924420> accessed 25 May 2019

- Correa CM, 'Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective' (June 2016) UNDP Working Paper <https://www.researchgate.net/publication/304396604_Carlos_Correa_Guidelines_for_Pharmaceutical_Patent_Examination_Examining_Pharmaceutical_Patents_from_a_Public_Health_Perspective_UNDP_New_York_2016 > accessed 13 March 2021

- Correa CM, 'Guidelines for the examination of pharmaceutical patents: Developing a Public Health Perspective' (January 2007) WHO- ICTSD- UNCTAD Working Paper < https://www.researchgate.net/publication/23777563_Guidelines_for_the_Examination_of_Pharmaceutical_Patents_Developing_a_Public_Health_Perspective > accessed 16 February 2019

- Correa CM, 'Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries' (October 1999) South Centre Working Paper No 5 < http://www.iatp.org/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf > accessed 1 August 2019

- Correa CM, 'Some Assumptions on Patent Law and Pharmaceutical R&D' (June 2001) Quaker UN Office Geneva Occasional Paper 6 < https://quno.org/sites/default/files/resources/PatentLaw-R-D.pdf> accessed 23 February 2020

- Correa CM, 'Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?' (January 2019) South Centre Policy Brief No 57 < https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-

Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf> accessed 12 April 2020

- Dimitrijevic V, 'Customary law as an Instrument for the Protection of human Rights' (2006) ISPI Working Paper-7 < https://www.ispionline.it/sites/default/files/pubblicazioni/wp_7_2006_0.pdf > accessed 17 September 2019

- Ducimetière C, 'Second Medical Use Patents - Legal Treatment and Public Health Issues' (December 2019) South Centre Research paper No 101 < https://www.southcentre.int/wp-content/uploads/2019/12/RP101_Second-Medical-Use-Patents-Legal-Treatment-and-Public-Health-Issues_EN.pdf > accessed 12 August 2020

- Gervais DJ, 'TRIPS and Development' (28 August 2013) Vanderbilt Public law Research paper No 13-46 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2313836 > accessed 20 September 2020

- Gervais DJ, 'TRIPS and Development' (28 August 2013) Vanderbilt Public law Research paper No 13-46 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2313836 > accessed 20 September 2020

- Gurgula O, 'The 'Obvious to Try' Method of Addressing Strategic Patenting: How Developing Countries Can Utilise Patent Law to Facilitate Access to Medicines' (April 2019) South Centre Policy Brief No 59 < https://www.southcentre.int/wp-content/uploads/2019/04/PB59_The-obvious-to-try-method-of-addressing-strategic-patenting_EN.pdf > accessed 29 January 2021

- Hunt P et al, 'Neglected Diseases: A Human Rights Analysis' (2007) Special Topics in Social, Economic and Behavioural Research Report Series No 6, 34 < https://www.who.int/tdr/publications/documents/seb_topic6.pdf?ua=1> accessed 8 November 2019

- International Law Association, 'Report of the Sixty-Sixth Conference Held at Buenos Aires, Argentina' (14 to 20 August 1994)

- Kingsbury B and Donaldson M, 'From Bilateralism to Publicness in International Law' (January 2011) New York University School of Law, Public Law Research Paper No 11-07, 79 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1753063> accessed 18 December 2019

- Lanjouw JO, 'The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?' (1998) National Bureau of Economic Research Working Paper 6366 < http://www.dklevine.com/archive/lanjouw.pdf > accessed 15 April 2019

- Médecins Sans Frontières, 'Neither Expeditious nor a Solution: The WTO August 30th Decision is Unworkable' (XVI International AIDS Conference, Toronto, August 2006) < https://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_NeitherExpeditiousNorSolution_WTO_ENG_2006.pdf > accessed 15 August 2019

- Moon S, 'Implementation of the Doha Declaration on the TRIPS Agreement and public Health: Technical Assistance-How To Get it Right' (WIPO Conference on the International Patent System, International Conference Centre of Geneva, 28th March 2002) < https://oxfamilibrary.openrepository.com/bitstream/handle/10546/112363/implementation-doha-trips-agreement-public-health-280302-en.pdf;jsessionid=5A32CCCFD04C39083FD44FCD9891B7B5?sequence=1> accessed 10 January 2020

