A thesis submitted for the degree of Doctor of

Philosophy by

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TITLE

"The extent that Term Extensions, (SPCs), are creating a barrier to access to pharmaceuticals"

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Dedication: To my sons: the people who taught me to stay up all night and what multitasking truly means.

Profound gratitude to my unsung heroes, who supported me to see this research through, whose support propelled me to push forward even when odds appeared impossible to overcome. The notion that "Behind Every Successful Woman Is a Tribe of Other Successful Women Who Have Her Back", (reprinted on March 07, International Women's Day, 2020), rings very true from inception to finish.

My tribe consisted of a blend of personalities, in different time zones and countries and who performed varied, yet interconnected and totally unrelated roles: the ones who took care of my sons in my absence; those who assisted me financially; the ones who messaged and checked on my mental health; those who prayed for me; the ones who quietly watched in awe while I navigate through the different stages and the ones who kept me sane with the latest gossip and chit chat. A massive thank you for having my back and sharing the belief that if one of us succeeds, all of us succeed.

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ABSTRACT

This research critically assesses the development of Term Extensions, its impact and practicalities on generic market entry and with a focus on the European Supplementary Protection Certificates, the extent and effect on access to cheaper medication in terms of cost and availability. From a positivist theoretical perspective, using doctrinal research and secondary use of published data from the European Union, (EU), Canada and International bodies, this research provides in-depth illustration of the impact of term extensions on access.

Patent Term Extensions, PTEs, appear to be at the forefront of the EU battle-ground between pharmaceutical originators and generic companies. Policy making for pharmaceuticals requires considerations on availability and price. For developing countries, it appears impossible to form policy without promoting generic medicines, which is proving to be an effective health care remedy to access and availability.

A 20-year maximum patent term is generally recognised by originators to be insufficient with claims that it is inadequate to provide incentives for research into new active substances as the term is significantly reduced by delays surrounding securing regulatory approval enabling a product to be placed on the market. The EU's response was the institution of SPCs which have been officially administered since the 1980's but numerous complaints have been made on its efficacy and fit for purpose.

The findings in this research suggests that term extensions provide significant barriers to entry for generic medications, continued operations within the EU market will have extended effects on cost and availability and most significantly, has acted as a legal transplant on the Canadian system, which previously did not recognise extensions. Additionally, this research demonstrates that the actual workings of the system suggests that the cost implications represent one dimension of impact and that other legal ramifications are at play that affect overall access matters, which are explored.

Conclusions are drawn based on legislative review and re-analysis/interpretation of published data which facilitates suppositions on means of optimising existing legal structures and dissects practical solutions for addressing access and public health obligations under International Law, especially for countries with little or no manufacturing capabilities.

MAIN ACRONYMS

CI/HAI	CONSUMERS INTERNATIONAL AND HEALTH ACTION INTERNATIONAL
CIPO	CANADIAN INTELLECTUAL PROPERTY OFFICE
CJEU	COURT OF JUSTICE OF THE EUROPEAN UNION
EC	EUROPEAN COMMISSION
ECHR	EUROPEAN CONVENTION ON HUMAN RIGHTS
EDR	EMERGENCY DRUG RELEASE
EML	ESSENTIAL MEDICINES LIST
EPC	EUROPEAN PATENT CONVENTION
EPO	EUROPEAN PATENT OFFICE
EU	EUROPEAN UNION
FDA	FOOD AND DRUG ADMINISTRATION
FTA	FREE TRADE AGREEMENT
IALS	INSTITUTE OF ADVANCED LEGAL STUDIES
ICESCR	INTERNATIONAL CONVENTION ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS
IND	INVESTIGATIONAL NEW DRUGS
IP	INTELLECTUAL PROPERTY
IPR	INTELLECTUAL PROPERTY RIGHT
LDCS	LEAST DEVELOPMED COUNTRIES
LMICS	LOWER AND MIDDLE INCOME COUNTRIES
MA	MARKETING AUTHORISATION
NDS	NEW DRUG SUBMISSION
NOC	NOTICE OF COMPLIANCE

PCT	PATENT COOPERATION TREATY
PMRB	PATENTED MEDICINE PRICES REVIEW BOARD
PTE	PATENT TERM EXTENSIONS
SPC	SUPPLEMENTARY PROTECTION CERTIFICATE
TA	TRADE AGREEMENTS
TRIPS	TRADE RELATED AGREEMENT ON INTELLECTUAL PROPERTY
UKIPO	UNITED KINGDOM INTELLECTUAL PROPERTY OFFICE
UN	UNITED NATIONS
UNDP	UNITED NATIONS DEVELOPMENT PROGRAMME
USPTO	UNITED STATES PATENT AND TRADEMARK OFFICE
WHO	WORLD HEALTH ORGANISATION
WIPO	WORLD INTELLECTUAL PROPERTY ORGANISATION
WTO	WORLD TRADE ORGANISATION

INTRODUCTION

Almost inevitably, most, if not all, conversations on pharmaceuticals, whether it is production, administration, marketing, selling or deciding which one to choose, includes some discourse on patents. It is surely not by accident that this occurs as without patents, the pharmaceutical industry would not exist in that they provide the means for the innovators of pharmaceuticals to recoup their investment into drug discovery through the grant of market monopolies, for a fixed term.

In the simplest form, a bout of research and development being performed to discover a new chemical entity, usually, the first step, which has become almost a reflex action, is to make an application for a patent to protect the new molecule. Despite being costly and time-consuming, this represents just one step. There will be pre-clinical and later clinical studies to demonstrate safety and efficacy. Another step involves getting a marketing authorisation to enable the new drug to be sold. Marketing and sales follow which adds to the total cost of bringing the drug to the market. It means that the cost of the patented product at the start is normally substantial but would drop at the end of the 20-year period,[1] after which the original product falls into the public domain and generic companies can make use of the information.

The advantage to generic companies in using data in the public domain is that they have not invested in neither the research and development process, the clinical process nor the marketing of the product but are now able to produce the very product from that information. It is not to say that generic companies are totally without costs as the product they produce must be bio-equivalent to the original patent to rightfully be called a generic.[2] Nonetheless, whatever costs incurred by the generic companies appear minimal as they are able to offer for sale the same product at approximately 1/10th of the original cost.

[1]This is the maximum term of protection countries should offer patent holders as mandated by The Agreement on Trade Related Aspects of Intellectual Property Rights, 1994, (TRIPS Agreement). The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994 and is enshrined in all major patent systems including the Patent Cooperation Treaty. That 20-year rule represents the general principles and standards in patents administration.

[2] Council Directive (EC) 2004/27 of 31 March 2004 amending Council Directive (EC) 2001/83 on the Community code relating to medicinal products for human use, OJ L136/34 (Medicines Directive).

Whereas the factors that contribute to the cost of the product is not definite, innovators claim that the maximum 20-year period of patent protection is insufficient to recoup those costs incurred during the life of the product, from research and development to the end of the 20-year period. The use of term extensions became a tool to assist in that regard and has been adopted in different formats in developed countries, including European Community (EC), United States of America (USA), Japan and Australia. In most instances the protection offered by the basic patent is extended to up to five years, beyond the 20 years and in some cases more. In the EU, the system of term extensions is enshrined in the patents legislation and effectively adds additional time or delay to generic companies using data pertaining to such drugs.

From an access standpoint, countries around the world rely on research and development and innovation in pharmaceuticals but must firmly consider the cost of medication to its citizens, particularly when there is an outbreak of infectious disease or in cases of a national emergency, as evidenced by steps taken during the Covid-19 pandemic season. The use of generic versions presents a welcome alternative to the costly innovator drugs especially in low-income countries where manufacturing is non-existent. The availability of essential medicine to a country is not considered a privilege but more of a basic right.[3] It means that all drugs must come from somewhere and must be made available when it is required.[4] The use of term extensions is seen to not only give extra time to the innovators but less time to the generics, which presumes that it may take more time for the drugs to become cheaper and readily available.

This becomes more of an issue as one-third of the world's population lacks access to the most essential medicines.[5] Similarly, most of the world's population lacks access to safe and appropriate medical devices, according to the World Trade Organisation (WTO) Fact sheet.[6] Developing and least developed countries are the most affected by limited access to medicines and medical devices. Most countries rely on the World

[3] General Comment No. 14 (2000) and Article 12 of the International Covenant Economic, Social and Cultural Rights. 22nd Session, E/C.12/2004, 11 August 2000 and subsequent reports of the UN General Assembly, Report of the Special Rapporteur of the Commission on Human Rights

[4] UN General Assembly. Report of the Special Rapporteur of the Commission on Human Rights. 61st Session, 13th September 2006, A/61/338.

[5] Hans V. Hogerzeil & Zafar Mirza, 'The World Medicines Situation 2011, Access to Essential Medicines as part of the Right to Health' (2011) WHO/EMP/MIE/2011.2.10

[6] Hembadoon Iyortyer Oguanobi, 'Broadening the Conversation of the TRIPS Agreement: Access to Medicines Includes Addressing Access to Medical Devices' (2018) 21 JWIP 70-87

Health Organisation (WHO), Model List of Essential Medicines[7] (EML), to provide guidance on various active ingredients suitable for diseases and ailments, which ultimately results in policy considerations on cost-effective drugs for their populaces. That list allows for customization to each country's needs but ultimately must be considered in conjunction with the pharmaceuticals that are actually available or more affordable.

Access to more affordable medication has been an issue at the forefront of the international scene and although it is most often considered a developing country issue, more recently it has become a talking point for all countries as all countries are mandated to make available pharmaceuticals at minimal cost to citizens or governments, particularly in the circumstances and advent of the Covid-19 pandemic.

This research investigated term extensions, in particular the European SPC system, with a view to determining its effect on the real cost of pharmaceuticals in the EC, particularly, on whether it in fact contributes to delayed access in terms of cost and time for generics to enter the market. To this end a quasi-comparative analysis of what obtains in Canada became the focus purely due to the fact that Canada is one of the countries in the Organisation for Economic Cooperation and Development (OECD), which before 2017, (the start of this research), unlike many other developed countries, did not have a provision that extends the patent protection period to compensate for delays in the marketing approval process.[8] Consequential to the Comprehensive Economic and Trade Agreement (CETA), between Europe and Canada, Canada recently introduced a patent term restoration system much similar to the European SPC system, with a maximum period of 2 years. Although CETA allows for the possibility of exceptions during the term for purposes of export to third countries, it has effectively resulted in transplanting a system of extension into Canada's patent administration which, no doubt, is directly attributed to its bilateral arrangements with

[7] WHO Model List of Essential Medicines 20th List (March 2017) (Amended August 2017), <https://apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=1-> accessed 12 March 2019 and WHO Model List of Essential Medicines for Children 6th List (March 2017) (Amended August 2017), <https://www.who.int/medicines/publications/essentialmedicines/6th_EMLc2017_FINAL_amendedAug2017.pdf -> accessed 12 March 2019.

[8] Charles Rivers Associates, *Assessing the Economic Impacts of Changing Exemption Provisions During Patent and SPC Protection in Europe,* (2017) pg.67, EUROPEAN COMMISSION, Directorate-General for Internal Market, Industry, Entrepreneurship and SME, February – 2016, Luxembourg: Publications Office of the European Union, 2017 ISBN: 978-92-79-73301-7, doi: 10.2873/673124, (herein referred to as Charles Rivers Associates 2017).

the EU. Literature Review revealed that little work or studies have been conducted in this area and most references to term extensions are mainly centred on comparisons made between USA/Canada, USA/Japan[9] and other jurisdictions utilising extensions.

Further, during the course of this research, patenting and pharmaceuticals have been under the radar including the SPC system resulting in developments in three areas of patents where proposals for legislative changes are underway and which have already taken effect. These changes are incorporated into the discourse on access.

Essential to understanding the information is to take into consideration the following: Timeline - the relevant dates for the state of law covered is as of December 2020, as such, does not incorporate recent legislative changes but makes reference to updates in industry that may have occurred during the writing up stage and before final submission of this research.

References to EC, EU, and Europe – These references do not denote specific political or geographical areas but are mainly based on the reporting styles and timelines of published data. Where specific reference is required, such will be given, otherwise such references, for the purposes of this project, applies to the jurisdiction of SPC Regulation.

Covid-19 - The events which followed the Covid-19 pandemic, although relevant to this research, is not covered as a specific subject due to ongoing developments and the ever-evolving technology directly related to medications/pharmaceuticals. Despite invaluable issues of access raised during and post pandemic, the timeline did not allow for deeper research and or focused conclusions to be drawn based on inadequate or premature data covering such and to do so would result in an injustice being done to its prominence. Nonetheless Covid-19 related responses are incorporated and appropriate references made where necessary.

Based on literature review and utilizing a combination of doctrinal desk research and analysis of published data the research makes the following claims/conclusions:

[9] Mary Atkinson, 'Patent Protection for Pharmaceuticals: A Comparative Study of the Law in the United States and Canada' (2002) 11 Pac. Rim L. & Pol'y J., 181

1. Availability –Time added - SPCs have added years to the effective protection period for those innovator products where the SPC is the last measure of protection to expire. The data reveals that 45% of the medicinal products have obtained an SPC in at least one of the European countries. While the protection for medicinal products in the EU is amongst the strongest in the world, the average effective protection period has decreased by approximately two years from 15 to 13 years since 1996. Companies choose to launch more medicinal products faster in larger and wealthier countries. Hence, not all new products are made available in all European countries and not at the same time, (data and discussion with appropriate references given at Chapter 3).

2. Accessibility- Cost and Generic entry – Pharmaceutical spending has increased in some therapeutic areas including oncology and care for certain rare diseases where many new medicines target small population groups and command higher prices. SPCs can cause delays resulting in an average price drop of approximately 50% following the entry of generics. Sudden large price increases for off-patent medicines have made important treatments unaffordable for patients, (additional data and discussion at Chapter 3).

3. Massive increases in cost for pharmaceuticals is envisaged in Canada based on post CSP projections. The Canadian experience offers a divergent workable system however there is no confidence that it will yield cost savings, (further discussion at Chapter 4).

4. A balanced system of protection and access requires a collaboration of key stakeholders and reorganisation of IP systems, (explored further in Chapter 5).

5. Conclusions on lack of access and optimisation of legal systems for increased access based on a system of fostering resilience, (details broken down at Chapter 6).

The foregoing claims/conclusions are structured in chapters based on a chronology which dissects the system from an access standpoint: Introductory matters which includes methodology and jurisprudential discussions; Background chapters providing historical analysis of patents, globally and regulatory concerns linking with SPCs; Interpretation and re-analysis of published data; Conclusions and optimisation of existing legal infrastructures.

INTRODUCTORY AND METHODOLOGICAL ASPECTS OF THE RESEARCH

Overall, this introductory section allows for an understanding of the initial thoughts, justifications, ontological and theoretical suppositions that guided the research as well as methodological processes. Thus, this section imparts insight into the work carried out, methodological and practical issues which arose in conducting the research.

In sum, the focus of the research was interdisciplinary - law in context,[10] using an explanatory and evaluative approach in testing whether rules work in practice, taking into account other important divergencies in the legal systems concerned. This is supported by legal history and law and economics theory, particularly when addressing EU systems and harmonisation by demonstrating evidence of systemisation. The level of comparison is based on conceptual framework of legal doctrine, with the research being more descriptive-interpretation, whilst utilising functional and structural schemes of intelligibility, through the lens of a positivist ideological perspective.

THE RESEARCH PROJECT

Research Question considered

How or to what extent Term Extensions, in particular, Supplementary Protection Certificates, (SPCs), are creating a barrier to access to pharmaceuticals.

The Problem which required investigation

It is well accepted in global health and pharmaceutical industries that adapting prices of pharmaceuticals to the purchasing power of patients and consumers in varying geographical or socio-economic contexts can improve access to and affordability of life-saving medication for the long term and immediate relief. Further, it can be effective as part of extensive attempts at ensuring that healthcare systems are sustainable. Access to pharmaceuticals, although mainly seen as a developing country issue, is relevant in the European context where the gaps between GDP and healthcare spend per capita and access to the latest innovative medicines have been widening and are significant. Right to health is considered a human right and so

[10] M V Hoecke, *Methodologies of Legal Research, Which Kind of Method for What Kind of Discipline? (Ed.),* (Oxford and Portland Oregon, Hart Publishing, 2011)1-17.

access, for the purposes of this project, is defined using the four principles of the right to health: availability; accessibility, acceptability and quality. Patents and the SPC system appear to touch all four principles however, the focus will be on availability and accessibility. Thus, the problem arises from the link between the cost and availability of pharmaceutical products and the impact that term extensions in EC legislation contributes to or hinders such access.

Objectives/Aims of the research project

To examine the extent of the extension given to pharmaceuticals by SPCs.

To study the impact of SPCs on the cost and availability of essential medicines.

To investigate to what extent SPCs increase the cost of pharmaceuticals and the impact on access.

To review the administration of SPC system considering generic access to the market.

To suggest possible solutions for functionality of the SPC system that may foster increased access.

To highlight instances where legal systems can me optimised to counter anti access regimes and foster increased access to pharmaceutical products.

Focus of the research

Access issues form the basis of this research in the sense of how the patent system is being used to delay generics from entering the market, which appears to have a domino effect on access. The right to health is considered a human right and so access, for the purposes of this research, is defined using the four principles of the right to health: availability; accessibility, acceptability and quality, (CESR, General Comment No.14(2000),[11] focussing on availability and accessibility, which translates to time and cost.

[11] Article 12 of the International Convention on Economic, Social and Cultural Rights, 22nd Session. E/C. 12/2000/4, 11 August 2000: Para 12.

Reason for choosing the research topic

The effects of patent rules on access to affordable medication in LDCs, provides significant impetus and motivation to investigate and understand some of the underlying legislative and industry specific policy considerations that drive growth and development in innovation of pharmaceutical products. To that end, the ramifications for the generic trade business and the direct impact on public health affordability are of primary concern. The introduction and use of PTEs, including SPCs, can be regarded as potential circumvention machinery thus require studies to be undertaken on the actual use and impact on access to affordable medication. The importance of this cannot be overemphasized, mainly due to the EU, being considered an international driver of standards on the administration of IPRs and, in most cases, are considered the authors and engineers of the major international instruments, TRIPS, being a prime example. Nonetheless, it seems as soon as developing countries gain some ground on the international scene, the EU resorts to tactics geared at saving key industries.[12]

These issues are not new per se, even the European Court has had certain questions referred to it from Member States. However, the validity of the sui generis right or its compliance with international obligations appear to be off limits. The literature suggests, and mostly accepts, that these sui generis rights are in fact legal extensions and do not question their validity or compliance with international obligations.[13]

Consequently, studies on SPCs have largely been based on economic foundations connected with data exclusivity; which, for the most part, appear speculative and devoid of direct linkages between the use of SPCs and the cost to the generic medication trade.[14] Studies on generic medication have always been linked with the use of compulsory licences and border measures.[15] Following the 2009 codification Regulation, there have been some discussion on the way the courts have been interpreting the legislation. Slanted with a bias towards the pharmaceutical industry, there is an absence in the information or real data on linkages of intellectual property,

[12] CLIP Report*, A Report by The Common Law Institute of IP*, (1991)

[13] Duncan Curley, *Extending Rewards for Innovative Drug Development– A Report on Supplementary Protection Certificates for Pharmaceutical Products- Prepared for the Institute of Intellectual Property*, (2007)

[14] Samuel A Oddi, 'Plagues, Pandemics, and Patents: Legality and Morality' (2011) 51 IDEA 1, 46

[15] Zita Lazzarini, 'Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the Case of Brazil' (2003) 6 Yale Hum. Rts. & Dev. L.J. 103

competition law and access.[16] Even the new reports on studies offer divergent views on various aspects of the SPC system but do not specifically address access, particularly from the perspective of LDCs.

Theory/Hypothesis

The settled theory is that SPCs extend the patent life of pharmaceuticals products, consequently, directly increasing cost.

The hypothesis is that the settled theory is not necessarily definitive because the degree or impact on cost, in most instances, is uncertain due to flaws in the system and other factors that affect patents in pharmaceuticals.

That although term extensions appear to add an additional burden for generic manufacturers, they do not automatically result in an award of extra time and that the direct impact on cost and access is not a given; further, there are other legal ramifications that affect the cost of pharmaceuticals.

[16] Catherine Katzka, 'Interpretation of the Term 'Product' in EU Council Regulation 1768/92 and 1610/96 On Supplementary Protection Certificates, (2008) 3 Journal of Intellectual Property Law & Practice, 650.

JUSTIFICATION AND CONTRIBUTION OF THE PROJECT

Part of the justification[17] for this project lies in the problems faced in using the SPC system itself. Other justifications include; the need for a degree of discerning whether the SPC system is achieving its intended purpose and what changes can be made to enhance its usability and or functionality, from an access standpoint. Additionally, the impact of SPC's on access matters did not seem to feature much, if at all, in the literature. Previously, studies on SPCs were purely based on the effects of patent rules, generally, on access, but without any direct linkage or assessment of the various segments of patenting. This research breaks down the theory further to provide insight into an integral part of patenting which adds a divergent dimension to the discourse. Key recent developments in patenting and EU regulatory changes are indicative of the need to have the system revamped.

Majority of previous studies on SPCs are linked with the use of compulsory licences and pharma regulatory aspects as such the literature reveals a lack of real data on the actual workings of the SPC system. From a practical standpoint, it became essential to understand the intricate workings of the system and to investigate the extent of patent protection period and real impact for drugs becoming cheaper in terms of access: time and cost. Previously, most of the literature give a fleeting overview of the possible overlap with competition law with little discourse on the legal nature and its interplay with international obligations.

Post Brexit scenario presents yet another reason for examining the SPC system, albeit from a UK perspective (although this research does not address specific, individual EU countries, a special mention of the UK is warranted). However, the UK will have to make decisions on SPCs, from a regulatory standpoint, as part of the necessary overhaul of legislation on pharmaceutical issues, in particular, clinical trials, marketing authorisations, quality assurance and product safety, pharmacovigilance, regulatory authorities and parallel imports. From patents viewpoint, the issue of unitary patent system, trademarks, designs and SPCs will definitely have to be reviewed. For SPCs the regulations enacted by the UK to bring the SPCs into effect will no longer apply, as such, it will be important to consider the fate of the SPCs in UK law, post BREXIT.

[17] Chatterjee Charles, *Methods of Research in Law*, (OUP 1997)

Notably, SPCs are currently granted and enforced at national levels, which can give rise to a lack of harmonisation as indicated through the decided cases. Herein lies one of the fundamental glitches with the system which has been recognised by the European Commission through its communication document on October 2015 entitled 'upgrading the Single Market: more opportunities for people and business'. The document proposed, (among other things), a targeted SPC manufacturing waiver to allow the manufacture of generic and biosimilar medicines in the EU during the SPC period for export to non-EU countries where there is no SPC protection and stressed the need for coherence between the Unitary Patent System, (UPS), and the current SPC framework.[18]

The Unitary Patent System, although not yet fully functional, when it comes on stream will have consequences for SPCs as all SPCs protected by Unitary Patents will be subject to the exclusive competence of the UPS. The position may change once the UPS is operational which was originally scheduled for Early 2022.[19] Of course concerns exist with the UPS System and how it will operate for patents and SPCs, in particular a disconnect between the Unitary SPC and the MA.

[18] *Commission Staff Working document- A Single Market Strategy for Europe-Analysis and Evidence-Accompanying the Document Upgrading the Single Market: More Opportunities for People and Business*, 28 Oct. 2015, SWD (2015) 202

[19] European Patent Office website publication, "When will the Unitary Patent system start?"

<https://www.epo.org/law-practice/unitary/unitary-patent/start.html> accessed 20 December 2020.

ORIGINALITY AND IMPLICATIONS/IMPACT OF THE PROJECT

The research contains two strands for originality: gap in literature concerning linkages with extensions and access to pharmaceuticals and the dimension/approach to comparative use of data on extensions utilised.

The originality of this research is inherent in the SPC system as it appears to be an area hardly researched through an access focus, with much of the literature making linkages with the use of compulsory licences and data exclusivity, with an academic glance on direct linkages to access issues. The existing literature mainly highlight academic and jurisprudential debates on access, patents and extensions, separately but do not offer more specific legal, cost and time implications, particularly from generics point of view. Thus, the research sought to provide such direct linkage by assessing the wider impact on the cost of pharmaceuticals.

The significance of this project cannot be overstated and is timely in light of the EU's intention to revamp the SPC system, according to a call for tenders: Study on the legal aspects of the supplementary protection certificates in the EU. That study has now been commissioned and intended to: "*be used by the Commission for an overall evaluation of the SPC system in the EU and to inform the decision on whether to come forward with a new SPC title at European level and whether to revise the existing SPC legislation….*"[20] This is an indication that the EC itself appeared to be uncomfortable with the way that SPCs have been subject to judicial scrutiny. It suggests that the EC understands that there have been major difficulties with using the system and have commissioned respective studies.

Since then, economic studies, a dimension not previously tackled, have been conducted on SPCs, reports of which became available, data from which became extremely useful during the data collection stage[21] and have been utilised in re-analysis and reaching conclusions. These studies were timely in that until recently, 2018-2019, studies on SPCs appeared unchartered territory however, from 2017 to

[20] Call for Tender 479/PP/GRO/IMA/15/15153, *Study on the legal aspects of the supplementary protection certificates in the EU*, European Commission, DG for Internal Market, Industry, Entrepreneurship and SMEs..., <https://etendering.ted.europa.eu/cft/cft-display.html?cftId=1206#caDetails> accessed 10 February 2018

[21] Kyle (2017), Meijer (2017), Max Planck Institute (2018) and Charles Rivers Associates (2018)

2019, new published reports surfaced on studies undertaken during the course of this research project. The findings presented in these reports reveal much timely and required data and appear to add much value to the literature gap on the topic. However, these reports are either academic or industry specific as they were commissioned for specific purposes, and they do not, in a strict sense undermine the contribution or originality of this project. Data from these studies form part of the information utilised in re-analysis in this research project.

Adding to the originality is that the project takes a view through the lens of the cost factor analysis of the SPC legal system. The value of economic analysis of law is that it produces normative conclusions of vastly greater certainty than other methods. The methodological rigor of law and economics produces normative conclusions that approach the certainty of positive scientific conclusions.[22]

The comparative approach provides an added original dimension as the literature reveals comparisons with the usual jurisdictions that allow term extensions. Canada has always been compared to the other Western Hemisphere countries but no revelation in the literature indicate comparison with the EC. The methodology of comparison with Canada in this project sets it apart from the studies undertaken recently, especially as Canada seems to be a novel player in the term extensions arena.

The importance of the research and Impact

The introduction and use of SPCs can be regarded as a potential circumvention machinery thus require studies to be undertaken on the actual use and impact on access to affordable medication particularly to vulnerable regions.

Reports and studies on SPCs have largely been based on economic foundations connected with data exclusivity; which, for the most part, appear speculative and devoid of direct linkages between the use of SPCs and the cost to the generic medication trade. Studies on generic medication have always been linked with the use of compulsory licences and border measures.

[22]Richard A Posner, "The Law and Economics Movement" (May 1987) 7(2) American Economic Review Papers and Proceedings 12

Further, much of the literature on this topic dates to the pre-Directive era and later around the time of amendment, 1996. The writings were more anticipatory without much expectation of legal confusion and lack of projections on the legal nature or on access issues. Following the 2009 codification Regulation, there have been some discussion on the way the courts have been interpreting the legislation. Slanted with a bias towards the pharmaceutical industry, there is an absence in the information of real data on linkages of intellectual property, competition law and access.

This research will be beneficial in the sense that it combines a law and economics approach and infused with comparative analysis whilst taking into account legislation and data from different types of government structures. It also combines a developing country perspective.

As an inter-disciplinary project, it projected to be beneficial to policy-makers government, the pharmaceutical industry including the generic industry, medicine procurement, trade, and food and drug administration, particularly in developing countries. Moreover, this research concludes that application of practical steps in optimising legal systems, particularly in the sense of reconsidering recent revision of the SPC system and guidance for countries who have not introduced term extensions, may cultivate positive access outcomes.

Currently it appears that the ultimate best result may rest in achieving the right balance between the development of new drugs at a cost that is affordable and accessible to those who need it most.

JURISPRUDENTIAL – LEGAL THEORY RELATING TO IPR'S AND ACCESS

The relevant legal theories offer some guidance on how such balance can be achieved. The research found that law and economics presented the most pragmatic approach to scrutinise the legal underpinnings raised in this project. Based on the philosophical justifications for IPRs, a law and economics dimension presented an avenue to make reasonable conclusions.[23] Using Posner's interdisciplinary perspective, it appears possible to use the methodology of law and economics to shed light on access issues in this project. Further the research project assumed the position that the economics of law are the set of economic studies that build on a detailed knowledge of some area of law; whether the study is done by a "lawyer", an "economist", someone with both degrees, and a lawyer-economist team has little significance. The application of economics to law is not new, what is new and controversial is the variety of problems in the field of law to which economics is now being applied.[24]

An important finding in the law and economics literature is that economic analysis can be helpful in designing reforms of the legal system. Another finding in the literature is that the quantitative study of the legal system is fruitful. The economic approach to law has enormous potential for increasing knowledge about the legal system, as is demonstrated in this research. Since economics is basically considered a positive science, a positivist standpoint will be taken during the research process.

Even more important is that Positivist[25] approach introduces the fact/value dichotomy - Logical Positivism suggests that a proposition is factual if it can be reduced to propositions of physics, which in turn are verifiable through observation or sensory experience. It is the empirical part that changes prudentia to Scientia. Positivists seek to distance the existence of legal rights and duties from moral judgements although they do not deny the importance of morality or that moral views influence the content of law.[26]

[23] Landes & Posner, *The Economic Structure of IP*, The Belknap Press of Harvard University Press (2003)
[24]Richard A Posner, 'The Economic Approach to Law' (May 1975) 53(4) Texas Law Review 757-82
[25] Tom Campbell, *Prescriptive Legal Positivism: Law, Rights and Democracy*, UCL Press (2004)
[26] Nigel E. Simmons, *Central Issues in Jurisprudence*, 3rd Edition, Sweet & Maxwell, (2008) pg. 147

Philosophical Justification of IPRs relevant to the research

Understanding the nature of SPCs requires an understanding and or elaboration of the philosophical justifications of IPRs and the patent system in a way that uncovers the theoretical jurisprudential standing of SPCs.[27] This is important to give an overview on the ontological principles which guides this research as well an understanding of the metaphysical construction attributed to the patent system and IPRs.

Prima Facie, Intellectual Property law covers a diverse range of transferable territorial rights which are not normally easily defined. Intangible rights can prove extremely valuable and although there may be some overlap, generally IP law normally seek to protect: ideas and inventions (patents and designs); information and data (confidential information, copyright and database); brand and trade names (trademarks and GIs).

As with other property rights, the value of these rights is not necessarily ownership but the ability to exploit them to generate revenue and to enforce them against third parties.

The general principles of IP law, in particular patents,[28] are generally seen as part of an interdependent mix of incentives and restraints that bestow benefits and impose costs on society and individuals alike. Some see patents as facilitating innovation, access and competition while others see patents as frustrating these important interests. However way it is seen, patent law is not a one size fits all regime, thus a nuanced approach to understanding the costs and benefits of patent law is needed to appreciate its effect on economic and social welfare, which, in this case, access to medicine.

Patent law is said to bestow negative rights in the sense that it does not give the inventor a positive right to make, use, or sell the invention but merely the right to exclude others from so doing. Dating back to ancient Greece, the idea behind granting of a patent was meant to be an incentive-based mechanism wherein a potential inventor is encouraged to disclose something new and useful to society.[29] Each school

[27] Michael Freeman and Ross Harrison, (eds) *Law and Philosophy, Current Legal Issues* , Volume 10, OUP (2007)
[28] Newman Kieff, Schwartz & Smith, *Principles Of Patent Law: Cases And Materials*, 4th Edition, Foundation Press, (2008)
[29] Laura A Underkuffler, *The Idea of Property: Its meaning and Power,* OUP (2003)

of thought places emphasis on varying aspects of IPRS and patent law. In unpacking the plethora of theories, it becomes even more apparent that IPR considerations requires some level of analysis.

Economic theorists take the quasi-monopoly stance however Posner[30] makes the case for a merger of law and economics and contends than an area of legal regulation of explicit markets is just beginning to ripen for economics is intellectual property, with special reference to copyrights and trademarks and that patents have long been an object of economic study. Nicola Searle and Martin Brassell[31] make more clear-cut theoretical assumptions and contend that there exist three main schools of thought in the economic justification of IPRs: incentives to innovate, labour desert theory; a rejection of IP rights. These issues will be given more attention in future sections.

Simultaneously, Natural law jurists will argue that IPRs are confined to personality rights theory and natural justice/rights. Those who advocate for the property theory contend that IPRs can be given protection of property rights as human rights. The reasoning behind this is that "things" bring into the play the whole discourse on the nature of the right in property law which may or may not include *Rights in a thing,* dominion in the form of ownership of a particular item of property or, *Rights against other people in that there is an inherent* right to use/exploit, right to revenue/profit and a right to receive payment in money if some right in property is contravened by a third person.

More modern understanding of property law suggests that property law represents a particular way of creating legal relationships around the possession and use of an object or resource that enables a novel legal analysis. Jesse Wall[32] asserts that categorising rights in things ultimate results in a focus beyond the thingness of the item to the content of the legally enforceable right which right includes the legal relationship between the rights-holder, the thing and the duty bearer. Thus, property rights focus on the exclusion of all other persons from an object or a thing.

[30] Richard A Posner, 'The Law and Economics Movement' (May 1987) 7(2) American Economic Review Papers and Proceedings 1-13

[31] Nicole Searle and Martin Brassell, *Economic Approaches to Intellectual Property*, OUP (2016)

[32] Jesse Wall, *Being and Owning*, OUP (2015) pg. 112

Others challenge that IPRs better serve their purpose by acknowledging their importance in imparting knowledge and that the ultimately effective way to achieve this is through making it accessible to most people, in particular, those who appear to need it most, at minimal cost, but preferably, free of cost.[33] This culture of sharing is more synonymous with copyright through the medium of the Creative Commons but recently, it is argued that this may be applied to other forms if IP.

Theoretically, examination of rights and obligations as it relates to property seem clear when talking about patents as the patents act clearly indicates what patents holders' rights and obligations are. Applying the property, knowledge or even sharing concepts to SPCs is problematic as it seems to exist under none of these categories. It begs the question as to why it was introduced under the patent system when SPC's appear not showing signs of being an IPR, thus the 'sui generis' status. It is this sui generis status that sets the SPC system apart and affords it the flexibility to be creative with its organisation and operation, which may contain advantages and pitfalls, more of which is discussed further.

In a nutshell, legal doctrine discipline is applied, studying law as a normative system, which limits the data to legal texts and court decisions however, the research systematically combines legal reality, law as it is, through law and economics.

[33] Olga Gurgula, 'Monopoly v. Openness: Two Sides of the IP coin in the Pharmaceutical Industry' (2017) 20 (5-6) Journal of World Intellectual Property 206-217

METHODOLOGY – SECONDARY DATA ANALYSIS/INTERPRETATION

Based on the subject-matter, this research claims to be inter-disciplinary as access to pharmaceuticals touches many subject areas including: IP and patents, regulatory, human rights issues, economic, public policy, politics and the international trading system which are all embedded in the study of access to medicines which fostered a practical approach to using a combination of methods.

This research attempted to view the SPC system through a positivist lens in the sense that it sought to understand the functionality of the system not just the intricate functioning but how that translates to an access viewpoint. Additionally, further analysis of previously collected empirical data, mindful of Systems Theory[34], facilitated critical analysis which assisted in fostering a clearer understanding of how systems impose impractical in-built nuances that hinder efficient functioning of such systems.

Indeed, the human rights element in access informed the investigation and was explored to delve into the significance of highlighting the challenges posed by increased monopolies and protectionist regimes instituted by countries to safeguard certain industries.

The aim was essentially getting a microscopic view of the real effect that term extensions, in particular, SPCs, have had on access with particular focus on the generic trade business and access in terms of time and cost implications. In this regard, a combination of research methods was employed.

The Scope of the work undertaken

- An in-depth examination of legislation pertaining to patents, SPCS and access, data from previous research, published data from established organisations with the responsibility of pharmaceutical regulation, patent registration which are public, published data from International Organisations dealing with public health, IPR and pharmaceuticals. This information proved significant as it represents trends in spending on pharmaceuticals.
- Examination of previously collected information was conducted from patent registration from jurisdictions before any form of extension, was instituted.

[34] Richard Nobles and David Schiff, *Observing Law Through Systems Theory,* Hart Publishing (2013)

- The search also included information from generic producers and organisations with responsibility for buying pharmaceuticals or policy making where this is concerned.

Methods used in uncovering information during the research

In order to achieve the above, it became imperative to combine various methods and approaches to achieve a balanced and sound outcome. This presented an opportune moment for a paradigm shift/change in legal research methodologies.[35] The information collection and analysis stage encompassed the following:

Doctrinal research

Doctrinal research, or "black-letter law" was used to determine what the law on SPCs are at present and was the key method employed during the literature review stage to determine the relevant literature that currently speak to not just SPCs but general pharmaceutical administration and patenting. That involved locating and interpreting relevant primary and secondary sources of law and synthesising those sources to form a rule or rules of law. Further, it assisted in the evaluation and critique of competing or inconsistent sources and was indicative of ways in which the law on SPCs should develop. Black letter law encompassed looking at the relevant rules for coherency, departure and to identify possible gaps.

Interpretation of Published Material

The project involved no original collection of research methods. According to Oliver Wendell Holmes "for the rational study of the law the black letter man may be the man of the present, but the man of the future is the man of statistics and the Master of Economics.[36] The project adopted this principle particularly as it appeared the most logical method having considered the project in its entirety. However, for reasons already mentioned, it became necessary to analyse secondary data to suit the information required in this project.

[35] T Hutchinson, 'Developing legal research skills: Expanding the paradigm' (2008) 32 Melb. UL Rev. 1065

[36] Holmes (1897, 469), *Lee Epstein & Andrew D. Martin, An Introduction to Empirical Legal Research*, Preface, OUP (2014)

Quantitative methods were previously contemplated as the preferred method associated with the information gathering from the pharmaceutical and generic companies as well as other regulatory and charitable agencies. However, limitations of the system of collecting such raw data indicated that challenges would have outweighed the usefulness of such data and that time constraints limited the feasibility of collecting sufficient and accurate data.

The main thrust of the data collection focused on doctrinal research although not in the strict black letter law approach and based on the very nature of the research area a combination of doctrinal and second-hand data analysis was utilised.

Comparative Approach

A comparative approach was adopted to investigate the historical and cultural context giving rise to the development of SPCs legislation in international and EC Law but also in a jurisdiction that, until recently, did not support term extensions for pharmaceuticals.

Comparative as a method and methodology[37] was used to assess law or legal system pertaining to SPCs, its aims, goals, substance or efficacy and attempted to identify common themes across different legal systems with the intention of showing how SPCs have a direct impact on the cost of pharmaceuticals in two contrasting systems. Here, the aim was not the harmonisation of laws, neither did it seek to determine whether a law reflects a consistent manner of dealing with behaviour across states or represents a local idiosyncrasy but simply to test the direct financial additions to the cost of pharmaceuticals as a result of legal transplantation of term extensions from the EC's SPC system compared with a system that previously did not, Canada. Further justification for this is that, Canada is regarded as a neutral country on the international trading system and has always adopted a pro generics stance in its administration of pharmaceuticals thus, has designed its legal system to support this. Comparing the EC's SPC system, a direct result of regulation with civil law origins with Canada's pluralistic system presented as idyllic for the purposes of this project.

[37]Robert Cryer, et.al, *Research Methodologies in EU and International Law*, Hart Publishing (2011) pg. 28

Tools - Desk Research and Statistical analysis

This project advanced based on sound desk work/research which was required for the legislative elements and historical analysis. Analysis of a quasi-qualitative manner was utilised during the secondary data analysis and became instrumental to dissect the information which previously existed in published materials. Although the statistical method of analysis does not represent a major part of this methodology, combined with comparative element, it was instrumental in the interpretation of data used to show how trends and concepts evolved in context to the relevant legal underpinnings and the pharmaceutical industry as a whole.

Approach: This included a deductive approach to secondary data to test the extent to which SPCs affect the cost of pharmaceutical products, thereby hindering access.

A *time frame* was utilised to identify any increase or trend in the type of active ingredients or the companies using the system. A five-year time frame appeared to be most appropriate for such analysis. In this regard, July 2013 to July 2018 was considered a reasonable time-frame in that regard so as to make the information more current and to be able to identify shifts in trends or strategies, if any existed.

Having assessed the available reports, a determination was made that available information may be adequate to cover the details required to address the research question appropriately or within the time frame to be covered. For this reason, no new data was required to be collected. Additionally, by the time the project was being conducted various EC Reports were either recently concluded or were released during the timeline considered above.

The Literature Review contained some aspects of the research trail[38] undertaken up to the 9-month Review and background information which should be read in conjunction with the various search results and the methodology, information from which is captured in the background chapters which follows.

[38] Peter Clinch, *Legal Research: A Practitioner's Handbook*, Second Edition, Wildy, Simmonds & Hill Publishing, (2013)

Sources used in re-analysis

The main sources of information used in this project included various databases containing legislative material, cases, reports and commentary. Where information was taken directly from various databases and reports, such are highlighted. Websites gave full reports published with appropriate copyright notices for use, particularly for educational purposes. Instances presented themselves where permission was required for use of slides and fact sheets and for those the necessary permissions were sought. The following represents the main data sources utilized. It does not represent an exhaustive list and other sources are referenced where applicable in the footnotes and the bibliography.

National Prescription Drug Utilization Information System (NPDUIS) Database, Canadian Institute for Health Information – provides pan-Canadian information on public drug programs, including anonymous claims-level data collected from the plans participating in the NPDUIS initiative from all Regions as well as Health Canada's Non-Insured Health Benefits (NIHB) drug plan.[39]

PMPRB Human Drug Advisory Panel (HDAP), (PMRB/HDAP) - evaluates data from patented pharmaceuticals at the market introductory stage and proposes enhancements to therapeutic material used in patented products. This informs the process of PMPRB price regulation and facilitates comparison between Canada and EU.[40]

Canadian Generic Pharmaceutical Association (CGPA) - to inform the savings from the use of generic prescription medicines from 2013 to 2017.[41]

[39] More detailed information available at, https://publications.gc.ca/site/eng/9.512490/publication.html accessed October 2018.

[40] See further, PMRB Website, http://www.pmprb-cepmb.gc.ca/en/regulating-prices/scientific-review, accessed 30 September 2018.

[41] The Canadian Generic Pharmaceutical Association Website, <https\\:www.canadiangenerics.ca> accessed 30 September 2018

The DrugBank Database – This is publicly available data on pharmaceutical targets in Canada which has enabled the discovery and repurposing of a number of existing drugs to treat rare and newly identified illnesses.[42]

Additional data sources where permissions and or subscriptions sought and access granted: Association for Accessible Medicines: Generics & Biosimilars; Canada Pharma Regulators; EFPIA, Intellectual Property and Pharmacy; EMA Reports; EU Canada pharmaceutical Industries; Government Studies on pharmaceutical access; Health Canada's Drug Product Database; International Generic and Biosimilar Medicines Association – IGBA; New reports from EU Studies: Meijer, Marx Planck; OECD Reports; The Canadian Agency for Drugs and Technologies in Health (CADTH) Common Drug Review (CDR) reports, and The Canadian Generic Pharmaceutical Association (CGPA); The European Medicines Agency's orphan drug database; The United Nations' world population statistics; WHO Reports; Lloyds List; SCRIP; OHE; Pharma Intelligence.

Boundaries of this research

Minor limitations on the availability of information obtained placed little restrictions on analysis, although no ethical concerns are raised. In practical terms, the data which was already publicly available, although tremendously useful, was collected for the respective purposes and at times may not have been suitably defined for this research. For example, data was not obtainable for Canada and the European countries for the same period. Although this project from the onset anticipated assessing data within a particular time - frame, 2013 to 2018, the data was simply not available nor obtainable in this particular format. In this regard a high degree of flexibility in assessing the information was required. However careful consideration employed during the process, some gaps may appear, however the general concepts are not necessarily damaged. Thus, the appropriate mention of irregularity in the data is highlighted in the respective sections, wherever such gaps exist.

Legislative arrangements that concern Patents and Access, which encapsulates the legal problem associated with this research, are considered next.

[42] See further, https://go.drugbank.com/about, accessed September 2018.

Chapter one

PATENTS AND ACCESS

This chapter breaks down the patent system and introduces discourse on prices and public policy which are often considered in managing local access to pharmaceuticals. Key theoretical and philosophical approaches to patenting are scrutinised which demonstrates major difficulties in the intricate workings of the system that give rise to the problem of monopolies, nationally, regionally and highlights the significant dilemma faced by countries in attempting to navigate what seems to be a tightly woven web of legal hurdles in balancing patents and access.

The significance of this centres on the need for a deeper understanding of the ramifications of such systems and how they have impacted use which gives rise to the problem of lack of access. The main arguments herein are concerned with problems associated with overall access to health discourse that relates to patents and demonstrates the inequalities enshrined in utilising international systems for protection. The case is made for a requirement to adopt a holistic approach to public policy on spending where pharmaceuticals are concerned based on the difficulties associated with the global patent monopolistic climate.

1.1. THE INFLUENCE OF PATENT THEORY AND PRACTICE IN CREATING MONOPOLIES

Patent theory and practice is important to understand the theoretical underpinnings giving rise to global IP systems. Discussions on theoretical perspectives on patenting are paramount since such influences directly impact the manner in which the pharmaceutical industry structures itself which in turn informs the overall impact on what obtains globally.

The jurisprudential/theoretical discourse on IPRs yields no strict formula for assessing such IPRs and varying perspectives abound. Patenting seems to be at the forefront of such tirade since various theories are at play. Understanding the modern system requires some background on the plethora of theories.

An important starting point is that although the patent laws are generally seen as part of an interdependent mix of incentives and restraints that bestow benefits and impose costs on society and individuals alike, it does not give the inventor a positive right to make, use, or sell the invention but merely the right to exclude others from so doing.

Early theorists believed in the incentive-based mechanism wherein a potential inventor is encouraged to disclose something new and useful to society, While Lockean Labour Theory and Natural Rights[43] favoured the inventor in patent law, utilitarianism,[44] Bentham injects the principle of utility. Bentham suggests that natural rights are simply nonsense: natural and imprescriptible rights, rhetorical nonsense-nonsense on stilts- the state should adopt policies that would maximise the happiness of members of its community. Bentham's theory goes deeper to explain that "by utility is meant that property in any object, whereby it tends to produce benefit, advantage, pleasure, good, or happiness or to prevent the happening of mischief, pain, evil or unhappiness to the party whose interest is considered: if the party be the community in general, then the happiness of the community: if the particular individual, then the happiness of that individual."[45] This is significant in comprehension of patents however, Robert Ostergard[46] argues that traditional theories (such as labour theory of property and inferences drawn from the utilitarian theory) fail to offer a rational and adequate theoretical justification for IPR, therefore consideration of IPR as human rights is indefensible.

A divergent view is taken in Economics of Patent Law which has demonstrated the causal link between intellectual property and the growth of national economies, contributing to technology transfer, foreign trade and promoting innovation and national economic development. The economics concept of monopolies is directly applicable to patent laws as patents are often branded with that somewhat, value-laden term. Some argue this may not really be correct. For instance, Giles S. Rich, offers a definition of the term monopoly which may be of significance:

[43] Scott F Kieff, Pauline Newman, Herbert Schwartz Smith, *Principles of Patent Law, University Casebook Series,* 4th Edition, Foundation Press, (2008) pg. 39
[44] Kieff et al, (2008), pg. 49
[45] Jeremy Bentham, *An Introduction to the Principles of Morals and Legislation*, in J.H. Burns and H.L. Hart (eds) Clarendon Press (1996) pg. 12
[46] Robert L Ostergard, 'Intellectual Property: An International Human Right?', (1991) 21(1) Human Rights Quarterly 156-178

"A monopoly is an institution…. For the sole buying, selling, making, working, or using, of anything, whereby any person or persons……. Are sought to be restrained of any freedom or liberty that they had before or hindered in their lawful trade…. Letters patents are not to be regarded as monopolies, but as public franchise, granted… for the purpose of securing…. As tending to promote the progress of……. The useful arts." [47]

Patents do give the potential for market, or even, monopoly power but patents themselves rarely lead to monopoly power. In fact, the average patent confers too little monopoly power on the patentee in a meaningful economic sense…. And sometimes it confers no monopoly power at all.