- Oxford Committee for Famine Relief (OXFAM), 'All costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines' (March 2007) Oxfam Briefing Paper < https://oxfamilibrary.openrepository.com/bitstream/handle/10546/114080/bp102-all-costs-no-benefits-trips-210307-en.pdf?sequence=1> accessed 5 May 2019

- Pauwelyn J, 'The nature of WTO Obligations' (2002) Jean Monnet Working Paper 1/02 < https://jeanmonnetprogram.org/archive/papers/02/020101.html> accessed 19 February 2020

- Ramanna A, 'Interest Groups and Patent Reform in India' (2009) E-Social Sciences Working Paper < http://www.esocialsciences.org/Articles/Show_Article.aspx?qs=ebKFqzOKbXo7se0+tFTcFgB/Qg9lMx8H7EcQyowRRVZ0EY1ajlgLHXfAf4Wg4kc9uuQBP/T5nsVG2x4L7FxRuLEqqJOArmSgOS3R0iOGFX8=> accessed 24 April 2019

- StillWell M and Tuerk E, 'Towards a Full Review of the WTO'S TRIPS Agreement Under Article 71.1' (April 2001) Centre for International Environmental Law Research Paper < https://www.ciel.org/wp-content/uploads/2015/03/Assessment_Trips_article711.pdf> accessed 19 March 2019


**Workshop Reports**


- WTO, 'Report of Joint Workshop Convened by the WHO and WTO on Differential Pricing and Finance of Essential Drug' (Norwegian Ministry of Foreign Affairs 2001) < https://apps.who.int/iris/bitstream/handle/10665/66919/a73725.pdf;jsessionid=F1D621F73B4A1AC92FD530343331CC0F?sequence=1 > accessed 28 August 2019

- WHO and WTO, 'Report of the Workshop on Differential Pricing and Financing of Essential Drugs' (Høsbjør, Norway, 8-11 April 2001) < https://apps.who.int/iris/bitstream/handle/10665/66919/a73725.pdf?sequence=1&isAllowed=y > accessed 10 April 2021


**Theses**


- Beckett JA, 'The End of Customary International Law? A Purposive Analysis of Structural Indeterminacy' (PhD thesis, University of Glasgow 2005) < https://core.ac.uk/download/pdf/40081051.pdf> accessed 15 July 2020

- Zain Jaffery, 'The Exceptions to Patent Rights under the WTO-TRIPs Agreement: Is the Right to Health Denied?' (LL.M thesis, University of Nottingham 2008) < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2213216> accessed 18 September 2020

**Newspaper Articles**

- Myers SL, 'South Africa and U.S. End Dispute Over Drugs' (The New York Times, 18 September 1999) < https://www.nytimes.com/1999/09/18/world/south-africa-and-us-end-dispute-over-drugs.html> accessed 11 March 2019
- Petersen L and Pear R, 'A Nation Challenged: CIPRO; Anthrax Fears Send Demand for a Drug Far Beyond Output' (The new York Times, 16 October 2001) < https://www.nytimes.com/2001/10/16/business/a-nation-challenged-cipro-anthrax-fears-send-demand-for-a-drug-far-beyond-output.html?auth=login-google> accessed 2 April 2020

**Verbal Communication**

- James Bacchus, ' "Woulda, Coulda, Shoulda": The Consolations of WTO Dispute Settlement' (Speech to the International Bar Association, Geneva, 20 March 2003) < http://www.worldtradelaw.net/articles/bacchusconsolation.pdf.download> accessed 17 June 2020

**Websites**

- '10 March 2021: South Africa Raises the Banner for the TRIPS Waiver at the WTO' (Knowledge Ecology International, 11 March 2021) < https://www.keionline.org/35578 > accessed 3 April 2021
- 'Access to Medicines - A Fundamental Element of the Right to Health' (Office of the UN High Commissioner of Human Rights) < http://www.ohchr.org/EN/Issues/Development/Pages/AccessToMedicines.aspx > accessed 11 September 2019
- 'Amendment to WTO TRIPS Agreement Makes Access to Affordable Medicines Even More Bleak' (Médecins Sans Frontières, 6 December 2005) < https://www.msf.org/amendment-wto-trips-agreement-makes-access-affordable-medicines-even-more-bleak> accessed 2 March 2020