A monopoly is described as an entire market. Markets tend to order themselves around consumer demand. Producers tend to sell what consumers will buy. In some instances, monopolies are confused with competition, in that new non-infringing products are invented around the original, which may supply the same market, giving rise to competitive products and prices.

Patents share some aspects of monopolies and a prime example is in the case of pharmaceuticals where the patent may provide an effective barrier to entry to the market in sales to at least a certain class of patients having an acute illness that they are unable to wait for the development of alternative non-infringing solutions or for patent expiration. In this case the limited market at this time and for these patients is a monopoly. In the longer term however, and for less acute patients, the market may be entirely competitive. In assessing patent and monopoly microeconomics, the important lesson is that no monopoly exists if there is a substitute available to sate consumer's demand. The more substitutes there are for the patented product, the higher the elasticity of demand, the more horizontal will be the patentee's demand curve.[48]

Thus, the economic theories underlying patents suggests four incentives that have been postulated to justify the patent system: The incentive to invent; the incentive to disclose; the incentive to commercialize; the incentive to design around. These

[47] Giles S Rich, 'The Relation between Patent Practices and the Anti-Monopoly Laws' (1942) 24 J. Pat. Off. Soc'y 85-106

[48] Giles S Rich, 'Principles of Patentability' (January 1960) 28 George Washington Law Review 2,

incentives form the basis of modern patenting systems and has meandered its way into the pharmaceutical sector, which forms the basis of this research project.

The illusion is that the patent system will deliver the protection and the information it is supposed to deliver. These costs are likely to be heaviest for those who are new to the system or lightest for those with more experience. This also encompasses the costs society incurs in frustrated expectations of innovation. In an attempt to further unpack this thought it appears that "The Costs of distortion" theory emerges. The system is supposed to help meet society's requirements for innovation, but it seems to happen the other way around. Discouraged innovation is seen by the empirical data from small and large firms. Nonetheless, proponents of a structured approach to innovation appear to suggest that patenting is averse to innovation.[49]

Sir Hugh Laddie[50] puts forward a different approach to looking at intellectual property: and contends that there is a significant difference between the civil law and common law approach to intellectual property rights. For civil law, the justification for creation and enforcement of such rights is the belief that the author has a moral right to retain control over his intellectual creations. In the latter, it appears that economic policies drive the justification.

Although the language of fairness may be used as an additional tool to sell intellectual property rights to the politicians and the public, both the existence of intellectual property rights and the scope of protection has to be justified on the basis that the commercial benefits to society outweigh the disadvantages of restrictions on competition.

Jim Lahore and Anne Duffy[51] argue that a legal system which offers protection to the creator of confidential information, while at the same time granting patent protection

[49] Stuart Macdonald, in Peter Drahos and Ruth Mayne, (EDS), *Global Intellectual Property Rights: Knowledge, Access and Development,* Basingstoke: Palgrave Macmillan, (2002), Drahos and Mayne (2002), pg. 35

[50] Vaver and Bentley, (eds) *Intellectual Property in the New Millennium: Essays in Honour of William R. Cornish*, Cambridge University Press (2004) pg. 91

[51] Vaver and Bentley, (eds) *Intellectual Property in the New Millennium: Essays in Honour of William R. Cornish*, Cambridge University Press (2004) pg. 202

to suitably qualified inventors, must accept that there may be hard cases when the two very different protection regimes come into conflict.

This is the type of conflict that has raised inquiry into the patent system and to investigate how a balance can be achieved in protection Vis a Vis access. The case is made even more significant for basic commodities which have been given special attention through the international rights system. Applying this concept to the health system requires in-depth analysis of the quadrants and no doubt incorporates access and cost considerations. Such considerations are significant in addressing public health requirements for cheaper medication which would assist in alleviating poverty.

Dissecting the figures reveal that poverty appears to be the reason why over two billion people have no regular access to even the basic list of a few essential drugs. It was suggested that when TRIPS is fully implemented, it will effectively deny access to essential drugs to many more millions of people which could lead to a situation where over 50% of the world population will have no access to essential drugs.[52] Kumariah Balasubramanian[53]contends that health is a consumer concern, poverty a major determinant on health, which is the commonest cause of ill health. The majority of households in developing countries pay for their own healthcare services. Poverty is the main cause of lack of access to drugs and poverty is on the increase according to UNDP, 1999. The Report by Consumers International and Health Action International (CI/HAI) studied the retail prices of sixteen drugs in 36 countries. Although the report appears to be a bit dated and new figures will need to be assessed, the study is indicative of the importance placed on assessing the cost issues surrounding pharmaceutical access.

An added dimension to the discussion includes an understanding of the linkages to other protection mechanisms, such as trade secrets and of course the significance to utilising the generics industry, which will be addressed in turn.

[52] R&D from UNDP Report (1999)

[53]Kumariah Balasubramanian, 'Access to Medicines: Patents, Prices and Public Policy- Consumer Perspectives', in Drahos and Mayne (2002), pgs. 90-107

The link with Trade Secrets as a possible method of protection.

This section makes a case for appropriate linkages with patents and trade secrets. The importance of this is to indicate various means that innovators can utilise in protecting their inventions.

When an inventor has achieved an advance in the art, there is a key initial decision to make. One must determine whether to keep the advance secret and rely on the law of trade secrecy or disclose the invention to the public in the hope of obtaining the temporary monopoly accorded under the Patent Act. Although inventors can rely on trade secrets, such are only offered protected by common law against illegitimate disclosure or misappropriation. However, anyone who achieves the same result independently is entitled in law to use it and may even be able, under certain conditions, to obtain a patent for it that is valid as against the first inventor who decided to keep the invention secret.[54] A trade secret is good against the world as long as it is not known. There are advantages for this mode of protection provided that the workings of a device or a process or a formula can effectively be kept secret.

A patent on the other hand is a secret that everybody knows, but trade secret is good only for so long as secrecy can be maintained. Nobody has a monopoly on knowledge or ingenuity. There is always the risk with a trade secret that it can be learned through legitimate acts or reverse engineering, or required disclosure, as is the case in pharmaceuticals. Patents normally triumph in the end which is harmonious with the purpose of the patent system, which is simply that a temporary monopoly is given by the state in order to encourage invention, disclosure and investment.

To the extent there is tension between the antitrust and IP laws, the IP laws in question are almost always the patent laws. There has been virtually no instance where enforcement of trade secret rights has been held to constitute antitrust violations, and relatively few instances of copyright assertions running afoul of the antitrust laws. There are a number of cases where antitrust violations involving trade-marks have been asserted, however the vast majority of cases involving IP/antitrust involve patents.[55]

[54] John C Stedman, 'Trade Secrets', (1962) 23 (1) Ohio State Law Journal

[55] Dr. Bertold Bär-Bouyssière, Marta Lozano Bueno and Ivanka Zdravkova, DLA Piper UK LLP, "Pharmaceutical

Understanding the interplay among Patents, Generics and Competition Law

Originators have over the years sought to use patent law to impede activities associated with bringing drugs to the market.[56] Patent infringement issues and defences mainly encountered in the context of generic entry includes the new Regulatory review defence in Europe, which may have led to the 2000 Canada Patent Protection of Pharmaceutical Products, where the Panel found that Canada's regulatory review defence is consistent with Art 30 TRIPs but found a manufacturing and stockpiling defence not to be. Differences in national implementation of the Regulatory Review defence in Europe are rampant.[57]

Until recently, outlawing abuse of a dominant position in the relevant market, has featured little in the pharmaceuticals sector in Europe. In part this has been because of the general practice of the Commission in determining the nature of the 'relevant market' in the pharmaceuticals sector, to analyse this at the third level of the Anatomic Therapeutic Classification (ATC).[58]

It reflects the view that a monopoly of a single pharmaceutical does not confer dominance in the market for treatment of those conditions for which that particular pharmaceutical is indicated and the mere ownership of a patent or other intellectual property right does not of itself confer dominance, and that its mere exercise cannot in and of itself constitute an abuse.

IP and Competition Law in the EU: Overview", Thompson Reuters (2017)

[56] Case C-74/03 *SmithKline Beecham PLC v Lægemiddelstyrelsen* [2005] ECR I-00595, Opinion of AG Jacobs 16 (September 2004)

[57] Art 31 TRIPs and Competition Law Issues – Art 82 EC Treaty – Case T-321/05, *AstraZeneca AB and AstraZeneca PLC v. European Commission*, [2010] ECR I-02805

[58] Phillip W Grubb*, Patents for Chemicals, Pharmaceuticals and Biotechnology, Fundamentals of Global Law, Practice and Strategy*, Fourth Edition, OUP (2004)

The introduction of defences such as the *Bolar exemptions*[59] seem to provide a much-required balance in that it allows information to be shared for experimental use and in some cases, supplying for experimental purposes and stretches to extemporaneous preparation of a pharmaceutical product. Nonetheless, this defence comes with its own set of limitations but for now the defence appears to be the saving grace for generic companies and governments wishing to address efforts on access.

The contribution of the international patent system in monopolising private rights.

Based on the theoretical and jurisprudential approaches to patenting some insight into the practicalities of patent system is required, highlighting international system, the EU and Canadian system and an introduction into SPC's. This information is necessary to understand the background to genesis of extra layers of protection justified by industry which consequently, distorts access efforts.

The international standard mandated for the registration of patents for any invention sets the premise of this discourse on patenting. The standard includes: the invention is must be a patentable subject matter, passed the three-step test of novelty, inventive step and utility and enablement. Once an application is lodged and the minimum formality requirement is met, the invention gets protection for twenty, (20), years from that date. Under TRIPS Term of Protection[60] means "*The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date*."[61]

Although an application can be made via different routes: nationally,[62] regionally,[63] internationally,[64] the basic requirements are observed through all routes. National applications are made through the respective countries system where each country

[59] Article 30 TRIPS and Article 10.6. Council Directive (EC) 2001/83 on the Community code relating to medicinal products for human use [2001] OJ L311/67 *(*Medicines Directive).

[60] Article 33, TRIPs

[61] It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

[62] National route through the IP office in each country where protection is being sought

[63] Through systems such as the EPC or the African States- OAPI

[64] Patent Cooperation Treaty, administered though WIPO

follow their own legislation, which by now ought to be TRIPS compliant. The PCT system allows for a quick simplified formalities process where protection is sought in multiple jurisdictions. PCT[65] applications are lodged at WIPO but ultimately gets granted through the national offices. It is important to note that the PCT application does not give any rights per se as it does not result in a grant but it is converted to a number of national or regional applications with all formality checks conducted at the international Bureau.

Interestingly, norm-setting in IP appears to have been shifted from the ambit of WIPO and has become a major trading matter which is governed through the WTO system, in particular the TRIPS Agreement. The Agreement sets the tone for a harmonised trading standard where IP is concerned which has caused a plethora of issues and an active post agreement era which saw the emergence of legislative changes, circumvention and anti-circumvention mechanisms as well as systems being instituted to safeguard particular industries, the pharmaceutical industry being key to this.

Despite the modest ambitions of TRIPS, *"Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade",*[66] it has become much more as any discussion on IP is incomplete without reference to TRIPS.

What difference does TRIPs make? It puts IP on a world stage with patent at centre stage. Essentially it is meant to allow the developing world the advantages that use of, and invests in, modern technology can bring, whilst the developed world secures an adequate return on its research and development. In return for enforcing patent rights, the developing world becomes eligible to join the international high technology community.

There is a parallel to be drawn between developing countries and most firms in the developed world but their interest in the patent system is not dissimilar. The attitude of large pharmaceutical firms towards the enforcement of their patents in the

[65] Patent Cooperation Treaty (PCT), Done at Washington on June 19, 1970, amended on September 28, 1979, modified on February 3, 1984, and on October 3, 2001
[66] Preamble to TRIPs

developing world has prompted some questioning of the motivation behind TRIPS and of the implications of the new world patent order. The experience of large pharma denying drugs to the poor lest their patent position in the world's richest markets be compromised, seems at odds with the promise of TRIPS to operate in a manner conducive to social and economic welfare, balancing rights and obligations. This brings to the play the use of mechanisms to foster the balancing of rights including the compulsory license regimes, particularly, in cases of emergency. James Love[67] in his assessment of the government authorisation to use patents without the permission of the patent owner in developing countries through compulsory licences summarized that the hurdles are endless: administrative processes, government use, setting compensation, discrimination by field of technology.

The relevance of TRIPS to this discourse is two-fold: firstly, to demonstrate that the SPC system may have had its roots as a circumvention system post-TRIPS, and secondly, to illustrate the genesis of access to health issue. According to the Agreement Members shall give effect to the provisions of this Agreement and May, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.[68]

One of the areas that Members have used sparingly and have tried to circumvent involves the term of protection which saw the SPC system being codified into EU law just about 2 years post TRIPS and during that intervening period the international trading system, as it relates to patents, saw an ultra-active time.

[67] James Love, 'Access to Medicine and Compliance with the WTO TRIPS Accord: Models for State Practice in Developing Countries', Drahos and Mayne 2002 pgs. 74-89
[68] Article 1(1), TRIPS

1.2. THE IMPACT OF EUROPEAN IP LEGISLATION ON PATENTS AND ACCESS.

This section demonstrates the relationship between EU law and IPRs and fosters an understanding of how the European legislation utilised international concepts within its system which gave rise to the use of term extensions, consequently given rise to more intense monopoly.

The terms European, EU, EC are used interchangeably to refer the EEA which consists of the EU, Norway, Iceland and Lichtenstein and for the purposes of this research, the terms European, EU and EC refer to this block of countries except where the information shows a divergent view or is specific to a particular country or sub-region within that area. In the same light the reference to Member States and or Community relates to the EEA, specifically where the SPC Regulations are in effect.

Intellectual property law is impacted by Community law in one of two main ways: under the Treaty, taking into account the provisions of non-discrimination, free movement and competition; and in areas where substantive IP legislation in Member States have been harmonized, in most cases, supplemented by a communitywide unitary protection through the use of a Directive. Directives appear to be the preferred vehicle for achieving harmonisation particularly as they normally have direct effect on national legislation. Although different mechanisms are employed nationally to implement EU legislation which most times depends on the type of legislation, a treaty must be ratified by a referendum or an act of Parliament. An EU Regulation has general application and Member States, at national level, are not required to legislate in order for an EU Regulation to have direct effect but a Directive does not automatically become law nationally, it has to be implemented by national legislation. Although a Directive sets out the Member State's obligations, Member States are free to determine the manner in which it implements these obligations.

The European Commission and the Court of Justice of the European Union (CJEU) ensure that the obligations of the Member States under EU legislation are fulfilled. Any suspicions of infringement of EU Law, the Commission may refer such matter to the CJEU to investigate and rule on the matter. If the Court rules that the Member State has not fulfilled its obligations, the Court will order the Member State to cease the infringement immediately or face penalties. The EC is also a party to the European

Economic Area (EEA) Agreement.[69] These include the Member States of the EC and Iceland, Norway, Sweden, Switzerland which is referred to as European Free Trade Area (EFTA). In the early days of the EC, mindful of the potential impact of IPRs on the efficient functioning of the Common Market, working parties on patents, trademarks and designs were set up with a view to establishing Community-wide or unitary regimes, however such did not come until later on.

It appears that whatever the right being protected, it ought not to breach Article 1 to Protocol 1 of the European Convention on Human Rights (ECHR), in that natural persons are entitled to the peaceful enjoyment of possessions and ought not to be deprived of such except in the public interest and subject to the conditions provided for by the general principles of international law. The ECHR appears more prone to find that Article 1 to Protocol 1 applies to granted intellectual property rights[70] as well as applications,[71] but less reluctant to find breach of Article 1 to protocol 1.[72] The issue here is mainly that many of the cases on pharmaceutical patents and access are centred on corporations, which, most often, falls outside the ambit of the ECHR but more as a matter for patenting and regulatory rules and procedures.

Such procedures are enshrined in national patent laws although considerations are also made for applications facilitated by the European Patent Convention, EPC, through the European Patent Office, EPO**.**[73] Patent protection through this medium

[69] The Agreement on the European Economic Area of 2 May 1992 (1994) OJ Li/1.
[70] *Smithkline & French Laboratories v the Netherland* (Application no 38817/97, decision of 9 September 1998)
[71] *Anheuser-Busch v Portugal* (Application no 7349/01, Judgment of 11 January 2007)
[72] 2009/2241(INI), *Institutional aspects of accession by the European Union to the European Convention for the Protection of Human Rights and Fundamental Freedoms* <https://oeil.secure.europarl.europa.eu/oeil/popups/printbasicinformation.pdf?id=583164&lang=en> accessed 30 September 2017

[73] The EPC contains the text of the Convention on the Grant of European Patents (EPC) applicable since 13 December 2007 the EPC Implementing Regulations as in force since 1 May 2016; also included is an amendment to those regulations which enters into force on 1 November 2016, the rules of procedure of the European Patent Office's boards of appeal and Enlarged Board of Appeal which are included for the first time in the edition of the EPC, the protocols which are integral parts of the EPC (Protocol on the Interpretation of Article 69 EPC, Protocol on Centralisation, Protocol on Recognition, Protocol on Privileges and Immunities, Protocol on the Staff

does not remove the requirement for national filings but facilitates simplified procedures and multi-state filings despite the fact that it is not an automatic right, as the EPC is not fundamentally an EU law construct. Noteworthy, since 2010, further agreements provides for European patents to have effect in non-contracting states ("validation agreements") which have far reaching effects as these validation agreements are not limited to European countries.[74]

The significance of this is that, in a simplistic view, the EPC provides for Applicants for a European patent have a simple and cost-effective way of obtaining patent protection in such countries. If an applicant submits a request for extension or validation and pays the requisite fee(s) in due time, European patent applications and patents can be extended to/validated in these countries, where they will in principle have the same effect as national applications and patents, will be subject to national law and will enjoy essentially the same protection as patents that the EPO grants for EPC contracting states. Nonetheless, patents remain a national grant for applicants wishing to just use the national route. It is important to note that registration, maintenance and prosecution of patents continue to follow national procedures.

A snapshot of the future of patenting in the Europe shows that the unitary patent may have an impact on how SPC's operate and on access overall**.** The model of the new patent system for Europe was finalised in 2013 and has two main limbs: the establishment of a Unified Patent Court; and regulations creating a Unitary Patent. To date, (the cut-off date), the system is still in its infancy but when it goes live, it may radically alter the patent landscape in Europe. For now, 24 of the 28 Member States will be part of the system when it comes into effect and although a date is not fixed but is not likely to begin operation until 2022.[75]

Complement) an extract from the EPC Revision Act of 29 November 2000 the Administrative Council's decision of 28 June 2001 on the transitional provisions under Article 7 of the Revision Act and the Rules relating to Fees.

[74] Official documentation on such matters can be viewed - JURI/5/20581; JURI/7/00061, accessed from <https://oeil.secure.europarl.europa.eu/oeil/home/home.do> accessed 25 September 2017

[75] Announcement on EPO's website available at <https://www.epo.org/law-practice/unitary.html> accessed August 2020.

Looking ahead, the system which was originally due to begin at the end of 2017 seeks to provide patentees with the option to apply for a single, pan-EU Unitary Patent covering most of the EU, on a EU-wide basis and unlike the EPC, this system will allow three possible routes for making filings: National patents, to be granted at the local IP office; A European Patent, prosecuted centrally by the EPO and giving the applicant on grant, a bundle of national patents covering the chosen countries; A Unitary Patent, also prosecuted by the EPO, but giving the applicant a single patent covering however many European Member States are signed up to the system at the date of the patent grant. With the United Kingdom's exit of the EU, how this affects patenting in the UK remains to be assessed.[76]

The final point on the European system of patents involves an introduction to the SPC's which, arguably, confer a separate right that comes into effect immediately on patent expiry but confers, in relation to the relevant active ingredient, authorized as a medical product, the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations. The relevant EU legislation came about as France and Italy had already legislated nationally for patent term extensions, introducing a potential barrier to the free movement of goods within the Community trade.**[77]** At the time, the EPC was not a community measure and it could not be amended sufficiently rapidly to provide for the true patent term extensions. This prompted the new legislation to address extensions and further codification of all previous legislation exists in the newest Regulation.[78] More recently, a proposal for a Waiver has been accepted and the new Regulations became operational in July 2019, details if which will be explored further in later chapters.

[76] Revision and Updates given in Charles Rivers 2018-2019 Report

[77] See further discussion on the Regulation in Trevor Cook, *Pharmaceuticals, Biotechnology and the Law* Reed Elsevier (UK) Ltd, (2009) pg. 576

[78] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (SPC Regulation)

1.3. THE IMPACT OF CANADIAN IP LEGISLATION ON PATENTS AND ACCESS.

In order to understand how the specific focus works in the Canadian context a comparative assessment of the systems is required. This section reveals that there are divergent systems of patenting in operation, albeit, in adherence to international standards which is examined.

Patenting in Canada does not present a radical shift from what obtains globally, however, the country utilises its plurilateral political system in its medical industry and by extension, pharmaceuticals. Canada's system appears to facilitate greater access of generics to the market and contains the most active compulsory licences system. Canada does not legislate term extensions under its patent laws but instead grants "restoration for time lost", details of which will be discussed in a different section.

In Adherence to international obligations, Canada has ratified a number of international conventions or agreements relating to the protection of intellectual property, which are important to developing an understanding of Canadian law. The Paris Convention for the Protection of Industrial Property, the Agreement establishing the World Trade Organization, North American Free Trade Agreement, and the Berne Convention are of significance.[79] It is important to note that in Canada, a treaty or convention must be implemented by domestic legislation as they do not have direct effect although a treat may be referred to in the context of interpreting the provisions of the legislation implementing it.[80] Ultimately, in Canada the Parliament of Canada has reserved Federal jurisdiction over patents of invention[81] and the Federal Court has exclusive jurisdiction over conflicting applications for a patent and all matters relating to patents.[82]

The Patent Act[83] overseas many patents related issues and consequently all matters relating to matters of contract between private parties but the Federal court does not have overall jurisdiction, even though the subject matter may relate to a patent. A

[79] John S McKeown, *Canadian Intellectual Property Law and Strategy: Trademarks, Copyright and Industrial Designs,* OUP (2010) pg.2

[80] Gordon F Henderson, (Eds), *Patent Law of Canada*, Carswell Thomson Professional Publishing (1994) pg.4

[81] *Halsbury Laws of Canada*, First Edition, Volume HPT (2016 Reissue) Pgs 143 -591

[82] Constitution Act, 1867 (U.K.), 30 & 31 Vict., C. 3, S.91(22)

[83] (CAN) Act, R.S.C. 1985, c. P-4.

superior court of a province may deal with questions of contract and patent infringement or validity between the parties however, no court may make a declaration in respect of letters of patent of invention when such declaration is not expressly or impliedly contemplated by the Patent Act or other statute within the legislative jurisdiction of Parliament but in the end Federal Court has jurisdiction in respect of an issue concerning compulsory licences under the Patents Act as it relates to infringement.

A further look into the system shows that in terms of rights, the Patent Act gives the owner thereof the exclusive right of making, constructing and using an invention and vending it to others to be used, subject to adjudication.[84] In effect a patent excludes others from the exploitation of the claimed invention rather than to confer rights with respect to the invention on the patent holder and operates in the usual manner statutory monopoly which operates as a bargain entered voluntarily by the patentee with the duty of disclosure where the inventor must give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a person skilled in the art to which the invention relates, to contrast or use the invention when the period of monopoly expires.[85] The international standards on term of protection appears to be adequately adopted in that, the period of protection for applications filed prior to October 1st 1989, 17 years from the date that the patent was granted.[86] Where such a patent had not expired as of July 12, 2001, the term is 17 years from the date of grant or 20 years applies from the filing date, whichever term expires later.[87] For a patent granted upon an application filed after October 1, 1989 the period of patent protection is 20 years from the date of filing the application in Canada. [88]

Certain safeguards are built in to the system where the Competition Act[89] prohibits the exploitation of a patent that unduly limits the facilities for transporting, producing, manufacturing, supplying, storing or dealing in any article or commodity which may be

[84] (CAN) Patent Act, R.S.C. 1985, c. P-4, s. 42.
[85] *Consolboard Inc. v. MacMillan Bloedel* (Saskatchewan)Ltd., [1981] S.C.J. No.44, [1981] 1 S.C.R. 504 (S.C.C.)
[86] (CAN) R.S.C. 1985, c. P-4, s.45(1)
[87] (CAN) Patent Act, R.S.C. 1985, c. P-4, s. 45(2)
[88] (CAN) Patent Act, R.S.C. 1985, c. P-4, s. 44
[89] (CAN) R.S.C. 1985, c. C-34

the subject of trade or commerce,[90] restrains trade or commerce in relation to any such article or commodity,[91] prevents the manufacture or production of any such article or commodity or unreasonably to enhance the price thereof[92] and prevents or lessons, unduly, competition in the production, manufacture, purchase, barter, sale, transportation or supply of any such article or commodity.[93] Relief is available in the Federal Court on information of the Attorney-General of Canada but Competition law violation may operate as a defence to patent infringement. Interestingly, a compulsory licence to import a medicine may operate to avoid infringement.[94] A clearer picture of how this operates will be discussed in a later section on to show how Canada has handled access matters however, this section turns to patent term extension, "Restoration" in Canada with a view to facilitating an understanding of the influence the EU foreign policy has on domestic legislation of other countries it contracts with, in this case Canada, and provides an indication of legal transplant which impacts access.

Grasping the nature of the new Canadian system for added time: "Extension" or "Restoration"?

Whether it is norm setting or transplantation, the EU appears to be influencing the manner in which other countries handle their affairs, in particular, as it pertains to IP, a look at what obtains in Canada provides insight.

A prime example surrounds the 2014 Comprehensive Economic and Trade Agreement (CETA) between Canada and the EU, in negotiation since 2009.[95] Although the agreement touches most areas of trade, it appears that the area that has seen the most controversy or debate is the potential impact on the pharmaceutical industry. Adam Falconi[96] has dissected this issue and suggests that despite the fact that adequate protection is provided for in Canada for pharmaceuticals, the CETA proposes additional protection which includes: the availability of patent term

[90] (CAN) Competition Act, R.S.C. 1985, c. C-34, s. 32(1)(a)
[91] CAN) Competition Act, R.S.C. 1985, c. C-34, s. 32(1)(b)
[92] CAN) Competition Act, R.S.C. 1985, c. C-34, s. 32(1)(c)
[93] CAN) Competition Act, R.S.C. 1985, c. C-34, s. 32(1)(d)
[94] *Wellcome Foundation Ltd. V. Apotex Inc*., [1990] F.C.J. No. 1175, 34 C.P.R. (3d) 191 (F.C.T.D.).
[95] This landmark agreement was signed on October 30, 2016 and entered into force on September 21, 2017.
[96] Adam Falconi, 'CETA: An Opportunity to Fix Canada's Broken Pharmaceutical Patent Linkage System' (2015) 27 Intellectual Property Law Journal 326-354

restoration for time lost in pharmaceutical regulatory processes and the implementation of equivalent and effective right to appeal for all litigants that engage in a linkage mechanism where the granting of market authorisation for pharmaceuticals is linked with patent protection.

This not only indicates the usual tactics employed by the major players in WTO trade but is commensurate of the way in which the decisions and norm setting at the international level has the wholesale effect of changing whole industry sector legislation and administration. Apparently, Canada seems to be a usual target in this regard as due to TRIPS and the 1993 NATFA, it was forced to change its approach to the smooth entry of generics to the market by abolishing its compulsory licensing system which commenced since 1923.

CETA, in effect introduced a 2 year "restoration" for lost time and although the system appears to be a copy of the SPC system, it operates differently in certain respects and many experts have not considered it a term extension as such.[97] CETA also represents a progressive trade agreement that upholds and promotes the values that Canada shares with the aims to boost trade, generate growth and jobs. CETA anticipates changes in barriers to trade with European countries, including lowering of customs tariffs which may see an adoption of usually elevated standards associated with manufacturing and human rights in Europe.[98] In light of the Agreement the patenting system in Canada has undergone some review which resulted in wide-ranging legislation implementing various provisions of the federal budget introduced in Parliament in February 2018.[99] The relevant legislative review concerns the codification of the experimental use provisions relating to infringement under patent law and generally, these amendments appear to comply with international obligations in patenting.[100]

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[97] See further Commentary/Announcement by the European Commission <https://ec.europa.eu/trade/policy/in-focus/ceta/index_en.htm> accessed 15 April 2018

[98] See further, https://warwick.ac.uk/fac/soc/law/elj/jilt/2003_1/macdonald/

[99] In particular, The *Budget Implementation Act, 2018, No. 2*, Statutes of Canada 2018, received Royal Assent on December 13, 2018.

[100] https://www.lexology.com/commentary/intellectual-property/canada/smart-biggarfetherstonhaugh/five-important-changes-to-patent-act-now-in-effect

1.4. THE CONVERGENCE OF THE HUMAN RIGHT TO HEALTH, ACCESS AND PATENTED MEDICINES

The right to health and access discourse through international rights systems is key to achieving an overall view of the issues affecting access to pharmaceuticals as such rights are clearly defined in international instruments. Further, a causal link to access to patented medicines can be achieved through existing, appropriate channels, albeit, laden with hurdles.

Right to health and access to medicines is by far a contemporary phenomenon. The normative development of the Human Right to Health and of the Access to Medicines can be seen as originating from the U.S. President Franklyn Roosevelt in his famous "four freedoms" speech. The right is to health appears in Article 25 of the UDHR and in the preamble to the WHO Constitution. Stemming from these instruments, it has been captured in a plethora of agreements and national constitutions. Article 12 of the ICESCR[101] specifically recognises the right to everyone to the enjoyment of the highest attainable standard of physical and mental health, a right which is dependent on state obligations to take steps, to the maximum of its available resources, to achieve full realization of this right including those necessary for: the provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; the improvement of all aspects of environmental and industrial hygiene; the prevention, treatment and control of epidemic, endemic, occupational and other diseases; the creation of conditions which would assure to all medial service and medical attention in the event of sickness.

The United Nations[102] adds it voice to the call and reminds states that the right to health is closely related to and dependent upon the realization of other human rights and sternly encourages countries to practise non-discrimination in health facilities in that goods and services must be accessible to all, especially the most vulnerable or marginalised sections of the population. The UN comment stressed that the right to health, in all forms and at all levels, contains two interrelated and essential elements:

[101] International Convention on Economic, Social and Cultural Rights, adopted December 16, 1996, S. Exec. doc. D, 95-2 (1977), 993 U.N.T.S. 3 (entered in force January 3rd, 1976) [ICESCR]
[102] General Comment No. 14, The Right to the Highest Attainable Standard of Health (Art.12), U.N. Doc E/C.12/2000/4 (2000)

Availability and accessibility and within the context of this research, availability and accessibility will ultimately depend on cost and States public health's rapport with local patients having timely access to treatment. Numerous authors and theorists contend that a direct relationship presents itself between access to cheaper medication matters and a government's ability to provide adequate healthcare to its citizens[103] within the public health sphere.

Public health measures tend to fall into two overlapping categories; health promotion and or disease prevention and control. Health is usually the responsibility of the individual but when the state of health becomes beyond one's control and more particularly, if one's state of health becomes a threat to others, then the time for individual action has passed and it may be necessary for government to step in to institute measures to protect the community, even when it entails threats to the rights of the immediately affected individual. Matters are complicated by the fact that threats to public health can appear quickly, without warning but with potentially devastating effects around the world, for example, the H1N1 in Mexico in April 2009, Ebola in Africa in 2014 and more recently Covid-19 pandemic.

A prime example of this demonstrated in greatest public health concern of all time, HIV/AIDS. The virus attacks the human immune system leaving the individual exposed to any number of opportunistic diseases. Around 34.2 million people worldwide were living with the virus[104] and by November 2020, the number reached 38 million.[105] Developing an anti-retroviral drug which can slow the progress of the disease has been a key factor addressing the global situation but significant public health issues remain, in particular, access to those drugs, most especially in developing countries. Numerous countries also continue to impose restrictions on entry, stay, residency and access to adequate care for people living with HIV. Yet, States, now seem to take more interest in the health of their citizens than before. This may be a simple matter

[103] See further, J.K. Mason & G.T. Laurie, Mason & McCall Smith's, *Law & Medical Ethics*, Ninth Edition, OUP (2011) pg. 30ff

[104] *UNAIDS Report on the Global AIDS Epidemic* (2010), available at <http://www.unaids.org/en/> accessed 12 September 2019

[105] *Report on The Global Impact of HIV & AIDS* (2020), <http://www.HIV.gov - https://www.hiv.gov/hiv-basics/overview/data-and-trends/global-statistics> and UNAIDS, Global HIV and AIDS Statistics - 2020 Fact Sheet - <https://www.unaids.org/en/resources/fact-sheet> accessed 23 December 2020.

of sound investment or a largely economic policy designed to avoid longer term, greater costs dealing with a chronically ill population. Either way, governments spend vast sums of money trying to persuade or gently coerce their citizens into healthier lifestyles.

In so doing governments have had to update and upgrade their public medical law which appeared scattered in a wide range of international treaties, covenants, agreements and laws which collectively seek to address human rights holistically, incorporating liberties intrinsic to sustaining human lives.[106] Such no doubt incorporates healthcare rights. Many states do little more than pay lip service to these measures and continue to implement domestic laws in flagrant breach of their provisions.[107] Understanding these rights make more sense in gaining a deeper understanding of TRIPs and its contribution to the discourse.

TRIPS as a generator of challenges and benefits

TRIPS related matters are paramount as it may be considered almost incomplete if any discussion on patents in pharmaceuticals without a discourse on access issues which does not touch on TRIPS. As a matter of fact, access and certain TRIPS provisions are synonymous and totally inseparable. Whereas there is legislation totally dedicated to pharmaceuticals and IP/patents, respectively, the situation on the ground dictates that there ought to be legislation that bridges that gap. Indeed, the international organisations, amid the constant battles between originators and generics and governments, have sought to attempt to address the situation. Whether it is a solution or whether it has spurned additional issues is a matter for discourse.[108]

The TRIPS Agreement remains the leading multilateral treaty regulating the protection of inventions, including pharmaceutical patents.[109] Numerous academics have delved into the background and negotiations leading to the adoption of TRIPs in 1994, the changes in IP protection and enforcement and implications for the developing

[106] J Griffin, *On Human Rights,* OUP (2008)

[107] J.K. Mason & G.T. Laurie, Mason & McCall Smith's, *Law & Medical Ethics*, Ninth Edition, OUP (2011)

[108] Andrea M Curti, 'The WTO Dispute Settlement – Understanding: AN Unlikely Weapon in the Fight Against AIDS' (2001) 27 American Journal of Law & Medicine 469-485.

[109] The TRIPS Agreement which came into effect on 1 January 1995, is to date the most comprehensive multilateral agreement on intellectual property.

countries in particular. Most, if not all, have given stellar accounts of the difficulties the Agreement imposed on the developing South and have sort of dissected the Agreement, highlighting the various social, economic and practical as well as political issues surrounding its implementation. Their views are also based on certain cases that occurred before, during and after TRIPs coming into effect. They all agree to some extent that patent protection adversely affects access to medicines, thus the human right to health finds much support academically[110] although their writings do not anticipate or lack an acknowledgement of the use of SPCs.

Actually, SPCs were in use in Europe even before the TRIPs Agreement. The concerns at the TRIPS negotiations were surrounded on capabilities of the South to administer TRIPS, compulsory licences, border measures and of course access issues were on the front burner. Cases from the Europe show that even during this time litigation concerning SPCs were growing but most appeared concerned with ensuring that the system works in favour of the pharmaceutical originators. The next chapter will focus on the development and use of SPCs but it is important to mention here that problems associated with using the system have led to numerous changes which resulted in the 2009 EC Regulation, but even then, most of the writings were centred around the technical side of SPCs and patenting regime rather than how its use affects access or whether the system itself is bonafide.

The main provisions of TRIPS that directly relate to this study are those on patents and flexibilities that provide an avenue for WTO Member States to promote public health and increase access to medicines, however, many of these flexibilities are concerned with the intersection of patents rights and counterfeiting and piracy.[111] Counterfeiting and piracy are often regarded as "*plagues which affect every country and appear to weaken interconnected economies and societies"*[112]*,* which most often

[110]*TRIPS: A More Detailed Overview of The TRIPS Agreement*, WTO Publication <https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> accessed 15 March 2018

[111] *Intellectual Property: WHO-WIPO-WTO Hand-Book*, Chapter 2: The Policy Context for Action on Innovation and Access, <https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch2b_trilat_web_13_e.htm> accessed 17 February 2018.

[112] Olivier Vrins & Marius Schneider, (Eds) *Enforcement of Intellectual Property Rights through Border Measures*, OUP (2012) pg. 106.

results in government spending and consumers being most affected. The EU's enforcement mechanisms have sought to address these issues head on.

Another EU construct in the arena of IPR protection, regulation and enforcement is found in the Border Measures, which has also wormed its way into the international instruments and not surprisingly embedded in the TRIPs Agreement.[113] The idea being that even if IPR regulation and administration is a domestic affair, in the event that goods or services which are not just proven to be counterfeit or pirated, but suspect, once they are moving from one domestic space to another, they ought to be intercepted at any stage. Directly towards that end the EU restricts, for want of more strict terminology, goods that are in transit through the EU, even if not intended to remain there, and are destroyed. Further, the EU has been seen to refuse to enter trade deals with countries that do not possess border measures as part of their IP regime. Notable example is the Trade Agreement between the CARICOM and the EU, where all Member States of CARICOM were to ensure that all IP legislation contained such provisions and if not, were required to give undertakings on when those would be legislated.

The international community fosters the environment for strict border measures to exist and thrive and does more than encourage LDCs to have those implemented in their legislation. In fact, there are programmes designed to assist LDCs in ensuring that their legislation is compliant with the international standards and the TRIPs Agreement.[114]

It stands to reason that SPCs are not immune from border measures in that once patents are infringed, SPCs can be infringed. In essence, despite the 20-year patent protection period has ended, a generic manufacture who produces a drug, once there is a valid SPC, that drug will be confiscated as long as it is transiting through the EU. It will be regarded as pirated. This begs the question of whether generic drugs ought to be considered pirated.

[113] Article. 66.1, TRIPs

[114] WIPO Development Agenda - The Agenda was formally established by WIPO's member states in 2007, in a decision which included the adoption of 45 Development Agenda Recommendations, grouped into six clusters, and the establishment of a Committee on Development and Intellectual Property (CDIP).

Globally, the issue of counterfeit and piracy is a worrying one which has largely been ignored until it got to the point where food for babies and medication were among the victims of what is now considered crimes. Producers of IP claim that the cost to the system is disastrous as the loss has a trickledown effect on advancement in research and development, which in turn stagnates innovation and creation. Studies show that proceeds from the sale of counterfeit and pirated goods end up in the hands of organised crime and in certain instances have amounted to deaths. While it is not within the scope of this project to tackle the merits of these claims, it is important to highlight some of the issues that arise as it touches the SPC system and interferes with access to generic drugs.

Internationally, minimum standards for border measures were set very early from the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works, which were considered a bit soft since they mainly dealt with goods bearing false trade names and indications and infringing copies of copyright material. In that era, Europe needed to protect its wines and liquors as well as music and the text sufficed. As other types of goods become massed produced and traded it became more imperative that stricter controls were required.

Another deficiency of the early conventions was that they did not touch goods in transit. The TRIPs Agreement sealed that gap. Border measures were introduced into the TRIPs Agreement as a subset to the enforcement section and was influenced by the US 301 Trade Sanction.[115] During the Tokyo round of the General Agreement on Tariffs and Trade (GATT) negotiations,[116] with the intention of strengthening the

[115] The Special 301 Sub-Committee of the Trade Policy Staff Committee (TPSC) advises the United States Trade Representative on which countries to designate as "priority foreign countries" or to include in the Watch-List. The Special 301 Sub-Committee is chaired by the Office of the United States Trade Representative (USTR) and its members include the Department of Commerce, the Patent and Trademark Office, the Department of State, the Department of Health and Human Services, the Department of Agriculture, the Copyright Office, the Council of Economic Advisers, and other agencies. U.S. companies provide extensive comments in the annual National Trade Estimate Report. The Special 301 Sub-Committee also takes the views of foreign governments and the views of U.S. embassies on intellectual property rights.

[116] *Understanding the WTO: Basics, The GATT years: from Havana to Marrakesh*, WTO Publication, <https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm#:~:text=The%20Tokyo%20Round%20lasted%20from,industrial%20products%20down%20to%204.7%25> accessed 12 October 2017

enforcement of IP, the US and the EC put forward a text on Draft Measures to Discourage the Importation of Counterfeit Goods. This led to a Draft Agreement to Discourage the Importation of Counterfeit Goods with the USA, EC, Japan and Canada being the engineers. It was that draft Agreement that formed the basis of the TRIPs Agreement.

From the viewpoint of access, supporters argue that patents restrict access in two ways: Firstly, by increasing the cost of pharmaceuticals and thus limiting their availability to individuals unable to afford the monopoly price charged by patent owners; and secondly, by channelling private firms to research treatments for diseases prevalent in industrialized countries whose affluent populations offer lucrative markets for new drugs and medical technologies. They consider this the "10//90 disequilibrium".[117]

An attempt was made at addressing the problem which resulted in the compulsory licencing system. With the intention of fixing the disequilibrium matter TRIPS[118] offered a consolation of allowing patented drugs to be used in special circumstances, particularly where there is an epidemic and there is no manufacturing. The consolation itself presented with its own hierarchy of administrative hurdles and as such caused a major upset in the patenting world and appears to have widened the north/south gap. Cases such as the Brazil/US Bayer AIDS medication in 2001[119] offer relevant learning on the state of play at the time. Other cases, mostly to do with drugs that are not readily available, demonstrate the flaws in the system.

In this vein, a review of Canada's case suggests that: If it were necessary to prohibit manufacture and use of a patented product by a competitor for the full twenty-year term, the result would be that the stream of monopoly rents to the patent holder would extend beyond the twenty-year period to the length of time after the patent had expired

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[117] Médecins sans Frontier, *Access to Essential Medicines Campaign & Drugs for Neglected Diseases Working Group, Fatal Imbalance: The Crisis in Research and Development for drugs for Neglected Diseases* 10 (2001).
[118] Article 31, TRIPs
[119] *USA VS BAYER IN 2001* - This issue came to the fore in October 2001, when the United States negotiated with Bayer to lower prices for the patented drug Cipro, which is used to treat anthrax. See further Keith Bradsher, *Bayer Agrees to Charge Government Lower Price for Anthrax Medicine*, N.Y. TIMES, (Oct. 24, 2001), at Al.

that it took the competitor to engage in testing for regulatory approval and manufacture for the market.[120]

Had it followed the requirements of the Vienna Convention, the Panel would have had to consider the meaning of the word “limited” in reference to Article 7 of TRIPS, which evokes the mutual advantage of producers and users, the notion of a balance of rights and obligations and, moreover, the notion that protection and enforcement of intellectual property rights should be undertaken “in a manner conducive to social and economic welfare”.

Recognition of the significance of the levels of protection in the TRIPS Agreement as a maximum required under WTO law is to be found in Article 1.1 of TRIPS, which explicitly states that Members shall not be “obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.”

The operation of dispositions of the TRIPS Agreement, taken together, could have the effect of conferring, overall, more extensive protection than that provided as a matter of law by each individual provision. As a study for the World Health Organization notes: “These general provisions were included in the Agreement to make for a balance between the rights of patent holders and their obligations vis-a-vis society. Member States may therefore base certain particular provisions of their national regulations on these provisions. The case at hand is a perfect illustration of this. Article 33 of TRIPS provides a legal guarantee of monopoly rents (i.e., exclusion of competition) for a twenty-year period. However, the operation of Article 28, by including the right to prohibit making or using in the patent right, acts in combination with Article 33, to provide effective monopoly rents beyond the twenty-year period guaranteed as a matter of law by Article 33. In such a circumstance, what TRIPS, Article 1.1 tells us is that a member may act to avoid the operation of the TRIPS Agreement from leading to effective protection in excess of that explicitly and legally guaranteed in the Agreement, which is, in this case, twenty years of monopoly rents. And this gives a

[120] Robert Howse, ‘The Canadian Generic Medicines Panel a Dangerous Precedent in Dangerous Times’ (July 2000) 3 (4) Journal of World Intellectual Property 493–507

coherent meaning to “normal exploitation”, namely exploitation within the limited period of market exclusivity explicitly guaranteed to the patent holder by law in Article 33.

It is significant in this respect that, while most of the developed countries who intervened as third parties in the litigation, most notably the United States and Japan, viewed the stockpiling provision as different from the testing provision, and not justifiable under Article 30, the developing country intervenors, including Brazil, Ecuador, Cuba and Thailand generally saw the two provisions as linked, and viewed both as acceptable under Article 30.

The root of the controversy may be gleaned from the attempted solution itself, Article 31 of TRIPS. Article 31 of TRIPs sets the guidance for compulsory licenses generally, however this mechanism appears to be rarely used, except in the case of pharmaceuticals, particularly outside of Europe. Article 31 now requires that a grant of compulsory licenses be subject to strict limits, such as being predominantly for the supply of the domestic market and local health emergencies which may amount to detrimental limit on their use as it does not permit for export. This itself possess a problem as many of the least developed countries lack their own domestic manufacturing capacity for pharmaceuticals and so to have wholly unable to avail themselves of the compulsory licencing in this sector by import. LDCs have challenged this which has led to a relaxation of the use of Article 31 whereby compulsory licences can now be deployed for the manufacture of pharmaceuticals for supply to those least developed countries that lack the infrastructure to manufacture their own such products.[121]

Helfer and Austin,[122] in assessing whether patents create a barrier to access to medicines, propose a refocusing of the debate away from the contribution patents versus other factors and to focus instead on how to limit the impediments that patents do impose. They did however acknowledge that it is a challenge to find how to expand affordability while also taking into account other barriers to access and maintaining incentive structures to reward medical research and innovation.

[121] DOHA WTO Ministerial 2001: Ministerial Declaration, WT/MIN (01)/DEC/1 – (20 November 2001), Adopted on 14 November 2001

[122] Laurence R Helfer and Graeme W Austin, *Human Rights and Intellectual Property, Mapping the Global Interface*, Cambridge University Press (2011) pg. 142.

Revisiting the balancing act and the Article 31, the international community, through the WTO, sought some level of success through the Doha Declaration.[123] The main thrust of the Doha Declaration, the Waiver and the subsequent Amendment was that it allowed LDCs to defer until 2016 the obligation of TRIPs, to extend patent protection to pharmaceutical products and affirmed the right of all countries to issue compulsory licences to produce low-cost drugs in national health emergencies, while acknowledging that states with insufficient domestic manufacturing capabilities cannot make effective use of such licenses. The Declaration directed the TRIPS Council to facilitate the export of generic drugs to poor countries with limited or no local manufacturing capacity.

Many commentators, in 2003, hailed this as a success and a breakthrough for access to medicines but by 2007 and 2008,[124] scholars have characterised the waiver and the amendment as so saddled with unnecessary administrative hurdles that make the export of generic versions of patented drugs neither simple nor expeditious and governments with limited capacity still have numerous practical obstacles to overcome to effectively make use the system. Both exporting and importing countries required an almost overhaul of their legislation to use the system compounded by lingering sanctions or threats previously under the earlier compulsory licencing scheme, makes developing countries reluctant to seek exporting countries. The new compulsory licences scheme also provides for remuneration to the rights holder which possess an additional burden to LDCs.