- ‘Changing Patterns of Pharmaceutical Innovation’ (EURACTIV, 29 January 2010) < https://www.euractiv.com/section/health-consumers/opinion/changing-patterns-of-pharmaceutical-innovation/ > accessed 12 July 2019
- ‘COVID-19 and World Trade’ (WTO) < https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm > accessed 10 February 2021
- ‘Development of Remdesivir’ (Gilead, 2020) < https://www.gilead.com/-/media/gilead-corporate/files/pdfs/covid-19/gilead_rdv-development-fact-sheet-2020.pdf> accessed 28 February 2021
- ‘Dispute Settlement’ (WTO) < https://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm#:~:text=The%20WTO%20has%20one%20of,350%20rulings%20have%20been%20issued> accessed 1 September 2020
- ‘Disputes by Agreements’ (WTO) < https://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A26> accessed 2 August 2020
- ‘Essential Medicines and Health Products’ (WHO) < https://www.who.int/medicines/services/essmedicines_def/en/ > accessed 19 October 2019
- ‘Essential Medicines’ (WHO) < http://www.who.int/topics/essential_medicines/en/ > accessed 19 October 2019
- ‘Global Health History: Origin and Development of Health Cooperation’ (WHO) < http://www.who.int/global_health_histories/background/en/ > accessed 20 September 2019
- ‘Global Pharmaceuticals Industry Analysis and Trends 2023’ (Report Linker, March 2019) < https://www.reportlinker.com/p05750669/Global-Pharmaceuticals-Industry-Analysis-and-Trends.html?utm_source=GNW> accessed 25 February 2020

- 'Historic Development of the WTO Dispute Settlement System' (WTO) < https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c2s1p1_e.htm#fnt2 > accessed 18 July 2020
- 'History of the Universal Declaration of Human Right' (UN) <https://www.un.org/en/about-us/udhr/history-of-the-declaration> accessed 15 September 2020
- 'International Covenant on Civil and Political Rights' (UN Treaty Collection, 12 May 2021) < https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-4&chapter=4&clang=_en> accessed 12 May 2021
- 'International Covenant on Economic, Social and Cultural Rights' (UN Treaty Collection, 12 May 2021) < https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-3&chapter=4&clang=_en> accessed 12 May 2021
- 'Mainstream Human Rights into Trade Agreements and WTO Practice – UN Expert Urges in New Report' (Office of the High Commissioner of Human Rights, 13 September 2016) < https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=20473&LangID=E> accessed 19 April 2020
- 'Make the Pledge to Share Your Intellectual Property in the Fight Against COVID' (Open COVID Pledge, 2020) < https://opencovidpledge.org/ > accessed 9 March 2021
- 'Members and Observers' (WTO) < https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm> accessed 1 July 2020
- 'Members Approach Text-Based Discussions for an Urgent IP Response to COVID-19' (WTO, 9 June 2021) < https://www.wto.org/english/news_e/news21_e/trip_09jun21_e.htm> accessed 6 September 2021

- ‘Members Discuss TRIPS Waiver Request, Exchange Views on IP Role Amid a Pandemic’ (WTO, 23 February 2021) < https://www.wto.org/english/news_e/news21_e/trip_23feb21_e.htm > accessed 17 March 2021
- ‘Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role for Small Business’ (WTO, 11 March 2021) < https://www.wto.org/english/news_e/news21_e/trip_11mar21_e.htm > accessed 3 April 2021
- ‘Modern Slavery and Child Labour: Asia’s Unacceptable Record’ (International Labour Organization, 16 November 2017) <https://www.ilo.org/asia/media-centre/news/WCMS_601896/lang--en/index.htm> accessed 18 March 2020
- ‘Optional Protocol to the International Covenant on Economic, Social and Cultural Rights’ (UN Treaty Collection, 12 May 2021) <https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3-a&chapter=4&clang=_en> accessed 12 May 2021
- ‘Over 5 Billion People Worldwide Lacking Access to Essential Medicines, Says UN Report’ (UN News, 3 March 2015) < https://news.un.org/en/story/2015/03/492482-over-5-billion-people-worldwide-lacking-access-essential-medicines-says-un> accessed 21 November 2020
- ‘Patentability Requirements’ (Justia, June 2019) < https://www.justia.com/intellectual-property/patents/patentability-requirements/> accessed 12 November 2020
- ‘Section 5: Background Information on the ICESCR’ (ESCR-Network) < https://www.escr-net.org/resources/section-5-background-information-icescr#:~:text=Since%20the%20ICESCR%20is%20an,the%20standards%20contained%20in%20it > accessed 13 March 2020
- ‘Sofosbuvir (Sovaldi)’ (Hepatitis C Online) < https://www.hepatitisc.uw.edu/page/treatment/drugs/sofosbuvir-drug#:~:text=Sofosbuvir%20is%20manufactured%20as%20Sovaldi,Pharmasset%20as%20compound%20PSI%2D7977 > accessed 11 January 2021