The issues are further exacerbated by developments prior and post the Declaration and Waiver.[125] It seems the main reason that developing countries are not jumping forward in using the system is that it may violate the TRIPs Plus regional or bilateral treaties they have ratified. Once more, due the lack of capacity and with the anticipatory positive ambit of the goings on at the time the developing countries ratified a number of treaties negotiated with the EU and US, in particular. These treaties

[123] Doha Declaration, Decision and Waiver - Doha WTO Ministerial 2001: The ACP-EC Partnership Agreement WT/Min (01)/15, 14 November 2001

[124] Pauwelyn Joost, 'WTO Compassion or Superiority Complex: What to Make of the WTO Waiver for Conflict Diamonds' (2003) 24 Mich J Int'l L 1177

[125] The text of the waiver can be found in the revised waiver request. WTO Council for Trade in Goods, Waiver Concerning Kimberley Process Certification Scheme for Rough Diamonds: Communication, G/C/W/432/Rev.1 (Feb. 24, 2003)

incorporate patent protection rules more stringent than those found in TRIPS. The combined effect of those treaty provisions only goes to strengthen the position of big pharmaceutical firms and erect barriers to the introduction of generic pharmaceutical products.

According to Professors Abbott and Reichman, [126] these provisions contain a common structure: extending the scope of patent protection to cover new uses of known compounds, Swiss type claims; providing patent term extensions to offset regulatory delay; limiting the scope of permissible exceptions to patent rights; prohibiting effective granting of marketing approval by the health regulatory authority during the patent term without the consent or acquiescence of patent holders; prohibiting parallel importation; limiting the grounds for granting compulsory licensing in some higher income countries.

For those who strongly support access from a human rights point of view, the SPC system appears to be more than just an elephant in the room. There is great cynicism on reasons why the EU in particular would want LDCs to adhere to TRIPS and on the other hand bind them to TRIPS Plus, in this case SPCs.

WIPO's Development Agenda attempts to provide some assistance to developing countries in an attempt to implement the 45 Resolutions adopted in 2006,[127] in particular technical assistance programmes. It is doubtful however how far these can reach as it appears that norm setting with regards to IP has been snatched from WIPO in favour of TRIPS and the WTO. Whichever international organisation is handling norm-setting, ought to consider access matters and how best to facilitate that. In so doing appropriate linkages ought to be made with the key for access being a balanced relationship with the generic pharmaceutical industry.

[126] Frederick M Abbott & Jerome H Reichman, 'Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 J. INT'L Econ, L.921, 921, 932

[127] WIPO, The 45 Adopted Recommendations under the WIPO Development Agenda, para. 10, <http://wipo.int/ip-development/en/agenda/recommendations.html> accessed 12 October 2017

1.5. LINKAGES BETWEEN ACCESS AND GENERICS AS KEY TO FORMING POLICY CONSIDERATIONS

The practicalities of considerations on reliance on generics when forming policy for public health matters is prudent. The significance of such linkages with the generic industry is that it contributes to attempts at lowering costs associated with pharmaceuticals. The key arguments made in this section surround lack of adequate access worldwide, particularly in least developed and developing countries and additional cost and time added through the use of term extensions which effectively delay generic entry to the markets.

A fundamental starting point is to bear in mind that one-third of the world's population lacks access to the most basic essential medicines.[128] Similarly most of the world's population lacks access to safe and appropriate medical devices.[129] Developing and least developed countries are the most affected by limited access to medicines and medical devices. The problem of access is multifaceted and includes: lack of a national health technology policy that ensures an efficient use of resources for the planning, assessment, acquisition and management of medicines and medical devices; inappropriate selection of drugs; improper use of drugs; counterfeit drugs; logistical problems; storage problems; lack of infrastructure; diversion of pharmaceuticals donated by international organisations. Many of these issues appear to be developing country problems but they are far reaching.

Developing countries rely on a list of essential medicines, known as the WHO Model List of Essential Medicines (EML),[130] as guidance to identify the drugs available as part of their attempts to provide cost-effective drugs for their populaces, customized to each country's needs with vaccination is a key component in the access-to-medicines agenda. It is a crucial public-health initiative and nation's health care systems depend on it. However, access to vaccines is unattainable if the prices are so

[128] Hans V. Hogerzeil and Zafar Mirza, *Access to Essential Medicines as Part of the Right to Health. The World Medicines Situation* (2011) WHO/EMP/MIE/2011.2.10, (2011), (Hogerzeil & Mirza, 2011) <https://www.who.int/medicines/areas/human_rights/articles_docs/en/> accessed 20 October 2017

[129] See further Hogerzeil & Mirza, 2011.

[130] Last updated 2019 available at <https://list.essentialmeds.org/> accessed 15 December 2020

high that people cannot gain access to it. Nevertheless, suggestions are that access to vaccines can be balanced if public policies and incentives mechanisms are put in place to address the affordability gap that makes vaccines unaffordable for developing countries.

Olga Gurgula[131] assesses two divergent concepts in patenting of pharmaceuticals: strong IP protection and open innovation. The Open Innovation model has increasingly been followed by some research institutions and pharmaceutical companies aiming at facilitating the creation of new and affordable medicines, as well as providing transparency in order to enhance safety and efficacy of drugs. Developments such as Copy-left in the copyright system are being mimicked and more and more it appears that intellectual property can be used as open sources, facilitating the creation of new medicines through providing free access to IP protected information. This open innovation model which is increasingly followed by some research institutions and pharmaceutical companies aiming at facilitating the creation of new and affordable medicines, as well as providing transparency to enhance safety and efficacy of drugs. Open science in drugs development but such is mainly driven by academics, NGOs and public research institutions.

Senai Andermeriam contends that competition from the generic business poses a major challenge to the pharmaceutical industry.[132] After an initial phase of "paper compliance" with TRIPS, followed by the efforts to manage the welfare costs of its implementation, a number of developing countries searched for ways to optimize the implementation or reimplementation of the Agreement to foster domestic competitiveness and innovation[133] resulting in displacing the geographical centres of innovation with substantial political and economic impacts.[134]

[131] Olga Gurgula, "Monopoly v. Openness: Two Sides of the IP Coin in the Pharmaceutical Industry" (2017) 20(5-6) The Journal of World Intellectual Property 206-217

[132] Senai W. Andermeriam (2007) 415, 419

[133] Daniel J Gervais '(Re) Implementing the Agreement on TRIPS to Foster Innovation' (2009) 12(5) JWIP 348.

[134] Ying Zhang and Xuezhong Zhu, 'Intellectual Property Right Abuses in the Patent Licensing of Technology Standards from Developed Countries to Developing Countries: A Study of Some Typical Cases from China' (July 2007) 10 (3-4) Journal of World Intellectual Property 187-200

Tactically, some of these measures included adopting generic production and sourcing of generic drugs which have been consequently empirically tested to be driving large price decreases in pharmaceuticals.[135] The results show that generics offer options to developing countries to make medicines widely affordable and accessible to all population segments.[136] The introduction of generic versions of drugs has often resulted in an increase in the consumption of the agents involved. A classic example is provided in the case of both drop in the cost and increased use of ciprofloxacin in Denmark.[137]

Crucial to cheaper medication discussion is the situation with SPCs which extends the period of patent protection for up to five years from the first marketing authorisation in the EC, whichever is less.[138] Arguably, it is not the term of the patent itself that is extended but the protection conferred by the patent and hence it confers the same rights and is subject to the same limitations as the patent.[139] Garland and Larusson explored the effect of SPCs on the generic trade and speculated that SPCs may have tremendous negative effects on the generic trade. [140] That speculation was based on the increased use of SPCS which are granted if at the date of application, the innovative drug is protected by a basic patent in force, a valid market authorisation is in place and the product has not already been subject of an SPC.[141] The main issue is whether the SPC only protects the product in question in the specific form mentioned in the marketing authorisation or whether it protects the active substance in the specific, authorised form and all other forms protected by the basic patent. In

[135] Rajnish Kumar Rai, 'Effect of the TRIPS-Mandated Intellectual Property Rights on Foreign Direct Investment in Developing Countries: A Case Study of the Indian Pharmaceutical Industry' (2008) 11(5-6) JWIP 404-431

[136] J Kuanpoth, 'Patents and Access to Antiretroviral Medicines in Vietnam after World Trade Organization Accession' (2007) 10 (3-4) JWIP 201-224

[137] U.S Jenson ET. Al., 'Effect of Generics on Price and Consumption of Ciprofloxacin in Primary Healthcare: The Relationship to Increasing Resistance' (2010) 65 J Antimicrob Chemother 1286, <1291<doi:10.1093/jac/dkq093> accessed 23 August 2019

[138] Article 13 SPC Regulation

[139] Article 3 SPC Regulation

[140] Paul Garland and Kristjan H Larusson, 'Data Exclusivity, Bolar Exemption and Generic Drugs in the EU' (2007) 4 EIPR 128

[141] Article 3 SPC Regulation

Farmitalia Carlo Erba Srl[142], the ECJ clarified that the certificate is capable of covering the active ingredient as well as its various derived forms such as salts and esters, as medicinal products, in so far as they are covered by the protection of the basic patent. The decision and the SPC Regulation appear to ensure that third parties are prevented from obtaining market authorisation for the same active ingredient/substance merely by using a different form for it.[143] Further, the Amendment introduces eight-year data exclusivity where generic manufacturers will be barred from referring to pre-clinical tests and clinical trials of the original, innovative drug, until after eight years from the date of authorisation of that drug. Market exclusivity has been introduced to prevent marketing of a generic drug during the two years following the expiry of the data exclusivity period. In effect it is an overlapping ten-year market exclusivity, which, practically, a generic manufacturer cannot put a generic version on the market before ten years has elapsed, protecting the market exclusivity period.[144] A further one year for" new therapeutic indications" is added if during the eight years, the innovative company brings a significant clinical benefit in comparison with existing therapies. Additionally, in the event that the product in question is considered a paediatric product, a further six months can be applied on top of the SPC time.

Dr. Hembadoon Iyortyer Oguanobi[145] makes the case for access to medicines debate to include addressing access to medical devices. His argument is that such broadening is not only a necessity in the age of technological advances in the medical field, but is an essential element of realizing the proper functioning of effective public health care for all nations. He asserts that access to medicines and medical devices go hand in hand as in many situations, physicians cannot identify which medicines to prescribe for patients without the necessary kits and equipment to diagnose a patient's

[142] Case C-392/*97 Farmitalia Carlo Erba Srl* [1999] ECR I-5553 - Judgment of the Court (Fifth Chamber) of 16 September 1999.

[143] Garland and Larusson (2007) 128, 129.

[144] V Y M Kunisawa, 'Patenting Pharmaceutical Inventions on Second Medical Uses in Brazil' (2009) 12(4) JWIP 297-316

[145]Hembadoon Iyortyer Oguanobi, "Broadening the conversation on the TRIPS agreement: Access to medicines includes addressing access to medical devices' (2018) 21 The Journal of the World Intellectual Property 70-87

ailment. Similarly high-tech surgical devices are required to perform necessary operations after diagnosis.

Thus, developing countries must include access to medical devices in the discourse on access to medicines. The effects of the patent structures within the TRIPS Agreement should be re-conceptualized to include medical devices and technologies. Medicines and medical devices are among the foundations of human progress: they reduce morbidity and mortality and improve the quality of life for millions of people around the world. This applies particularly as the granting of patents on medical devices is not a position that the majority of WTO members take. Over 80 countries prohibit the patenting of medical procedures.[146] The US and Australia are the most liberal in that regard. Australia is most liberal as it allows for the patentability of medical treatments.

The reality remains that there is grave concern that patents increase the cost of medical devices and restrict access to modern medical devices, thereby escalating the public health crisis in developing countries to achieve good health. In fact, most people in the developing world have no access to the types of surgical and therapeutic devices that require advanced technologies and /or are implantable, which put millions of lives at risk. Access to high technology diagnostic and therapeutic equipment is required for people to live longer and healthier, in the same way that they need access to pharmaceuticals. Integral to access and the medicines controversy is the so-called Bolar Exemption which appears deeply grounded in EC legislation, particularly as it relates to pharmaceuticals.[147] The research exemption refers to an exception to the rights conferred by patents and is particularly relevant to pharmaceuticals. This exemption, despite the patent rights, allows for performing research and tests for preparing for regulatory approval, and will not amount to infringement for a limited term before the end of patent term and allows generic manufacturers to prepare generic drugs in advance of the patent expiration. This facilitates timely

[146]Priyanka Rastogi, 'World Wide Legal Status Of Medical Method Patents: An Overview', (May 2014) Singh & Associates, Available from MONDAQ - <https://www.mondaq.com/india/patent/311404/world-wide-legal-status-of-medical-method-patents-an-overview> accessed 02 September 2019.

[147] The principle behind the Bolar exemption is that generic companies should be in a position to take the necessary preparatory measures in order to be able to enter the market without delay once patent protection expires." in Decision T 0223/11 dated 22 May 2012 of the Board of Appeal 3.3.02 of the European Patent Office, reasons 2, fifth paragraph.

placing of products on the market, as soon as the patent expires which in Europe is referred to as the bolar exemption[148] and in Canada, the Bolar provision or Roche-Bolar provision[149] which was introduced and called "early working" exemption as well as a stockpiling exemption.

It is forecasted that the use of the exemption, if utilised by generic companies, can yield cost savings but such appear to be smothered with hurdles, which may have spurred the world health policy that endorses measures aimed at rapid market availability of generic medicines, *"WHO supports implementation of the TRIPS Agreement to ensure prompt availability of generic drugs upon patent expiration. WHO has long promoted use of generic drugs of assured quality. Experience from countries with 'generic-friendly' policies clearly demonstrates that the market competition created by these policies increases the affordability of medicines, stimulates true innovation with the research-based industry, and encourages increased production efficiency by the generic industry*."[150]

Chapter summary

The provision of a thorough account of patent theory highlighted various issues in the practical application and operation of the patenting systems, internationally and locally, concludes that the main problems encountered in addressing public health needs centres on the controversies in achieving an appropriate balance between access and regulation. It illustrated the confusion faced by international cross-border patenting matters regarding access to medication but further delineates that the imperfect system is not near to finding a solution. Thus, world health policy suggests and encourages that the protection of public health entails, among other measures, early working exceptions for patents, (Bolar).

[148] (as amended by Directive 2004/28/EC) and 2001/83/EC (as amended by Directives 2002/98/EC, 2003/63/EC, 2004/24/EC and 2004/27/EC).

[149] Named after the case *Roche Products Inc. v. Bolar Pharmaceuticals. Co. Inc,* 733 F.2d 858; 1984 U.S. App. LEXIS 15006; 221 U.S.P.Q. (BNA) 937 - through the introduction in its Patents Act, 1993, section 55.2

[150] Dr Gro Harlem Brundtland, World Health Organization, Office of the Director-General, *International Trade Agreements and Public Health: WHO'S Role, Conference on in easing Access to Essential Drugs in a Globalized Economy*, Amsterdam, (25-26 November 1999)

Chapter Two

EXPLAINING SUI GENERIS RIGHTS IN THE CONTEXT OF PHARMACEUTICAL ACCESS

The development of term extensions and data exclusivity have always been considered sui generis rights, not belonging to either legal, IP, medical, not even strictly regulatory. With special carve outs in industry, understanding both term extensions and data exclusivity requires in-depth assessment of their relationship in both patent law and pharmaceutical regulatory systems.

Regarding term extensions, the EC itself is cognizant of the somewhat cumbersome effect that the SPC system has had on patent administration and has commissioned studies with a view to revamp it. Nevertheless, the fundamental questions remain: Has the pharmaceutical industry gone too far in its use of the SPC system? How does this impact access to more affordable medication, not just in the EU? These issues are dissected here with an exploration of the theoretical legal obstacles and ramifications imposed by such systems and makes candid linkages to hindrance to access to medicines.

By delving into the intricate workings of protection schemes, it is argued that sui generis systems operate in a manner that consequently impacts access in cost and time, the system is flawed operationally and significantly creates legal hurdles for generic entry of pharmaceutical products which may be the solution to cheaper and more available drugs.

2.1. THE EUROPEANIZATION OF PATENT TERM EXTENSIONS

Scrutinizing the development of SPC's in EU legislation allows for understanding its legal characteristics which is profound in gaining a clear picture of the prescribed administrative and legal issues associated with using the system. The section also highlights the major difficulties encountered by the courts in reaching decisions based on the legislative arrangements which, no doubt, results in the myriad of problems that exists which leads to the conclusion that the system is broken and requires urgent attention if it is to operate without causing hindrances to access.

2.1.1. The development and extent of Term Extensions in European patent systems.

In the EU term extensions are referred to as Supplementary Protection Certificates (SPCs). The system began in the 1980s, although not as a Communitywide entity, where individual countries attempted to circumvent the 20-year rule and not long after, its use started interfering in the free movement of goods within the Community. The subsequent court cases from *Farmalita* up to *AstraZeneca*, show controversy and highlights major defects in the system as well as problems Member States have encountered in trying to understand and utilise what is currently considered an EU legal construct. The EC Regulation of 2009 attempted to codify all the previous Community attempts to regularize this concept as sui generis right.[151]

It appears settled that SPCs were introduced with the sole aim of allowing innovators of pharmaceutical products to recoup what may have been lost during the regulatory period and may be considered a purely economic matter. The European Court of Justice noted that SPCs had as their primary objective, the shortcomings of the system for protecting pharmaceutical research which arise from the need to obtain marketing authorisations in order to make use of the innovation.[152] The legal relevance of SPCs is that it appears to extend the patent term using its own rules rather than purely patent principles. The economic relevance of SPCs is that it delays, analogously to a patent, the marketing authorisation of generic products and the inherent pricing competition.[153] The 20-year minimum patent term mandated by Article 33 TRIPS is generally recognised to be insufficient in the pharmaceutical and agrochemical sectors adequately to provide an incentive for research into new active substances because the term is significantly reduced by delays surrounding securing regulatory approval enabling a product to be placed on the market.[154]

Countries in the developed world have used this strategy in different models. For instance, in the US: Drug Price Competition and Patent Term Restoration Act (the

[151] See further discussions on the special nature of IP in Peter Drahos, *A Philosophy of Intellectual Property.* Dartmouth Publishing Company (1996)

[152] Case C-350/92 *Kingdom of Spain v. Council of the European Union* [1995] ECR I-1985 at 15

[153] Maximillan Haedicke and Henrik Timmann*, Patent Law, A handbook on European and German Patent Law*, Verlag C.H. Beck oHG, Wilhelmstabe, Germany, (2014) pg. 1038

[154]Trevor Cook*, EU Intellectual Property Law*, Oxford University Press, (2010) pg. 542

Waxman-Hatch Act) of 1984,[155] which regulates the term extensions for pharmaceutical products and applies to regulated food additives and to certain medical devices. Japan uses its own system of extension through its 1987 legislation. Provisions to extend the term of pharmaceutical patents in Japan became effective on 1 January 1988. The legislation provides that the patent term can be extended for up to five years from the original expiration date of the patent.[156]

Developments in the law in the other developed nations which had developed term extensions in their national markets from as early as 1984 in the USA and 1988 in Japan may have given an extra push for the system in the EU. In 1990, the EC published a proposal for a Council Regulation for the creation of SPC for medicinal products.[157] This was partly due to concerns that if something similar was not done in the EU, there was the risk of a decrease in research due to insufficient resources and relocation of research centres away to non-member countries that offered better protection and an environment better suited to innovation. Since France and Italy had begun their own form of extensions, the Regulation sought to prevent heterogeneous development of pharmaceutical patent extensions in different Member States.

The model adopted by the EU appears to be the most detailed and administratively taxing, so much so that that even the EC itself has seen it fit to revise the system and commissioned studies on the issue, which are shown in the next chapter.[158] As an illustration of the issues, six challenging areas were highlighted by the Tender document into studies on the SPC: The lack of a European SPC; Potential legal uncertainty or ambiguity in the current text of the SPC regulations and jurisprudence, as well as a need to codify part of existing jurisprudence in the SPC regulations; Ambiguity and need of additional harmonisation of the grant procedures at national level; Need to update in light of the evolution of the pharmaceutical and agrochemical innovation and business models; Risk of discrimination for new products or sectors with comparable features; The question of the 'optimal' duration of the SPC protection. Up to May 2016, the contract had not been awarded and in August 2016, a revised

[155] Public Law No. 98-417, 98 Stat. 1585 (1984).

[156] Margaret Smith, *Patent Term Extensions for Pharmaceutical Products, Law and Government Division*, Parliamentary Research Branch, Documents Reference MR-144E, (20 February 1997)

[157] COM (90) 101 final [1990] O.J. C114/10. (The Explanatory Memorandum)

[158] EU Tender Document Number: 559/PP/GRO/IMA/15/15153

call for Tender was published.[159] These studies were later commissioned and provide different dimensions of study to address the issues raised.

Delving into legislative background for the administration of the SPC system, the first Regulation for SPCs for medicinal products was enacted on June 18, 1992, EEC Regulation 1768/92 and entered into force on January 2, 1993. The Regulation was intended to be a simple and transparent system for those who needed to use it. It provided for an extension of the patent exclusivity period which was dependent on the time lost before the first authorization to place the relevant product on the market had been obtained, with a maximum extension of up to five years. It allowed for a transitional period to address products already on the market. Four years later, protection for plant protection products was granted by EEC Regulation 1610/96, the Plant Protection Regulation, 1996.[160] The SPC Regulation was again adjusted in 1994 when the EEC Agreement came into force on January 01. To date the EEA consists of the EU, Norway, Iceland and Lichtenstein and for the purposes of this research, the terms, EU, European, EC refer to this block of countries except where the information shows a divergent view or is specific to a particular country or sub-region within that area. In the same light the reference to Member States relates to the EEA.

A crucial point which concerns SPCs is that the duration set by Article 13 of the Regulations is governed by the first authorization anywhere in the EEA. This spurned some early problems and the accompanying litigation[161] for example, Spain's challenge to the validity of the MPR, which was rejected.[162] Other amendments to the text include those done when there were accessions to the European Union in 1994, 2003 and 2005, respectively. Article 20 provides for additional provisions relating to the enlargement of the Community. 2006 saw the amendment of the Medicinal Products Regulation 1768/92 to include the possibility of a paediatric extension of the duration of up to six months, intended to encourage pharmaceutical companies to

[159] Sally Shorthose, (Ed), *EU Pharmaceutical Regulatory Law*, (Kluwer Law International B.V. 2017)
[160] The relevant EU legislation is Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96 on SPCs covering pharmaceutical and plant protection products respectively, referred to as The SPC Regulation.
[161] Novartis Case - *Novartis Ag V Comptroller-General Ministre De L'economie V Millennium Pharmaceuticals Inc.*, [2005] R.P.C. 33
[162] Case C-350-92 *Kingdom of Spain v Council of the European Union* [1996] FSR 73.

extend the scope of their authorisations to include treatment for children.[163] In an attempt to achieve some level of simplicity legislators adopted a codified version of the MPR and on May 6 2009 that version was published in the Official Journal and which drew together all the relevant amendments made to the earlier regulation which is intended fully preserve the content of the acts being codified.

These SPC Regulations are instruments of EU law and as such are to be treated in the usual manner as EU law. Transitional arrangements were provided under Article 20, where the provisions are not to apply to certificates granted in accordance with the national legislation of a Member States before 2 January 1993 or to applications for a certificate filed in accordance with that legislation before 2 July 1992 with particular measures being carved out for the benefit of Austria, Finland and Sweden, not to apply to certificates filed in accordance with their national legislation before 1 January 1995 and with regards to SPCs granted in accordance with the national legislation of Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Malta, Poland, Slovenia and Slovakia prior to May 1 2004 and Romania January 1 2007.[164]

It was anticipated that these provisions would provide a harmonised system of operation for the SPC system in the EEA, the effectiveness of which is not fully covered in this research but is given attention in the recently concluded studies. What is crucial to this research is the legal character of SPCs and how it operates in real time to impede access. The importance of the legal character forms the backbone of in its *sui generis* nature and for this reason deserves some attention. Despite having revised Regulations to address the various deficiencies in the SPC system, the legal character appears to be in the balance.

2.1.2 Exploring the "Rights" given under SPCS

Part of the unsettled nature of SPCs is that it appears purely regulatory under the marketing authorisation scheme and competition law, but it takes effect under patent law and is incorporated in most patents administration, nationally. This raises the

[163]Margherita Colangelo, 'Reverse Payment Patent Settlements in the Pharmaceutical Sector under EU and US Competition Laws: A Comparative Analysis' (September 2017) 40 (3) World Competition 471-504.

[164] Article 22 repealed Regulation (EEC) No 1768/92 as amended.

question of whether a separate right is attached to an SPC and in so doing considers aspects of registration relevant to such considerations.