- ‘Solidarity Call to Action: Making the Response to COVID-19 a Public Common Good’ (WHO, 1 June 2020) < https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action > accessed 25 February 2021
- ‘Solidarity Therapeutics Trial Produces Conclusive Evidence on the Effectiveness of Repurposed Drugs for COVID-19 in Record Time’ (WHO, 15 October 2020) < https://www.who.int/news/item/15-10-2020-solidarity-therapeutics-trial-produces-conclusive-evidence-on-the-effectiveness-of-repurposed-drugs-for-covid-19-in-record-time> accessed 14 February 2021
- ‘Special Representative of the Secretary-General on Human Rights and Transnational Corporations and Other Business Enterprises’ (Office of the UN High Commissioner for Human Rights, 2011) < https://www.ohchr.org/EN/Issues/Business/Pages/SRSGTransCorpIndex.aspx> accessed 19 December 2019
- ‘Technical Information on Anti-Dumping’ (WTO) < https://www.wto.org/english/tratop_e/adp_e/adp_info_e.htm > accessed 11 February 2021
- ‘The Pharmaceutical Industry in Figures’ (European Federation of Pharmaceutical Industries and Associations, 2019) < https://www.efpia.eu/media/413006/the-pharmaceutical-industry-in-figures.pdf> accessed 25 February 2020
- ‘The Patent Act, 1970’ (Intellectual Property India) < https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_113_1_The_Patents_Act_1970_-_Updated_till_23_June_2017.pdf > accessed 25 September 2021
- ‘The Ten Principles of the UN Global Compact’ (UN Global Compact) < https://www.unglobalcompact.org/what-is-gc/mission/principles> accessed 19 December 2019
- ‘Trading into the Future’ (WTO, March 2001) < https://www.wto.org/english/res_e/doload_e/tif.pdf> accessed 10 June 2020
- ‘TRIPS Council Agrees to Continue Discussions on IP Response to COVID-19’ (WTO, 20 July 2021) <

https://www.wto.org/english/news_e/news21_e/trip_20jul21_e.htm > accessed 8 September 2021

- 'Universal Declaration of Human Rights: The Foundation of International Human Rights Law' (UN) < https://www.un.org/en/about-us/udhr/foundation-of-international-human-rights-law> accessed 1 October 2020
- 'WHO Declares COVID-19 Outbreak a Pandemic' (Pharmaceutical Technology, 12 March 2020) < https://www.pharmaceutical-technology.com/news/who-declares-covid-19-pandemic/?utm_source=Army%20Technology&utm_medium=website&utm_campaign=Must%20Read&utm_content=Image> accessed 9 February 2021
- 'Would a Prize Help Speed Development of Ebola Treatments?' (CPR News, 21 August 2014) < https://www.cpr.org/2014/08/21/would-a-prize-help-speed-development-of-ebola-treatments/ > accessed 19 September 2020
- 'WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines' (WTO News Items, 23 January 2017) < https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm> accessed 29 April 2020
- 'WTO News: 1997 Press Releases: Fiftieth Anniversary of the Signing of the General Agreement on Tariffs and Trade' (WTO, 27 October 1997) < https://www.wto.org/english/news_e/pres97_e/pr81_e.htm > accessed 25 July 2020
- Baker BK, 'A Full Description of WTO TRIPS Flexibilities Available to ARIPO Member States and a Critique of ARIPO's Comparative Study Analyzing and Making Recommendations Concerning Those Flexibilities' (Boston University Global Development Policy Center, 5 March 2019) < https://www.bu.edu/gdp/2019/03/05/a-full-description-of-wto-trips-flexibilities-available-to-aripo-member-states-and-a-critique-of-aripos-comparative-study-analyzing-and-making-recommendations-concerning-those-flexibilities/ > accessed 28 September 2021

- Elahi M, 'Case Analysis on *Novartis A.G. v. Union of India*, 2007' (Academia Platform) < https://www.academia.edu/3060975/Case_Analysis_on_Novartis_A.G_Vs._Union_of_India_2007> accessed 8 November 2019