Generally, IPRs, especially those associated with patents, occur almost automatically on creation or once an application for registration is submitted. This is not the case with SPCs as they depend on factors outside the patent system to be in harmony for their very existence and subsistence. Outside of an application being made, there is always copyright protection and other forms of IPRs that can be invoked to protect an invention. The IPRS that require registration, in practice, must undergo a formality check after which, details of the application are published. The information is public, but others are restricted in their use of it. Even when the invention is registered, if the subject matter is so special, the government can utilise the compulsory license scheme. In the case of pharmaceuticals, the government agency merely must show that it is required because of a national emergency and use the invention with or without remuneration.

Normally an IPR is not really granted, it just exists. Registration allows other rights to be added, mostly economic, which restricts what other persons can do with that right. It naturally follows that if a right is totally dependent on other rights subsisting and the result of that right is purely economic, this leads to a belief that such a right may be devoid of whatever it is that signals it being ‘special’ and it should find protection under systems that protect economic rights. Protection for economic rights are afforded under the patent system and forming a quasi-patent system within the patent legislation appears a little more than devious.

A look at the acknowledgement of wines and liquors under trademark legislation lends a classic example of how rights can have some special characteristics but without the need for registration. Some were not special enough to be GI’s and TM did not adequately provide for them. Even if they are protected under GI’s, trademark law allows some form of protection, but there is no system of registration under TM law, they are automatic. It must be noted though that the special nature of wines and liquors appears to be a European injection. The system is so special that there now exists in the WTO a deposit system for names of wines and liquors. Can SPCs become so special?

Additionally, registered IPRs usually are required to pass the originality and or novelty test. A look at the SPC system shows no such requirements. Normally patents rights are not considered primary rights but are based on compensation for loss. As a regulatory matter, SPCs may find themselves more at home there. An attempt at a definition the term regulatory is that it is largely composed of liability rules designed by the state to incentivise people to act in ways which the state considers to be in the public interest.

Importantly an SPC cannot be obtained under the EPC.[165] The main issue with its legal character rests with interpretation of the terms "product" and "basic patent" which have given rise to much controversy but is specified as "any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use … under the terms and conditions provided for in this Regulation, be subject of a certificate."[166]

In a simplistic way, a reading of Articles 1 and 2 suggests that an SPC can be applied for any medicinal product, protected by a basic patent, which is designated by its holder for the purpose of the procedure for grant of an SPC, protected in the territory of a Member State and subject prior to being placed on the market as medicinal product, to an administrative authorisation procedure. Article 3[167] attempts to make sense of it all and provides for a certificate to be granted on application, if at the date of that application: the product is protected by a basic patent in force; a valid authorisation to place the product on the market as a medicinal product has been granted; the product has not already been the subject of a certificate; the authorisation

[165] In the UK, Schedule 4A was inserted by the Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007 (SI 2007/3293) reg.2 with effect from December 17, 2007 and was amended by the Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2014 (SI 2014/2411), with effect from October 1, 2014.

[166] Article 2 SPC Regulation

[167] Article 3 SPC Regulation – granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate.

referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

Interpretation of these sections reveals that the SPC is dependent on the subsistence of conditions outside the patent system which questions its operations as an IPR. The issues raised in the courts indicate that the legal nature appears to be still in the balance. *Prima facie*, it appears that, inherently, SPCs give very little rights, if at all, and merely extending the term of patent that gives rights.

This very issue raises questions in the overall administrative process and affects the practicalities of making applications, grant and post grant matters and most definitely the scope of protection offered. In understanding the scope of protection, the SPC is said to confer a separate right, comes into effect immediately on patent expiry but confers, in relation to the relevant active ingredient authorized as a medical product (or as a plant protection product), the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations. A sharp contrast is provided by Dr. Kunz-Hallstein[168] who argued that the SPC would create a separate right which will differ from patents which are subject to the EPC. Dr. Kuntz-Hallstein's idea of the "Certificate for the Restoration of Protection" (CRP), would create a right separate and distinct from the patent right which would be allowed only in relation to products subjected before marketing authorisations procedure and then only in respect of those authorisations. It was not intended to be granted in return for the disclosure of an invention, nor is the scope of protection defined by reference to any claims. A precondition for obtaining a SPC is the patent, defined in the claims but creates a new right whose extent is determined by the authorisations, thus the SPC is not an extension of the patent term but a new right, which is not consistent with Article 63.[169]

[168] Dr H Kunz-Hallstein, "The Compatibility of a Community 'Certificate for the Restoration of Protection' with the European Patent Convention" [1990] European Intellectual Property Review 209

[169] A Report by The Common Law Institute of IP, (1991) (CLIP) Report, pg. 15

Other jurisdictions offer divergent legislative framework and more emphasis is placed on the opinion of the regulatory authority, for example, in the USA[170] if the FDA is satisfied that the criteria are met, it advises the USPTO accordingly. In the EU there is no linkage between the national Patent Offices and the national regulatory authorities in that manner however the extent of these "rights" are governed by a peculiar relationship between these institutions.

The extent of the "Rights" under SPCs

A preliminary point to understanding that relationship requires a decoding of the extent of these rights, in terms of, the term of protection, what is protected, and who is protected.

The Regulation for medicinal products establishes a five-year maximum period for the SPCs duration with fifteen years maximum effective monopoly. The duration of an SPC is calculated by taking the time elapsed from filing the application for a basic patent to the date of first marketing authorisation and subtracting five years subject to a maximum of five years total duration. If the period between patent filing and first marketing authorisation is less than or equal to five years, no SPC will be granted. If the period between patent filing and first marketing authorisation is less than or equal to five years, no SPC will be granted. If the period between filing and first marketing authorisation is greater than or equal to ten years, the maximum duration of the SPC will be granted. Conditions for obtaining an SPC were reiterated in *BASF's SPC Application (2000).*[171]

The term of protection is linked to what is protected. The product defined in respect of an SPC application must have undergone safety and efficacy testing before being "placed on the market in the European Community as a medicinal product for human use". Otherwise, that product will not be subject of a certificate. Although the basic patent may expire before the certificate is granted, it is not possible to apply for an SPC after patent expiry. Dissecting the system suggests that the proprietor of a patent

[170] See Pamela J Clements, 'The Hatch-Waxman Act and the Conflict between Antitrust Law & (and) Patent Law' (2007) 48 IDEA 381, 408

[171] *BASF's SPC Application (2000)*

and an SPC will enjoy an overall maximum of 15 years of exclusivity from the first marketing authorisation placed in the community.

The Regulation does not define "protected". *Farmitalia*[172] suggests that due to a lack of harmonisation, this will be determined nationally and be based on the interpretation of the claims. ECJs ruling in Farmitalia[173] indicated the issues that are likely to pose problems and sought to tackle them early nonetheless, the uncertainty regarding what amounts to a product under the Regulation spurred a myriad of cases including *Takeda* and *Estellas* which resulted in the Court of Appeal referring several matters relating to the interpretation of Art. 3(a) and art. 3(b) in relation to combination products, in particular multi-disease vaccines, to the CJEU for a preliminary ruling under *Medeva.*[174] Many questions were posed concerning the criteria for determining the product protected by the patent in force, active ingredients, and multi-disease vaccine, comprising multiple antigens, whether all antigens are protected by the basic patent, single active-ingredient or combination of active ingredients. This case was joined by *Georgetown University et al*[175] which concerned questions on whether single or combination active ingredients were protected.

Again, the term "active ingredient" is not adequately addressed by the Regulation and so the courts have been rather busy trying to entangle the various scenarios that present themselves for resolution. The decisions range from: where an SPC for a combination of active ingredients has already been granted on the basis of a patent protecting that combination, Art. 3(c) does not preclude the grant of an SPC to a single active ingredient which, individually, is also protected by the same patent.[176] In other instances it was held that where an SPC for an "innovative" active ingredient has been

[172] Judgment of the Court (Fifth Chamber) of 16 September 1999. - Farmitalia Carlo Erba Srl. - Reference for a preliminary ruling: Bundesgerichtshof - Germany. - Proprietary medicinal products - Supplementary protection certificate. - Case C-392/97, *European Court reports 1999 Page I-05553*, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61997CJ0392&qid=1606948422870> accessed online 22 October 2019

[173] Catherine Katzka, 'Interpretation of the Term 'Product' In EU Council Regulation 1768/92 and 1610/96 On Supplementary Protection Certificates' (2008) 3 (10) Journal of Intellectual Property Law & Practice 650.

[174] C-32/10 *Medeva BV v Comptroller-General of Patents, Designs and Trade Marks* [2012] R.P.C. 25. CJEU considered; *Novartis v MedImmune* [2012] EWHC 181, [2012] F.S.R. 23, Pat Ct

[175] Georgetown University, Loyola University, and University of Rochester's SPC application BL O/401/09

[176] Georgetown University ET. Al. (2013)

granted on the basis of a patent protecting that active ingredient, then art. 3 (c) precludes the grant to the same proprietor and on the basis of the same patent of further SPC for combination of that active ingredient with another active ingredient, where that other active ingredient is not protected by "as such" by the patent.[177]

The differing views raised further questions which the CJEU sought to answer in the Judgement in *Actavis v Boehringer*[178] where the Court observed that it is possible, in principle, on the basis of a patent which protects several different 'products', to obtain several SPCs in relation to each of those different products, provided, inter alia, that each of those products is 'protected' as such by that 'basic patent' within the meaning of Article 3(a) of Regulation No 469/2009, in conjunction with Article 1(b) and (c) of that regulation. Without providing any guidance on the law, the CJEU concluded that grant of an SPC for an active ingredient which constitutes 'the sole subject-matter of the invention' of the basic patent precludes the grant of a second SPC based upon a claim in the same application.

The non-harmonisation of laws in the EU Member States results in the answered questions not being addressed harmoniously and so more questions were referred to the CJEU. In *Eli Lilly,*[179] the same questions were referred to the CJEU with the addition of the case of a claim to an antibody or a class of antibodies, is it sufficient that the antibody or antibodies are defined in terms of their binding characteristics to a target protein, or is it necessary to provide a structural definition for the antibody or antibodies, and if it is, at what cost? It was clarified in the ruling given on December

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[177] *Actavis Group PTC EHF v Sanofi [2013] Reports of Patent, Design and Trade Mark Cases*, Volume 130, Issue 8, August 2013, Pages 583–609, <https://doi.org/10.1093/rpc/rct048> accessed 15 December 2020

[178] Case C-577/13 *Actavis UK Ltd v Boehringer Ingelheim Pharma GmbH & Co. KG [2015] OJ C 146, 4.5.2015, p. 4–4*

Judgment of the Court (Eighth Chamber) of 12 March 2015 (request for a preliminary ruling from the High Court of Justice (Chancery Division) United Kingdom) Reference for a preliminary ruling relating to medicinal products for human use — Regulation (EC) No 469/2009 — Article 3 — Supplementary protection certificate

[179] Case C-493/12 *Eli Lilly and Company Ltd v Human Genome Sciences Inc, [2012] OJ C 9, 12.1.2013, p. 33–33*- Reference for a preliminary ruling from High Court of Justice (Chancery Division) (United Kingdom) made on 5 November 2012

12, 2013 that in order to satisfy Art. 3(a), it is not necessary for the active ingredient to be identified in the claims of the patent by way of a structural formula may satisfy the requirement of Art. 3(a) but only on condition that it is possible to reach a conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention.

Another problematic area exists in defining what is protected, concerns medical devices. The Regulation does not specifically extend to medical devices however the question was raised as to whether in relation to a medical device, authorised in accordance with the Medical Device Directive 93/42, which incorporates as an integral part a substance which if used separately can be considered to be a medicinal product within the meaning of Directive 65/65 (now replaced by Directive 2001/83), an SPC could be obtained for that substance.[180] The court took the view that despite the silence of the Directive, that need not be a bar to the application of the Regulation if the safety, quality and usefulness of the substance for which an SPC was being sought was verified as part of the authorisation procedure, being a procedure analogous to that for a medicinal product. Similar arguments may be put forward for other device Directives such as Directive 90/385 on active implantable medical devices and Directive 98/79 on in vitro diagnostic medical devices.

This makes the issue of extending SPCs to devices a live one as already highlighted by the section on open access and access issues. The significance of this is that since there is a distinct possibility that the SPC regime may be extended to cover medical devices, the scope will be tremendously broadened and so getting the system to work effectively will be paramount.

The complexities of time and product also stretches to who is protected, particularly where there are two or more applicants. In *Biogen*[181] the Court had already ruled that where a medicinal product is covered by a basic patent, the Regulation does not preclude the grant of an SPC to each holder of a basic patent. The court had not explicitly considered the situation where two or more applicants for the same product emanate from one patent holder whereas the practice of many patent offices is to allow

[180] *Genzyme Biosurgery Corp v Industrial Property Office*, BIE 70 (2002) 360-362 (Netherlands)
[181] *Biogen v SmithKline Beecham Biologicals* (C-181/95) [1997] R.P.C. 833

only one SPC from such applications as was done in *Takeda's* case.[182] The principle was applied subsequently[183] where the Hearing Officer found that it was not inequitable to deny a patent holder more than one certificate for a product whilst allowing other patent holders one certificate for that product.

In reaching decisions on this issue, it seems that the relationship between companies do not matter as such in determining whether to grant SPCs to multiple applicants and there are cases where the UKIPO for example has granted SPCs relating to the same product where the basic patents are in the name of different companies apparently belonging to the same group. The issue of granting multiple SPCs for different products granted on the basis of a single patent protecting more than one product, has been a live one for the courts[184] however it was held that only one certificate may be granted for each basic patent which protects an active ingredient or a combination of active ingredients and that the provision prohibits the grant of more than one certificate for each basic patent.

Currently, it seems the best way to evaluate the rights conferred by SPCs as well as the obligations of the holders, is through the decided cases and references to the courts. As indicated in previous sections the rights associated with IPRs are usually categorised as property, knowledge, moral and or open access. The courts appear to have been busy trying to understand use of the system by rights holders to untangle the various ambits of confusion. Cooke suggests that it is not, strictly speaking, correct, to speak of the SPC as conferring 'patent extension' even though it is convenient so to do, instead, the SPC is a separate right which comes into force, immediately on patent expiry, but confers a separate right in itself.[185] Issues surrounding the right will no doubt depend on how industry utilise them in practise by the pharmaceutical sector.

[182] *Takeda Chemical Industries Ltd.'s Applications* [2004] R.P.C. 2
[183] *Knoll AG's Application* BL O/138/05
[184] Case C-130/11 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents* [2012] Judgment of the Court (Fourth Chamber) of 19 July 2012

[185] Cooke 2010, pg. PG. 357

2.2.3. The Extension and its use by pharmaceutical companies

Separate and inherent right or not, having a valid SPC provides some form of extension to the patent term. Based on the legislation and decided cases, it is possible to get not just 5 years but an additional 6 months can be added to the already extended term under the MPR as an incentive to the industry to investigate and develop medicines for children,[186],[187] although "Zero Term SPCs" can be issued. A zero term SPC occurs where under normal calculation rules of Art.13 of the MPR results in a duration which mathematically left no time for extension or a negative number. *In Merck & Co's Application*[188] it was decided that an SPC could be granted although that a positive value for the term of protection does not result when the calculations are made. The decision appreciated the fact that the purpose of such a certificate was to keep open the possibility in future of applying for a paediatric extension.

Despite protests from the European Commission[189] that a zero term SPC should not be granted and that no basis for such an approach existed in the MPR neither the Regulation on Medicinal Products for Paediatric Use, the Court of Justice[190] subsequently approved the grant of zero term certificates based on the intended utility for applicants making use of the paediatric extensions. An applicant may have a choice in certain cases to either apply for a six-month extension on an SPC or a one-year extension under the data exclusivity clause which provides for extension on the premise that a new paediatric indication brings significant clinical benefit in comparison with existing therapies.[191]

To put the foregoing into context of how the pharmaceutical industry has navigated through the system, a look at the data is instrumental. Official data from study

[186] See Minutes of all meetings are available at: <http//thespcblog2.blogspot.co.uk> accessed 29 September 2017 - This issue was specifically addressed at the third meeting of national SPC experts on September 2008. The applicable legislation comprises of amendments to the MPR which became effective January 26th, 2007. These amendments now form part of the codified MPR as well as the Regulation on Medicinal Products for Paediatric Use (EC) 1901/2006.The aims and objectives of this amendment was concisely stated in *E I Du Pont Nemours & Co v UKIPO, E I Du Pont Nemours & Co v UKIPO*

[187] *El Du Pont Nemours & Co v UKIPO* [2009] EWCA Civ 996; [2010] R.P.C. 6, CA 31

[188] Decision BL 0/108/08 of 14 April 2008

[189] Notes from the First and Second Meetings, 3rd February 1995 and 9th October 2006

[190] Reference from the German Patent Office in Merck Sharp & Dohme Corp;
Case C-125/10: Judgment of the Court (Second Chamber) of 8 December 2011, Merck Sharp & Dohme Corp. v Deutsches Patent- und Markenamt.

[191] Article 36(1) of Regulation 1901/2006.

conducted on actual working time, by the EC[192], from 2006 to 2015, the 7 pharmaceutical companies, combined, filed 29% of all SPC applications within the EU. In comparing how large a percentage of the total SPC filings each company makes up to their 2015 sales, it appeared that a correlation was made between the size of the company, measured by 2015 sales and their relative share of all SPC filings. This may be particularly the case for companies such as Novartis, MSD, GSK, BoerhingerIngelheim and Bayer Group. Alternatively, when likewise looking at Janssen and Sanofi, this relationship seems to disappear. As such, the conclusion that there is a clear relationship between company size and the share of all SPC filings is not supported by the numbers.

The Copenhagen Economics report also indicates that on the issue of whether or not an SPC can be applied for is dependent on the development time, based on the premise that there is no clear relationship between sales and share of SPC filings, suggests that companies have different development profiles of their pharmaceutical portfolio. This might stem from companies concentrating on different therapeutic areas and that the development time for medicine in general differ across therapeutic areas.

The issue regarding the marketing authorisation being in place is ongoing and poses difficulty for applicants and the courts. In the UK for example a marketing authorisation must have already been granted.[193] A marketing authorisation for the same product in another Member State or granted later in the same Member State after patent expiry will not suffice and the Authorisation must include a summary of product characteristics.[194] It is important to note that a full marketing authorisation is required so a letter granting permission to carry out a clinical trial was deemed not sufficient.[195]

[192] Copenhagen Economics, *Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe*, (2018), pg. 243, European Commission website accessed 14th April 2019

[193] *Yamanouchi's SPC Application,* BL 0/112/93, noted I.P.D. 17136
[194] (SmPC) as required by Art. 8(1) (b).
[195] *British Technology's SPC Application* [1997] R.P.C. 118

2.2. UNDERSTANDING THE PHARMACEUTICAL REGULATORY ENVIRONMENT IN THE CONTEXT OF ACCESS

Access concerns should be examined alongside pharmaceutical regulatory issues which contribute to norm setting and the various legal underpinnings of medicinal drugs. This is important to demonstrate that there are factors outside the patenting system that co-exists with patents, to impact the cost of pharmaceuticals by causing further delay to generic entry and makes appropriate linkages with the regulatory requirements for pharmaceuticals and access. Such linkages reveal that the regulatory system, working in tandem with the SPC system, operates to contribute additional hurdles to generic entry. Operation of SPCs and the regulatory system for pharmaceuticals function in tandem and appear to be so intertwined that it is almost impossible to address one without the other. This includes discussion concerning technological Development, pharmaceutical production consumption and trade, in particular those factors that directly contribute to cost. Exploring the regulatory base for pharmaceuticals allows for a thorough understanding the key stages of a pharmaceutical product.[196] and the regulatory principles and the legislative hurdles that may operate and contribute to deterred access.

2.2.1. Exploring pharmaceutical prices through the lens of EU pharmaceutical regulatory framework

Key to exploring pharmaceutical prices centres around the cost associated with bringing a drug to the market. Bringing a drug to the market involves various processes, regulated via numerus legislative changes and through diverse institutions.

Several factors influence cost but patent and regulatory requirements remain huge contributors. Usually, the first step that companies take once they have figured out that they have a product or process that may be considered a pharmaceutical. Normally patents are supposed to signal ownership to the world and to stop others from using the idea, at least for a twenty-year period. Protection normally starts from

[196] EFPIA, *The Pharmaceutical Industry in Figures*, 2015 Edition <http://www.efpia.eu/uploads/Figures_2015_Key_data.pdf> accessed 19 August 2019

the filing date of the application, which is normally the earliest date when the necessary request and appropriate fee was submitted to the IP office and once the formality checks are complete. A grant of a patent is normally issued within five years of a filing date. Although details of the application are published within 18 months of the filing date only the applicant or any authorised person can make use of that information including produce, import, export, licence, sell and authorise others to do these acts. Even before they are sure that the product will pass the other stages, an application is made to ensure monopoly.

Then there are Clinical Trials[197] which represent a rigorously controlled test of a new medical product or device, on human subjects that is intended to determine the clinical pharmacological, pharmacokinetic and or pharmacodynamics effects of that agent or device or to identify any adverse reactions to that agent. These tests are required in order to assess the safety and efficacy of the investigational agent before it is authorised for release to the public. Clinical tests normally take place before the launch of a new product and is strictly regulated. In all cases approval is granted only if satisfactory information demonstrating the quality of the investigational agent and its non-clinical safety has been provided alongside a study plan those details how the trial will be conducted. The study plan must include a systematic investigation of the effects of the materials or methods to be studied and the study must comply with ethical guidelines and Good Clinical Practice (GCP) Guidelines.[198] The final authorisation for the conduct of the trial must be obtained from the Competent Authority of the Member State in which the trial will take place.[199]

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[197] In the EU clinical trials are legislated by Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

[198] Table 1 Principles of Good Clinical Practice

Principles of the Declaration of Helsinki - WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, 1964, 2013 Revision, available at <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> accessed 14 March 2018

See also World Health Organisation (1995) *Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products*, WHO Technical report Series, No. 850: 97–137.

Having completed the clinical trials, the pharmacovigilance process begins. This refers to the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long-term and short tern side effects of medicines. Pharmacovigilance is achieved through the collection, monitoring, assessment and evaluation of data on the adverse effects of medical products.[200] The data normally comes from healthcare providers and patients, which is then evaluated in order to understand the effects of the products on humans and to prevent harm to humans. Pharmacovigilance is an important step during the clinical trial for safety and efficacy reasons,[201] however some side effects may not become apparent during the testing phase therefore post marketing pharmacovigilance to reveal any patterns in adverse drug reactions, (ADRs) is extremely important and is legally required.[202]

Marketing Authorisations, (MA), come into play after the owner of a product makes a patent application, has gone through the clinical trials including the pharmacovigilance at various stages, before the product can be launched to the market. Normally the MA is granted following an assessment of the safety, efficacy and quality for that medicine based on the data provided by the applicant and will stipulate the conditions, indications, patient population and dosage etc for which the medicine is authorised, together with any conditions imposed on its use or on the MA holder in terms of post authorisation commitments.

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[199] Guideline for Good Clinical Practice, 1 December 2016, EMA/CHMP/ICH/135/1995 Committee for Human Medicinal Products, available at <https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf> accessed 14 march 2018

see also EU Directive 2001/20/EC and Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services, (2011)

[200] Communication from the Commission (CT-3), 2011/C 172/01 – Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use.

[201] WHO Technical Report No. 498

[202] Council Regulation (EC) 726/2004 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 L136/33*

MA is regulated by the 2001 Directive 2001/83/EC[203] which codified and consolidated in a single text all the previous Directives and many years of legislation and case law on medicinal products for human use. The Directive must be used in conjunction with the Regulation No (EC) 726/2004 which regulates the EMA as well as other legislation that concerns various types of medicines such as orphan drugs.[204] A MA is normally valid for five years from the date of grant and may be renewed after five years if, when the regulatory authority re-evaluates the product, it finds that the benefits still outweigh the risks. After an initial renewal, the MA is valid for an unlimited period, unless the regulatory authority decides that it should be subject to one additional five-year renewal which decision can be based on justified grounds relating to pharmacovigilance. Once a MA is issued then manufacturing, marketing and distribution of the product follows in whatever format suitable to the industry standards, which may also include other IPR's such as trademarks.