- Ellis J, 'Why Regulatory Data protection Matters for Medicines' (11 July 2017, Geneva Network for International Innovation, Trade and Development Policy) < https://geneva-network.com/research/regulatory-data-protection-matters-medicines/ > accessed 2 October 2021

- Fidalgo VP, 'Article 31bis of TRIPS: How Can African Countries Benefit from This Amendment' (Lexology, 9 June 2017) < https://www.lexology.com/library/detail.aspx?g=df73ba15-2a55-4337-86ed-756d2ba67e8b> accessed 29 March 2020

- FratiniVergano European Lawyers, 'Trade Perspectives: The EU Introduces Exceptions to the Protection of Medicines through Supplementary Protection Certificates to the Benefit of Biosimilar and Generic Medicines' Producers' (FratiniVergano European Lawyers, Issue No 12, 14 June 2019) < http://www.fratinivergano.eu/en/issue-number-12-14-june-2019/#_The_EU_introduces> accessed 12 February 2020

- Global Health and Human Rights Database < https://www.globalhealthrights.org/ > accessed 14 November 2019

- Goldsmith J, 'Is the UN Charter Law?' (Lawfare Institute, 16 April 2018) < https://www.lawfareblog.com/un-charter-law> accessed 29 March 2020

- Halle M, 'The Exhaustion of Intellectual Property Rights: Should Countries Favour Consumers or Private Interests?' (The International Institute for Sustainable Development, June 2007) < https://www.iisd.org/system/files/publications/com_exhaustion.pdf?q=sites/default/files/publications/com_exhaustion.pdf > accessed 20 January 2021

- Kaden JM, 'Patent Protection and the Novelty Requirement' (Gottlieb, Rackman & Reisman Professional Corporation, September 2016) <

https://grr.com/publications/patent-protection-novelty-requirement/> accessed 21 September 2021

- Khosla R and Hunt P, 'Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines' (Human Rights Centre of University of Essex, December 2012) < http://repository.essex.ac.uk/4425/1/human-rights-guidelines-pharmaceutical-companies-access-medicines.pdf > accessed 5 October 2021

- Killick J et al, 'The special Regime of Intellectual Property for the Pharmaceutical Industry' (Stockholm Network Experts' Series on Pharmaceutical Intellectual property Rights, 26 August 2009) < https://issuu.com/stockholmnetwork/docs/the_special_ip_regime_for_pharmaceuticals> accessed 11 July 2019

- Kleinlein T, 'Summary: Constitutionalization in International Law' (Springer Link, 1 November 2011) < https://link.springer.com/chapter/10.1007%2F978-3-642-24884-9_7> accessed 3 April 2020

- Kline D, 'Do Patents Really Promote Innovation?' (The Michelson Institute for Intellectual Property, 24 April 2017) < https://michelsonip.com/patents-really-promote-innovation/> accessed 12 January 2019

- Kohen M and Schramm B, 'General Principles of Law' (Oxford Bibliographies, 27 March 2019) < https://www.oxfordbibliographies.com/view/document/obo-9780199796953/obo-9780199796953-0063.xml?rskey=8M0OfB&result=1&q=Marcelo+Kohen+and+B%C3%A9r%C3%A9nice+Schramm#firstMatch> accessed 12 November 2019

- Kolb R, 'Introductory aspects of public international law' (Baripedia, 5 October 2018) < https://baripedia.org/wiki/Introductory_aspects_of_public_international_law#Classical_international_law> accessed 19 January 2020

- Ortiz-Ospina E and Beltekian D, 'Trade and Globalization' (Our World in Data, October 2018) < https://ourworldindata.org/trade-and-globalization#trade-from-a-historical-perspective> accessed 16 January 2020

- Oxfam New Zealand, 'Rich Countries Betraying Their Obligations to Help Poor Countries Protect Public Health' (14 November 2006, Oxfam New Zealand) < https://www.oxfam.org.nz/news-media/media-releases/rich-countries-betraying-their-obligations-to-help-poor-countries-protect-public-health/ > accessed 16 April 2019

- Rastogi P, 'Worldwide: Worldwide Legal Status Of Medical Method Patents: An Overview' (Mondaq, 6 May 2014) < https://www.mondaq.com/india/patent/311404/world-wide-legal-status-of-medical-method-patents-an-overview> accessed 26 September 2021