Consequently, the major EU Pharmaceutical Legislation being not contained in a single piece of legislation but encapsulates various stages of development of the pharma regulatory machinery.[205] The significance of the codification is that it brought together all relevant legislation in an attempt to reform.[206] Directive 2001/83/EC has been amended by twelve further Directives between 2003 and 2012 and was amended by a Corrigendum in 2007.This Directive, as amended, has been termed the Medicinal

[203] European Parliament and Council Directive of 6 Nov. 2001 on the Community code relating to medicinal products for human use, above

[204] Art 14(4) and 14(5) Regulation (EC) No. 726/2004; Art 24(4) and 24(5) Directive 2001/83/EC

[205] Sally Shorthose (ed.), Bird & Bird LLP, *Guide to EU Pharmaceutical Regulatory Law*, (Seventh edition, Kluwer Law International Bv, The Netherlands, 2017) See further Council Directive 65/65/EEC of January 1965, Directives 75/318/EEC/319/EEC of 20 May 1975, Directive 75/319/EEC established the Committee for Proprietary Medicinal Products (CPMP), which is today referred to as the Committee for Medicinal Products for Human Use (CHMP), Directive 65/65/EEC, Council Regulation (EEC) 2309/93.

[206] See Further Council Directives, 65/65 EEC; 75/318/EEC; 75/319/EEC; 89/342/EEC; 89/343/EEC; 92/25/EEC; 92/26/EEC; 92/27/EEC; 92/28/EEC; 92/73/EEC.

Code (MD)[207] and is also responsible for administering data protection and abridged applications for marketing authorisations in the pharmaceutical industry.[208]

The European Medicines Agency (EMA), being the central body responsible for drug and medicine regulation in the EU, has published a document explaining the general legislative framework and the hierarchy of the legislation and guidelines,[209] which, among other things, attempt to bring together all major ethical and regulatory matters concerning the production, testing, marketing and administration of pharmaceutical products on humans. Taking into consideration that the primary purpose of medical research for human subjects surrounds understanding the causes, development, and effects of diseases, and to reach and improve treatments and also includes prevention, diagnosis and therapeutic methods. In so doing medical products need to be evaluated constantly to ensure they meet the required standards of safety, effectiveness, efficiency and quality throughout the life of the product. Likewise, those involved in medical research have a duty to protect the life, health, dignity, integrity, right to self-determination, privacy and confidentiality of personal information of research subjects.[210]

These issues bring to the fore the correlation between the regulatory environment and protection for pharmaceutical manufacturers, provides substance to the overarching protectionist platform within which the industry strives and which it introduces the concept of regulatory data protection, data exclusivity.

[207] Council Directive 2001/83/EC as amended by Directive 2001/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components; Directive 2004/24/EC of the European Parliament and the Council of 31 March 2004; Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010.

[208] Ian Dodds-Smith, 'Data Protection and Abridged Applications for Marketing Authorisations in the Pharmaceutical Industry', *in Golberg and Lonbay, Pharmaceutical Medicine, Biotechnology, and European Law*, (Cambridge University Press 2000), pg. 93.

[209] EMEA/P/24143/2004 'Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework' (2009) Revised 18th March 2009.

[210] World Medical Association Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects (October 2013)

2.2.2. Linking protection with regulatory data (data exclusivity) that impacts access.

Regulatory Data Protection (RDP) refers to the protection that is afforded to the pre-clinical and clinical trial data generated by an innovative bio/pharmaceutical company in support of an application for a MA. It aims to protect innovative scientific data against unfair commercial use and is specifically addressed under provisions in the TRIPS Agreement.[211]

A biological medicinal product authorised in accordance with Article 8(3) of the Medicinal Code may serve as a reference medicinal product for the purpose of abridged applications, (to be discussed below), brought by other companies. Before any applicant can apply there are periods of protection afforded to the data regarding the so-called reference medicinal product. In summary, a supporting application will benefit from an eight-year period of regulatory data protection running from the date of the authorisation in the EEA/EU. An additional 2-year period of marketing protection can be added to the product and a further 1-year period of marketing protection (covering the full dossier) may become available if within the first eight years from the date of the authorisation, the MA holder obtains an authorisation for one or more new therapeutic indications. In effect, the generic or biosimilar applicant can apply for the MA after the eight-year period of RDP but they cannot enter the market until marketing protection expires. This is now commonly referred to as the 8+2+1 regime. The rules have been implemented in various ways across Member States but in the EU such protection can be traced back to Directive 65/65 and specific legislation to protect the required scientific data supporting the grant of an MA was introduced in the EU Legal framework by Directive 87/21/EC.

Because no medicinal product can be placed on the EU market without an MA. To obtain an MA the applicant must demonstrate the quality, safety and efficacy of the medicinal product by providing results of pharmaceutical tests, pre-clinical trials and clinical trials. These require significant financial investment and resources. In recognition of such investment, the medicinal code provides for a period of protection

[211] Article 39(3) TRIPS

during which the scientific data generated by the originator company in support of its MA cannot be referred to by a generic applicant in support of its own application.

The RDP period commences from the date of notification to the originator application for the MA. In contrast to patents, it does not create a monopoly in the market, in the sense that any other company that has undergone all its tests and has its own data even for a similar product can obtain RDP for its own data. Thus, the strength of the RDP is dependent on how complex and expensive it is for the third party to generate its own set of data. Under the new rules (after 30 October 2005), or 20 November 2005 if submitted through the centralised procedure, the harmonised period of 8 plus 2 plus 1 formula: 8-year period of RDP and two or three years of marketing protection. It means that a generic company has to wait 8 years before they can rely on the data or apply for an MA and cannot enter the market for another 2 or 3 years depending on the specific circumstances. The 1 year of market protection may be obtained if within the 8 years following the MA the holder obtains an authorisation for a new therapeutic indication which brings a significant clinical benefit in comparison with existing therapies. This incorporates 8 years – data exclusivity; 2 years – marketing protection; 1 year – significant clinical benefit.

The global concept of MA entails one period of RDP and marketing protection applies for all medicinal products of the same family authorised through the separate procedures including different member States. Therefore, a scientific data submitted to obtain authorisation for additional strengths, pharmaceutical forms, variations or extensions will be covered by the RDP and marketing approval afforded to the initial product. The global concept was introduced by the CJ ruling in *Novartis*[212] whereas attempts to circumvent the RDP and marketing protection see *Plavix.*[213] RDP is construed as an IP right with backing under TRIPS but not all Member States provide for the procedural means for defending IP regulatory rights which is sees as a violation

[212] See *Novartis Ag V Comptroller-General Ministre De L'economie V Millennium Pharmaceuticals Inc*., [2005] R.P.C. 33, (Novartis Case)

[213] Case C-385/08 *European Commission v Republic of Poland* [2010] ECR *I-00178* Judgment of the Court (Fourth Chamber) of 22 December 2010

of the EU legal obligations but the case of *Olainfarm*[214] supports the right of originators to in jurisdictions that do not provide or provide limited legal standing to challenge generic authorisations. This challenge to generic authorisations is regarded as the access blocker, in that, it prevents the data from being utilised by generic producers.

Further, a more relevant segment to RDP is the Abridged Procedure which allows an applicant to make use of already existing and accessible data with or without the initial MA holder's consent which allows for three types of procedures: Informed consent; bibliographic and generic products which is the procedure the project is mainly concerned with. How this works in real time is that following the pharmaceutical review of 2001, Directive 2004/27/EC introduced new definitions to further improve harmonisation throughout the EU. A special procedure for obtaining MA in the final paragraph and called the Proviso. Where the medicinal product is intended for a different therapeutic use from that of the other medicinal products marketed, or is administered by different routes or in different doses, the results of the appropriate toxicological and pharmaceutical tests and or of appropriate clinical trials must be provided which is referred to as the Hybrid abridged application procedure.[215]

Changes to this Hybrid procedure after October 2005 meant that the requirement of essentially similar is not captured in the definition of a generic product under Art 10. Thus, a generic manufacturer simply needs to produce pharmaceuticals with the same qualitative and quantitative composition of active substances which has the same pharmaceutical form as the reference medicinal product. This provision allows generic producers, in a sense, room for circumventing the RDP and marketing protection offered to originators.

Furthermore, the bibliographic application under Article 10(a) of the MC provides the legal basis for an applicant to support an MA by reference to appropriate scientific literature if they can demonstrate that the active ingredient has been well-established medicinal use within the Community for at least ten years with recognised efficacy and

[214] See Case C-104/13 Olainfarm AS v *Latvijas Republikas Veselības Ministrija and Zāļu Valsts Aģentūra* [2014] ECLI:EU:C: 2014:342, Opinion of Advocate General Wahl delivered on 20 May 2014, Request for a preliminary (Olainfarm Case)

[215] The issue was considered further in the *Novartis* case, 2005.

an acceptable level of safety. The *Plavix*[216] case provides an example of generic companies attempt to utilise this route to use pre-clinical and clinical test data and bypass marketing protection afforded to the reference product. The relevance of this is that it provides that link as to why originators required that extra time under SPC's since ultimately, the test data and other information required to effectively place pharmaceutical products on the market, protection for such would effectively be eroded and generics would be able to bring products to the market much faster, cutting both cost and delays.

In sum, it should be noted that the Regulation for medicinal products establishes a five year maximum period for the SPCs duration with fifteen years maximum effective monopoly. The duration of an SPC is calculated by taking the time elapsed from filing the application for a basic patent to the date of first marketing authorisation and subtracting five years subject to a maximum of five years total duration. So if the period between patent filing and first marketing authorisation is less than or equal to five years, no SPC will be granted. If the period between patent filing and first marketing authorisation is less than or equal to five years, no SPC will be granted. If the period between filing and first marketing authorisation is greater than or equal to ten years, the maximum duration of the SPC will be granted.[217]

SPCS and data exclusivity work in tandem and are indeed reliant on MA being intact. Many of these processes not only drives cost but delays access to pharmaceutical prices falling. Richard Golberg[218] suggests that the "so-called SPCS" were instituted to address the problem of patent life erosion caused by testing and authorisation requirements of new medicinal products. He posits that where hurdles of causation, defectiveness and the development risk defence have been overcome in favour of the claimant, pharmaceutical companies need to utilise insurance and self-insurance mechanisms to cover overwhelming costs from any drug disaster and that the

[216] Quincy Chen, 'Destroying a Pharmaceutical Patent for Saving Lives: A Case Study of *Sanofi-Synthelabo v. Apotex, Inc*.' (2011) 21 Alb LJ Sci & Tech 125 accessed online via <https://heinonline-org> 12 November 2020

[217] Trevor Cook, *Pharmaceuticals Biotechnology and the Law,* Reed Elsevier (UK) Ltd, (2009)

[218] Golberg and Lonbay, *Pharmaceutical Medicine, Biotechnology, and European Law*, Cambridge University Press (2000), pg. 197.

insurance premiums cannot be expected to resolve the problem of untoward injury costs in high risk and innovative areas involving medicinal products. This may have been the justification for the increase to the effective patent life of a pharmaceutical product which spurs discussion on the money value of the interplay between RDP and SPC's on pharmaceutical prices in the Canadian context. regulation.

2.3. AN OVERVIEW OF THE CANADIAN PHARMA SYSTEM'S APPROACH TO REGULATION IN THE CONTEXT OF ACCESS

The Canadian regulatory system for pharmaceuticals provides comparison and is illustrative of a similar system in terms of the legislation but different in terms of its application. The Canadian context shows more collaborative working environment that if properly administered may improve access conditions, however, the advent of CETA changes the landscape of pharmaceutical legislation and industry and despite attempts at balance, fundamental inefficiencies of the system operate to prejudice generic manufacturers and threaten their ability to provide effective generic competition.

2.3.1. Understanding the Canadian regulatory environment and its impact on access.

Significantly, it should be noted that SPC as a separate system, is not fully operational in Canada, however, until recently, Canada provided no system for term extensions but as a direct consequence of CETA, a system of Restoration was implemented.[219] Commentators appear to be divided as to whether the system can be classified as such due to its characteristics.[220] Full implementation of the "Restoration" amendment was effected in 2017 therefore an assessment of the extent of its impact may be a bit premature. Nonetheless there appears to be a somewhat pessimistic view that such amendment will only have the effect of delaying entry of generics, thereby raising the cost of pharmaceuticals.[221]

Since, compared to the EU system, Canada on the other hand did not accommodate term extensions, not in the strict sense as the EU, Canada has tailored its pharma

[219] Guidance Document: Certificate of Supplementary Protection Regulations
Date adopted: 2017/09/21, Revised Date: 2018/06/26 Effective date: 2018/09/04 Provisions 2017-2018 - Amendment of the Patent Act, CSP Regulations 2017 - These are miscellaneous amendments that are needed as a result of the substantive amendments to the Patent Act that received royal assent on May 16, 2017.

[220] Jennifer Ledwell, "Canada Introduces Patent Term Extensions for Pharmaceutical Patents", (September 8 2017) Marks & Clerk, available at <https://www.lexology.com/library/detail.aspx?g=5957d1c5-45b0-4719-9545-62ebe098c3db> accessed November 2018.

[221] Lexchin and Gagnon, "Globalization and Health" (2014) 10:30, available at http://www.globalizationandhealth.com/content/10/1/30 accessed July 2018.

system to strike a balance between effective protection and enhanced access, which ultimately benefits payers and suits the needs of its citizens. In recent times, the system has undergone some regulatory changes in light of CETA but references to the Canadian pharma system relates to a pre CETA, (2017), situation.

Canada's system of pharma regulation is not totally different than what obtains in the EU/EC, with the exception of the input by the FDA. The FDA has the primary purpose of ensuring the efficacy of drugs marketed and sold in Canada, irrespective of patent protection, it must receive a stamp of approval by the Minister of Health. The pieces of legislation at play in the Canadian pharma system include: The Patents Act;[222] The Food and Drugs Act;[223] The PM(NOC) Regulations; Regulatory Impact Analysis Statement (1988).[224] These Regulations were enacted in order to prevent the abuse of exceptions to patent protection under the Patents Act. They serve as a linkage mechanism that connects the regulatory approval of generic drugs with the patent protection of approved drugs which are referenced in the regulatory submission for generic approval. This represents a proactive effort to balance effective enforcement of patents rights and the early entrance of generic drugs.[225]

It means that a manufacturer must submit comprehensive safety and efficacy data that illustrate the drug's safety and efficacy through the "NDS", New Drug Submission. If the Minister is satisfied by the clinical data provided, a "NOC", Notice of Compliance, is granted which allows the drug to be marketed and sold in Canada. Normally NDS are filed by innovators or brand manufacturers, which according to pharma language are originators. A generic manufacturer will be required to file and "ANDS", Abbreviated New Drug Submission, to the Minister which provides data that establishes the bioequivalence with the approved reference drug. Once that is proved, the Minister grants the generic version a NOC which allows it to be marketed and sold

[222] Patent Act, R.S.C. [1985], available at <https://laws.justice.gc.ca/> accessed September 2017

[223] Food and Drugs Act R.S.C. [1985], available at <https://laws.justice.gc.ca/> accessed September 2017

[224] 132 C. Gaz. 7 II 923 at page 1058 [RIAS 1998].

[225] Michal. J Niemkiewicz, 'Data Protection in Canada' (2009) 2 Landslide 45 - accessed online via <https://heinonline-org> November 2018

in Canada. This is said to result in cost saving to generic company having bypassed the expensive clinical testing needed to establish safety and efficacy.

The linkage is based on the PMNOC which links the Patents Act and the FDA. Such linkage is achieved by mandating that the Minister maintains a public register of patents that contains a list of patents that correspond to each drug for which an NOC has been issued. Brand manufacturers submit their patents for inclusion on the register and when a generic manufacturer seeks a NOC approval through a regulatory submission[226] that makes reference to an approved drug, the submission must address each patent on the register that is listed for the reference drug. Such address should state that in regard to each patent on the register: that either they accept that a NOC for their drug will not issue until that patent expires, or allege that the patent expired, is invalid or that their generic formulation will not infringe. A NOA, Notice of Allegation must be served on the brand manufacturer, which contain the legal and factual basis for all allegations made. The brand manufacturer has 45 days to challenge in the federal court for an order prohibiting the Minister from issuing the NOC[227] for the generic drug until patents on the register expire. The PMNOC also contain provisions that are intended to provide compensation to a generic manufacturer who has been wrongly held off the market by proceedings, the 'generics rewards' system.

Inherent to the regulatory system is the central mechanism found in the institution of the Prices Review Board. Section 91 of The Patent Act provides the Patented Medicine Prices Review Board, (PMPRB), with the power to control excessive pricing and the duty to report to Parliament on a year-to-year basis on the overall research

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[226] Document: Patented Medicines **(**Notice **of** Compliance Regulations**)** available online, See also <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/notice-compliance/conditions/qualifying-notice-veklury-240551.html> accessed November 2017

[227] See further ''Patent Litigation Settlement Agreements: A Canadian Perspective, A Paper for the Global Antitrust Institute, George Mason University School of Law Conference: Global Antitrust Challenges for the Pharmaceutical Industry" (2014), available at <https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03816.html> accessed November 2017.

and development relative to sales of pharmaceutical companies.[228] Its primary role is to monitor prices to prevent patentees from taking undue advantage of their patent monopolies to the detriment of Canadian consumers and address the "mischief" that the patentee's monopoly might cause prices to rise to unacceptable levels.[229] The Board may require the patentee to provide information and documents in respect of an invention pertaining to a medicine and to reduce prices considered to be excessive.[230]

The obligation of disclosure to the Board should be on the standard of *bona fides,* disclosing all patents that relate in any way to the medicinal ingredient, whether the patents relate to the actual product to be commercialised or not. For these purposes, Section 79 of the Patent Act provides that an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine. The Board has the power to investigate and regulate excessive pricing, investigate sales and expense in Canada and investigate Canadian research and development.[231]

It follows that the information required to be furnished by a Patentee of an invention pertaining to a medicine is not dissimilar to what obtains in EU countries, for example the identity of the medicine; the price at which the medicine is being or has been sold in any market in Canada and elsewhere; the costs of making and marketing the medicine, where that information is available to the patentee in Canada or is within the knowledge or control of the patentee. Noteworthy is the fact that the board has no control beyond the factory gates and no power over someone who is not a patentee but a subsidiary of a patentee incorporated for the purpose of selling generic drugs in

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[228] See Patent Act (R.S.C., 1985, c. P-4) S.91 available at <https://laws.justice.gc.ca/eng/acts/P-4/page-23.html#docCont> accessed 19 November 2017

[229] *Celgene Corp v. Canada (Attorney General*), [2011] S.C.J. No.1 at para. 28, [2011] 1 S.C.R. 3 (S.C.C).

[230] John B Meixner and Shari Seidman Diamond, 'The Hidden Daubert Factor: How Judges Use Error Rates in Assessing Scientific Evidence' (2014) 2014 Wis L Rev 1063 - accessed online via <https://heinonline-org> November 2020.

[231] See further Bruce Rosen., "Expanding Canadian Medicare to Include a National Pharmaceutical Benefit While Controlling Expenditures: Possible Lessons from Israel", Special Issue: Canadian Medicare: Historical Reflections, Future Directions, (July-October 2018) 13(3-4) Health Econ. Pol'y & L. 323 343

Canada was held to be a patentee within the meaning of section 79(1) of the Act, even in the absence of a written licence agreement, as an implied licence entitled the subsidiary to exercise rights in relation to the patent.[232]

This covers a wide spectrum of medicines within the Board's jurisdiction including: patented single-source medicines; patented multi-source medicines including those which are subject to competition from a generic copy made under a compulsory licence; patented medicines sold as over-the-counter medicines or as prescription medicines; patented medicines sold as Investigational New Drugs (IND) or under the Emergency Drug Release (EDR) Program; patented medicines sold abroad but imported into Canada under a Special Access Programme.[233] Such access programmes may stretch to include compulsory licences and since Canada historically, has been pro compulsory licences, the legislation relating to compulsory licences also underwent legislative amendments[234] which are significant for generic manufacturers in their efforts to have products available sooner.[235]

Chapter summary

In sum, this chapter provided a complete break-down of the SPC system, exploring history and development, various legal underpinnings, discussed the myriad of issues surrounding 'rights' and highlighted the plethora of components that contribute to the adverse nature of utilising the system.Based on that background, it is understood that the SPC system came about in the EC to attempt to bolster research and development but more particularly to give innovators extra time on patents as a means of recouping any time lost during the regulatory process. It is also understood that the 20-year rule

[232]Emir Aly Crowne and Christina Mihalceanu 'Innovators and Generics: Proposals for Balancing Pharmaceutical Patent Protection and Public Access to Cheaper Medicines in Canada (Or, Don't NOC the Players, Hate the Regulations)' (2011) 51 IDEA 693- accessed online via <https://heinonline-org> June 2019

[233] March 12, 1993, effective date for the purposes of interpreting ss 10 to 13 is February 15th 1993.

[234] Terry N Kuharchuck, 'Bill C-91: Compulsory Licensing of Medicines in Canada' (1993) 17 LawNow 16 - accessed online via <https://heinonline-org> June 2019

[235] See further George Tsai, 'Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes under the WTO Doha Declaration' (2009) 49 VA J Int'l L 1063 - accessed online via <https://heinonline-org> June 2019

which is enshrined in the international instruments that govern the general principles and standards for patents administration appeared insufficient to innovator companies and so the use of term extensions became a tool to assist in that regard. Some form of the system is adopted in different formats in other countries such as the USA, Japan and Australia.

The use of term extensions theoretically, not only give extra time to the innovators but delays time for generics to access the market, which may mean that it takes more time for the drugs to become cheaper and readily available as in most instances the protection offered by the basic patent is extended to up to five years and in some cases more, particularly if the paediatric extension is used.

Having considered the plethora of court judgements and the references to the ECJ, it is apparent that some major inherent practical difficulties exist which extends to problems with deciding on products, rights, negative term or zero term extensions, time for filing and a host of other factors explained, which already have direct impact for not just generics but for innovators wanting to make effective use of the system. This highlights the question of the effectiveness of the system itself and whether inherently the theoretical obstacles operate as an additional bar to market entry, whether in time, money or a combination. Already one can glean that the system is far from perfect, if not in dire need of revamp. The correlation between extension and access appears to tell a story but how far or what impact is this correlation having on actual access is unclear. This adds the divergent angle to the operation of SPC's, its interaction with the regulatory environment. Based on the hybrid nature of SPC's and in order to understand the environment within which medical patents are made to thrive, it was necessary to consider all aspects of pharmaceutical regulation. In this regard a fundamental bridge was created between the patent system and the regulatory environment.

It was argued that the supposed interlock transcends borders as is evident in the legal and regulatory aspects of the Canadian pharma system which attempts to offer a divergent legislative and regulatory framework, albeit with its unique set of difficulties. Illustrating such bridges was necessary to link the literature and provide a more rounded understanding of the various issues at play which impacts both the SPC system and access.

Chapter Three

EXPLORING THE COSTS OF PATENTS IN PHARMACEUTICALS

Paramount to the investigation is whether those difficulties, practicalities and possible extension of time imposed by SPCs and the compounded effect of RDP contribute adversely to access and requires an assessment of the existing data to explore the actual cost of extension in pharmaceuticals.

Such data, through re-analysis of previously collected and available published reports demonstrates the direct economic impact that SPCs have had on the cost of pharmaceuticals and is indicative of quantified time and cost which directly has a bearing on delayed access. Ideally the findings attempt to reconcile extensions with higher prices; provides appropriate linkages between extensions and delayed access; illustrates cost implications on certain active ingredients; demonstrates time delays in bringing a generic drug to the market and confirms specific cost implications as a result of the extended protection period.

These results are based on a collection of reports from studies concluded between 2015 and 2018 on SPCs. Such studies were conducted from different key focal aspects of SPC administration however they address the key issues from varied perspectives. Collectively the reports allow for assessment of the impact of SPCs on access in terms of time to generic entry and cost to payers.

3.1. A SNAPSHOT OF WHAT THE DATA ON SPCS SHOW

Exploration of information from the Copenhagen study; PMRB data; Meijer Study; EFPIA; Drug Cost, OECD and the Kyle Report was analysed:

- Firstly, to determine the cost of medication in the relevant jurisdictions;
- Secondly, to investigate the cost to payers which includes governments, insurance companies, health departments, charitable organisations and individuals;
- Thirdly, to understand how SPCs contribute to that cost and delay;
- Ultimately to provide information from the generic industry.