- Saez C, 'Malaysia Grants Compulsory Licence for Generic Sofosbuvir Despite Gilead Licence' (Intellectual Property Watch, 15 September 2017) < https://www.ip-watch.org/2017/09/15/malaysia-grants-compulsory-licence-generic-sofosbuvir-despite-gilead-licence/ > accessed 11 January 2021

- Salazar S, 'Intellectual Property and the Right to Health'(WIPO Discussion on Intellectual property and Human Rights WIPO-UNHCHR/IP/PNL/98/INF/1 REV, Geneva, 9 November 1998) < http://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_3.pdf > accessed 12 February 2019

- Sharma A, 'Section 3(d) of Indian Patents Act 1970: Significance and Interpretation' (Lexology, 7 February 2014) < https://www.lexology.com/library/detail.aspx?g=3f92413f-107c-4886-aca7-24633a341e22> accessed 25 September 2021

- Smith D et al, 'Fatal Imbalance: The Crises in Research and Development for Drugs for Neglected Diseases' (Médecins Sans Frontières Access to Essential Medicines Campaign & The Drugs for Neglected Diseases Working Group, September 2001) < https://www.msfaccess.org/sites/default/files/MSF_assets/NegDis/Docs/NEGDIS_report_FatalImbalance_CrisisInR&D_ENG_2001.pdf> accessed 11 July 2019

- The Royal Society Working Group on Intellectual Property, 'Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science' ( Council of the Royal Society, 14 April 2003 ) < https://royalsociety.org/-

/media/Royal_Society_Content/policy/publications/2003/9845.pdf > accessed 30 September 2021

- UN Department of Economic and Social Affairs, 'The Least Developed Country Category: 2021 Country Snapshots' (2021) <https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/Snapshots2021.pdf> accessed 4 May 2021
- Verma SK, 'TRIPS Agreement and Access to medicines' (Kansai University Publications, 2016) < https://www.kansai-u.ac.jp/ILS/publication/asset/nomos/29/nomos29-06.pdf> accessed 1 May 2020
- WIPO, 'Committee on Development and Intellectual Property (CDIP)' < https://www.wipo.int/policy/en/cdip> accessed 19 November 2019
- WIPO, 'The 45 Adopted Recommendations under the WIPO Development Agenda' < https://www.wipo.int/ip-development/en/agenda/recommendations.html> accessed 19 November 2019
- WIPO, 'WIPO Treaties – General Information: Major Events 1883 to 2002' < http://www.wipo.int/treaties/en/general > accessed 10 April 2019
- WTO, '10-Year-Old WTO Declaration has Reinforced Health Policy Choices: Lamy Tells Symposium' (2011) WTO New Items < https://www.wto.org/english/news_e/news11_e/trip_23nov11_e.htm> accessed 3 July 2019
- WTO, 'Intellectual Property: TRIPS and Public Health: Amendment of the TRIPS Agreement' < https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 24 May 2020
- WTO, 'Intellectual Property: TRIPS and Public Health: Members and Dates of Acceptance' < https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 24 May 2020
- WTO, 'Overview: The TRIPS Agreement' < https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> accessed 10 March 2019

- WTO, 'Responding to Least Developed Countries' Special Needs in Intellectual Property' < https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm > accessed 13 June 2019
- WTO, 'TRIPS and Health: Compulsory licensing of pharmaceuticals and TRIPS' <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 23 July 2019
- WTO, 'WTO Members agree to extend Drug Patent Exemption for Poorest Members' < https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm> accessed 15 July 2019
- Zilka KJ and Kotab DM, 'Patent Novelty Requirements of the World and Strategic Foreign Patent Procurement Practices' (Silicon Valley IP Group, 2003) < http://www.zilkakotab.com/pdf/publication1.pdf> accessed 21 September 2021


Blogs


- Peters A, 'The Constitutionalization of International Law: Conclusions' (European Journal of International Law Blog, 28 July 2010) < https://www.ejiltalk.org/the-constitutionalization-of-international-law-conclusions/> accessed 3 April 2020
- Wenger I, 'Making the Dispute Settlement Understanding (DSU) Great Again' (KSLR Commercial and Financial Law Blog, 11 September 2018) <https://blogs.kcl.ac.uk/kslrcommerciallawblog/2018/09/11/making-the-dispute-settlement-understanding-dsu-great-again/> accessed 11 July 2020