Based on that methodology, the data from the different reports show roughly very similar findings on time/delay and cost implications:

- Approximately 19,000 SPC's were filed in Europe over the period 1991 to 2014.
- SPCS's delay an average price drop of approximately 50%.
- Total average length of SPC is 3.5 years.
- In recent years, the SPC has had the effect of prolonging the effective protection period by approximately 2.6 years for products where the SPC is the last IP protection scheme to expire.
- Total spending on medicinal products in the EU is USD 247bn. Hence a 10% change of total spending on medicinal products from originator products to generic products would entail a possible saving of USD 12.4bn.
- The potential savings attainable in case generic entry had taken place immediately upon loss of exclusivity of the originator medicine, could have led to additional savings of about € 3 billion. In other words, the generic savings could have been 20% higher.
- Even within a country there is a large variation in the speed of patient access to different products.
- Patient access to new Orphan and oncology medicines is highly varied across Europe, with the greatest rate of availability in Northern and Western European countries.
- At over US$700 per person per year, Canada spends more per capita on pharmaceuticals than any other country in the world except the US. When measured against comparator countries in the OECD, Canada's growth in drug spending per capita between 2009 and 2011 was 43% per year compared to the OECD average of 35%.

3.2. EXPLORING THE COST SPCS ON EU DRUG SPENDING

Importantly the data sheds light on spending and costs to EU governments or payers for pharmaceuticals, delay and the perceived dysfunction inherent to the SPC framework both legally and in industry.

The earliest report in the new studies commissioned by the European Commission and was based purely on optimising the internal market's industrial property legal framework where industrial property is concerned.[236] That report demonstrates that the starting point is patents in first place but also SPCs, together with data and market exclusivity, provide incentives for pharmaceutical companies to invest heavily in innovation. The Report stresses the importance of SPC's in Europe and provides statistics that indicates that approximately 1,650 SPC applications were filed in Member States in the whole 2014. Approximately 19,000 SPC were filed in Europe over the period 1991 to 2014, confirming the importance for the pharmaceutical industry of this protection right.[237] This lends support to the significance of the SPC system for EU countries' pharmaceutical industry and facilitates a theory that the industry requires the system for bolstered support and to advance research and development which will have a direct impact on increased innovation. Other reports offer different dimensions which is evident in the Copenhagen Economics Final Report.

This study represents another commissioned project by the European Commission with an economic methodology.[238] It means that the main focus was on finding the money value of the SPC system in the European countries using economic theories and statistics. The information from this study adds a profound contribution as it hones in on the direct cost impact of SPCS. In this study, a unique, new set of data was

236 European Commission's 2017 INCEPTION IMPACT ASSESSMENT - "Optimising the Internal Market's Industrial Property Legal Framework Relating to Supplementary Protection Certificates (SPC) and Patent Research Exemptions for Sectors Whose Products are Subject to Regulated Market Authorisations" (2019) accessed online via the EC website <https://ec.europa.eu/info/index_en> 14th April 2019, (Inception Impact Assessment, EC Commission, 2017).

237 Inception Impact Assessment, EC Commission, 2017, pg.5.

238 Copenhagen Economics, "Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe", (2018), accessed online <https://ec.europa.eu/info/index_en> 14th April 2019

analysed to assess the economic impact of SPC's and the pharmaceutical incentives and rewards in the EU. To that end, a measure was developed called the 'Effective protection period'. It reflects the time that elapses from a medicinal product obtains a marketing authorisation until the last measure of protection on it expires; this could be the original patent, an SPC or one of the other incentives and rewards in the pharmaceutical legislation. The study found that 45% of the medicinal products in the dataset to have obtained an SPC in at least one of the European countries. The study also found that the SPC has added years to the effective protection period for those innovator products where the SPC is the last measure of protection to expire.[239] While the protection for medicinal products in the EU is amongst the strongest in the world, the study found that for the medicinal products in the dataset the average effective protection period has decreased by approximately two years from 15 to 13 years since 1996 with some variation in individual cases.[240] The results of the study indicate that a longer effective protection period stimulates research and development into new medicinal products. The findings also show that it delays an average price drop of approximately 50%. Following the entry of generics. The study found that companies choose to launch more medicinal products faster in larger and wealthier countries. Hence, not all new products are made available in all European countries and not at the same time.

On patents, the study found that for 51 % of the 558 medicinal products across all 28 countries a patent is the last measure of protection to expire. For the remaining 49% either the SPC or one of the other incentives and rewards are the last measure of protection to expire.[241]

Looking at the timing of the SPC, the focus was on the 558 medicinal products alone. The question there was for how many of these products an SPC has been granted in at least one country. The study found that an SPC has been granted in at least one country to 45% of the 558 unique medicinal products in our dataset equal to 251 products. The average duration of protection for all granted SPC's is 3.5 years.[242] Analysing cumulative incentives, where the SPC expires last it adds on average 2.6

[239] Copenhagen Economics, 2018.
[240] Copenhagen Economics, 2018.
[241] Copenhagen Economics, 2018.
[242] Copenhagen Economics, 2018.

years beyond the patent, market or data protection, whichever would have been the final one to expire in the absence of an SPC.[243] Paediatric investigations of medicinal products is rewarded 6 months of extension of the SPC if an SPC exists.[244]

An Explanation on Actual Term Extensions from SPCs

The average length of granted SPCs across the EU member states seemed to have remained fairly consistent over the years, albeit with some yearly fluctuations. From 2004 to 2015 the median approval times for the European Medicinal Agency, including the time spent by the European Commission, has been slightly decreasing. In 2015 the median approval time for the EMA was 417 days. As a comparison, the median approval time for the FDA was 351 in the same year.[245]

At face value, the decrease in approval time should contribute to increasing the time a medicinal product is on the market and protected by IP rights. SPCs increase effective protection when they are the last IPR to expire.[246]

In the dataset, 45% of the unique products have obtained an SPC in at least one country. It was found that an SPC is the last protection scheme to expire for 10% of products across countries. In recent years, the SPC has had the effect of prolonging the effective protection period by approximately 2.6 years for products were the SPC is the last IP protection scheme to expire. Even with the possibility of filing for an SPC, a patent is still predominantly the last protection scheme to expire. However, when considering whether medicinal products are actually subject to an SPC application, the picture is quite different. When only looking at the medicinal products where an SPC is filed, the certificate is the last IPR to expire in more than 61% of cases.[247]

In recent years, the regulatory market protection and data protection have added an average of approximately 2.4 years of effective protection period to the pharmaceuticals in the sample. Since 2005, market protection sets a floor of at least

[243] Copenhagen Economics, 2018.
[244] Copenhagen Economics, 2018.
245 Copenhagen Economics 2018, pg. 182

246 Copenhagen Economics Report, 2018, pg. 184.

[247] Copenhagen Economics, 2018.

10 years of effective protection period for new innovative pharmaceuticals in the European member states, regardless of authorisation procedure. Before 2005, the minimum protection period of 10 years was already provided for centrally approved products.[248] For some products having obtained the 6-month extension, another protection scheme expires at a later point in time.

The paediatric extension of the SPC has a limited effect on the average effective protection period for all products where an SPC is the last protection scheme to expire. Out of all the products where an SPC is the last protection to expire, 5.1% have a positive PIP compliance check. However, in many cases the positive PIP compliance check fell later than 2 years before expiry of the SPC. For these products, an application for a paediatric extension of the SPC is void.[249]

The timing issue described above means that out of all products for which the SPC is the last protection scheme to expire, only 4.1% have had the possibility of applying for the paediatric extension even though 5.1% have a positive PIP compliance check. As such, when studying the average effect of the paediatric extension on all products where an SPC is the last protection scheme to expire, the difference depicted will naturally be small. Having considered in detail the timeframe added to the protection period, the study considered the effect the regulatory incentives has had on actual protection which is discussed next.

Understanding the effect of regulatory incentives on effective protection

Considering the effective protection and utilising the industry standard calculation, the period was calculated as the time elapsed from the date of marketing authorisation until the last protection scheme expires. In the period from 2010 to 2016, market protection prolonged the average effective protection period by 2.4 years so that for products where market protection is the last protection to expire the average extra period provided by market protection was 4.8 years in the period from 2010 to 2016.[250] Similarly, in the case of products where market protection is the last scheme to expire, the one-year extension based on approval for a second indication provides an average

248 Copenhagen Economics 2018, pg.260

[249] Copenhagen Economics, 2018.
[250] Copenhagen Economics, 2018.

increase in the effective protection period close to zero, which amounts to about 3.7 days in the years between 2010 and 2016.[251]

Market exclusivity for orphan medicinal products has on average provided 1.6 extra years of protection to the orphan medicinal products where market exclusivity was the last protection scheme to expire.[252] The paediatric extension has on average provided close to zero or 2.9 days of extra effective protection. This small average difference is mainly due to the fact that only 10% of products have an SPC as the last protection to expire.[253]

An indication of how SPCs affect Innovation

The number of orphan designations granted has increased from 14 in 2000 to 209 in 2016. As the number of orphan medicinal products obtaining marketing authorisation has also increased, this suggests that there has been an increase in innovation within the area.[254] In the period from 2008 to 2015, 859 paediatric investigation plans (PIP) have been agreed upon and 99 positive PIP compliance checks have been done. This entails quite a large increase in the body of information on medicinal products for paediatric use.

An indication of how SPCs affect Availability

The study deemed that the relationship between IP protection and launch of new medicinal products is ambiguous[255]. However, it can be seen from the analysis that orphan medicinal products are launched earlier and, in more countries, than non-orphan medicinal products. Whether this is due to the orphan incentives or the fact that orphan medicinal products have a smaller patient base and usually higher price in each individual country cannot be determined based on the available data.

An important consideration regarding availability is that in many EU countries central authorities decide whether or not to reimburse new innovative medicinal products. These decisions are often based on a Health Technology Assessment where price

[251] Copenhagen Economics, 2018.
[252] Copenhagen Economics, 2018.
[253] Copenhagen Economics, 2018.
[254] Copenhagen Economics, 2018.
255 Copenhagen Economics 2018, pg. 285

effectiveness is assessed. As such, there are two formal barriers to entering the markets for medicinal products in European countries. One is obtaining marketing authorisation, e.g., through the centralised procedure and the other is to obtain a positive opinion regarding reimbursement from the national.[256]

An indication of how SPCs affect Accessibility

As generics are priced lower than originator products, delaying their entrance entails higher spending on medicinal products[257] Insofar as the legislative instruments work to postpone the point in time when generic products can enter, the ensuing fall in prices is likewise deferred. As such, at face value the incentives work to contribute to higher prices for medicinal products.

However, the data found that that there was a positive relationship between longer effective protection period in all of the EU and the spending on pharmaceutical R&D. As such, this encourages more originator innovation. As there can be no generics without originator products, in some way the legislative instruments work to make more generics accessible in the future. Furthermore, more innovation increases innovator-on-innovator competition, which is one of the factors driving down prices before generic entry.

An understanding of the operation of the Paediatric Extension

A 2017 report from the European Commission on the "State of paediatric medicines in the EU" reviews the effects of the paediatric regulation. The economic results reviewed in the report are those of the 2016 study. In 2016, a study estimating the economic impact of the Paediatric Regulation was published.[258] The study estimated that between 2008 and 2015 the total cost to the industry of the obligations inherent in the Paediatric Regulation was EUR 16.8bn, corresponding to EUR 2.1bn annually or EUR 18.9m per PIP.[259] Using data on eight medicinal products and extrapolating these

[256] Copenhagen Economics, 2018.

257 Copenhagen Economics 2018, pg. 292

258 Copenhagen Economics 2018, pg. 299

[259] Copenhagen Economics, 2018.

findings, the study concludes that the combined adjusted economic value to the companies of the eight products studied was EUR 926m.[260]

Appraising the societal value of the regulation is much more difficult than estimating the associated cost. Some of the positive effects of an increase in paediatric studies might be improved quality of life for children, avoided mortalities, hospitalisation costs, outpatient costs, time lost by informal carers and other improvements stemming from better treatment of children.

It is also important to note that some clinical studies show that certain medicines are not suited for treating children. In these cases, the benefit to society is knowledge on what not to do. The study compares the estimated positive effects on society from the paediatric studies undertaken to the extra cost stemming from the fact that the paediatric reward of extending the SPC for 6 months delays generic entry and hence competition. It is important to note that these results are exploratory in nature, as appraising the monetary value to society is inherently difficult.

For two of the eight products, the study found a positive benefit-cost ratio. For the other six products, the ratio was negative. This means that for two products the value to society outweighed the extra monopoly rent paid to companies. For the other six products, society paid more, so to speak, than the studies were worth. However, when taking into account the fact that the regulation might entail certain spillover effects from investments in new R&D, contributing to job creation and growth, the study found that the total societal value outweighs the total extra cost. As such, for some of the parties involved, the regulation might entail additional expenditure, but from a societal perspective in general, the cost benefit ratio is positive.

In general, the report concludes that the paediatric regulation has led to more research and medicinal products being approved for children, as also shown in section 4.2. The report does, however, conclude that “the Regulation works well in areas where the needs of adult and paediatric patients overlap”, which is based on the observation that paediatric studies are often linked to therapeutic areas which are priorities within the adult population. As such, it seems that the paediatric regulation is helping to ensure

[260] Copenhagen Economics, 2018.

that the development of paediatric medicinal products has become a more integral part of pharmaceutical innovation. However, as the current reward is dependent on sales within the adult population, most knowledge exists in the fields most highly prioritised in the adult population.

An indication on how the Paediatric Extension impacts availability

The results of the Copenhagen study found that companies do not launch medicinal products in all countries in the EU and not at the same time.[261] The study found that companies choose to launch more medicinal products faster in wealthier countries, a trend, which is reinforced in countries with larger (patient) populations. This launch sequence fits with how some wealthier countries include poorer countries in their 'external reference pricing' basket. This practice incentivises pharmaceutical companies to launch first and foremost in (large) wealthy countries as these countries have then no poorer country benchmark to refer to when bargaining for lower prices.

Analysing the launches based on level 1 ATC codes[262]shows that availability varies greatly across this categorisation in that the pharmaceutical products with the highest availability belong to the ATC1 category of "Antineoplastic and immunomodulating agents", which contains many cancer medicines. These products see launches in more than half of the EU Member States within 2 to 3 years but the pharmaceutical products with the lowest availability belong to the ATC1 category of skin care products. These products launch in less than a quarter of the Member States even after 15 years of first market introduction.[263]

An indication on how the Paediatric Extension impacts accessibility

Once a medicinal product is available in a country, actual accessibility often becomes a matter of price.[264]The study found that as protection from generic competition runs

261 Copenhagen Economics Report 2018, pg.14

[262] Anatomical Therapeutic Chemical Classification System classification of active ingredients of medicinal products according to the organ or system on which they act

[263] Copenhagen Economics, 2018.

264 Copenhagen Report, 2018, Pg. 14

out, generic medicinal products enter the market at a significantly lower price than the original medicinal product pushing down the price of the original product as well.

Based on a small sample of products, the study found find that the prices of innovator medicinal products drop by approximately 40% on average in the period from 6 quarters before to 5 quarters following generic entry. However, innovator companies may find it optimal to increase prices even in light of generic entry. This is for example the case if healthcare professionals are reluctant to switch existing patients to new medicinal products. Furthermore, the study found that when generic medicinal products enter the market their price is on average 50% lower than the initial price of the corresponding innovator product in the first five quarters after the launch of the generic product. This means that the innovator product remains more expensive.[265]

The study's findings also reflect some evidence to suggest that the regulation spurs innovator-on-innovator competition. This means that competition between two or more medicinal products that are protected from generic competition by patents or the incentives and rewards. This was based on insight on the previous finding that the regulation stimulates innovation, and that more innovation, all else equal, leads to more medicinal products, which eventually result in more innovator on-innovator competition. The data on competition between innovator and generic medicinal products does not allow for an analysis of competition between innovator medicinal products.

A demonstration on price decreases after Generic entry

The analysis shows that the price of the original medicinal product decreases around the time period when exclusivity is lost. On average, original medicinal product prices steadily decrease by 40% during the period six quarters prior to and five quarters after the loss of exclusivity.[266] This is contrary to some of the results from the existing literature. Prices for generic medicinal products entering the market after the original medicinal product loses exclusivity are on average around 50% of the price of the original medicinal product over the first five quarters.[267] Interestingly, however, there

[265] Copenhagen Economics, 2018.
[266] Copenhagen Economics, 2018.
[267] Copenhagen Economics, 2018.

does not seem to be a sharp drop in originator prices immediately after generic entry, even though generic prices are 50% that of the originator price. Furthermore, even five quarters after generic entry, there still seems to be a price gap between originator and generic prices. This is comparable to the findings in the Sector Inquiry.[268]

The above suggests that brand value and or switching costs may play a role in the pricing strategy. If there were no brand value/loyalty and patients could immediately switch to the generic medicinal product post generic entry but nobody would buy the originator medicinal product when a cheaper, identical product is available.

Another possible important point is that there may be sluggishness in the market whereby doctors and patients only later learn about a new generic. This may be especially important for medicinal products, as in many EU countries, the cost is paid by either the government or private health insurance companies.[269] This means that, in many cases, neither the person writing the prescription nor the person using it has the same monetary interest in finding the cheapest product available as they would have, had they themselves paid for the treatment. However, it should be noted that this is not necessarily the case for all countries and all medicinal products, as such, it should not be seen as a generalised point but rather as a contributing factor in some instances.

Furthermore, when it comes to switching patients from an originator product to a cheaper alternative is that the propensity to switch may differ depending on whether the product in question is a chemical compound or biological. Many biologics are relatively new and the body of knowledge about this area is limited but recent studies point to no difference in outcomes for patients switching from an originator product to the biosimilar version. However, the aforementioned study still concludes that switching should remain a “case-by-case” decision. Nonetheless, the fact that the originator medicinal product begins its price reduction even before entry of the generic medicinal product suggests that the pricing strategy of the originator firm is influenced even before generic entry. This could be to increase market share before competition enters.[270] If the patient’s course of treatment is very long, a profit-maximising strategy

[268] Copenhagen Economics, 2018.
[269] Copenhagen Economics, 2018.
[270] Copenhagen Economics, 2018.

by the originator firm may be to decrease price prior to the entry of generics to increase market share. After the entry of generics, increasing prices may actually be the most rational strategy, as this “cash-in” action makes only a few patients switch. The alternative is to try to compete with the price of the generic, which may be an unfeasible strategy for the originator firm. Another factor in a price decrease prior to generic entry may be competition from other originator companies. The data unfortunately did not allow for such identification of this kind of competition.

The important point here is that insofar as the SPC delays the time when generics can enter the market, the time when the fall in prices, is also delayed.[271] In a hypothetical scenario where the effective protection period is decreased, it would be possible for generic companies to enter the market at an earlier stage. This would lead to more generic competition and the accompanying price saving being realised at an earlier stage for medicinal products. Thus, the total spending on medicinal products in the EU amounts to USD 247bn. Hence a 10% change of total spending on medicinal products from originator products to generic products would entail a possible saving of USD 12.4bn.[272] On the issue of fall in prices, the study was not able to find evidence that the SPC has supported the objectives of causing a fall in prices of SPC protected products relative to products without an SPC or the objective of giving extended protection that is justified by revenues and profits. Further, there appeared no theoretical arguments as to why the SPC would support these objectives.[273]

Yet such were considered in more depth in the Kyle Report.[274] Adding another dimension to the discussion this EC commissioned study adopts a policy focus, where the key findings were geared at forming policy on the future of the SPC system.

271 Copenhagen Economics, 2018, pg. 142

272 Copenhagen Economics, 2018, pg. 161

273 Copenhagen Economics 2018, pg. 179

274 Margaret Kyle, “Economic Analysis of Supplementary Protection Certificates in Europe”, (January 30, 2017), MINES Paris Tech (CERNA), PSL Research University and CEPR accessed online and is available at <http//www.ec.europa.eu> accessed November 2019 (The Kyle Report, 2017)

The Report involves a much larger timeframe and provides a more in-depth coverage of issue relevant to this research, cost and availability. The report uncovers that development times of pharmaceuticals developed from 1990-2015 have increased by more than 2 years on average, while the lag between the first global launch and the first EU launch has fallen by 1.4 years.[275]

The average period of protection provided by basic patents and SPCs, where applicable, is over 12 years. The use of SPCs has increased: a higher share of products, currently, 86% is covered.[276] In 80% of cases, SPC applications are tied to a single patent. However, in the remaining cases, firms have requested SPCs on additional patents. SPCs are less likely to be granted in such cases. The most common type of patent associated with an SPC is a product patent. Thus, SPCs and secondary patents, as well as the use of the centralized approval pathway appeared to be closely associated with faster generic entry. This is likely because more valuable products are more likely to be protected with SPCs and secondary patents as well as to attract generic entry.

The report suggests that since SPC applications sometimes have different outcomes in different countries, efforts to harmonize SPCs across member states, either through the use of a unitary SPC or through improved information sharing, would reduce the variation in the intellectual property landscape and the uncertainty for generic entrants. Furthermore, a more complete analysis of the effects of SPCs on entry and prices, as well as on R&D incentives, is important for understanding whether SPCs are a valuable policy instrument.

Significance of the data analysis[277] are that while the EU has achieved faster access to new drugs, the reduction in launch lags has not offset the overall increase in time elapsed between patenting and first global launch and the corresponding decrease in remaining patent term once the product arrives in the EU. Overall, innovators could expect about 12.68 years of legal protection before facing the threat of generic entry, though slightly less to around 12.46 in more recent years. Orphan drugs arrive more

[275] The Kyle Report 2017
[276] The Kyle Report, 2017
277 The Kyle Report 2017 - Tables 6 and 7 on pg. 16

quickly in the EU than non-orphans, and realize almost one additional year of SPC protection as well.[278]

The data also confirms that the use of SPCs has generally expanded. In the early 1990s, 75% of new drug introductions had an SPC in at least one country, and on average, an SPC in 6-7 countries. In more recent years, the share is 86% with at least one and 18-19 countries on average. The latter reflects both the expansion of the EU as well as an increased tendency to apply for SPCs in smaller markets, in addition to the fact that more products fall into the range of development times for which SPCs are relevant.[279] Products valuable enough to seek SPCs for would probably see earlier generic entry without the additional protection that SPCs give.

Although the study was geared at policy on SPCs, it concluded that specifically, a larger study was required, which incorporates market share and revenues in a structural model of demand allow consideration of policy such as the removal of SPCs or changes to the length of protection.[280]

The data appears to be generally consistent with other reports for studies undertaken for similar periods but with a different dimension. [281] The study was based more from a policy perspective and the results seem to have encouraged the suggestion for the SPC Waiver proposed for 2019 but remains the last major study on this SPC's in Europe, as such, much weight can be placed on its findings. Whilst these reports, in their divergent ways, have provided some insight into cost and legal ramifications of SPCs in Europe, understanding the direct impact on cost and availability depends on an assessment of what obtains in industry, which is pivotal in achieving a balanced and holistic viewpoint.

278 The Kyle Report 2017, in particular, pg. 18

279 The Kyle Report 2017, pg. 18, See also pgs. 19 to 24.

280 The Kyle Report 2017, in particular, pg. 29

281 Malwina Meijer, "25 years of SPC Protection for Medicinal Products in Europe: Insights and Challenges", (1 May 2017), pg. 8. Accessed online and is available at <http:// ec.europa.eu › docsroom › documents> March 2019

3.3. AN EVALUATION OF SPC'S AND ACCESS FROM THE STANDPOINT OF THE EU PHARMACEUTICAL SECTOR.

A holistic view of extensions involves the incorporation of industry specific studies undertaken with a view to understanding the inherent problems concerning access in order to potentially offer carve outs for future operations in the industry. Such industry specific focus is inherent in a study commissioned by the Pharmaceutical Sector Inquiry.[282] According to the Fact Sheet "Prices, time to generic entry and consumer savings",[283] in 2007, each European citizen spent on average approximately €430 on medicines. In total, the market for medicines was worth over € 138 billion at ex-factory prices and approximately € 214 billion at retail prices. This corresponds to approximately 2% of the GDP.[284]

Based on a sample of medicines that faced generic entry in the period from 2000 to 2007, the European Commission's report found that generic medicines enter the market at a price that was, on average, about 25% lower than the price set by originator companies prior to loss of exclusivity. Prices of generic medicines, after they have been available on the market for two years, are on average 40% lower than the former price of the medicine of the originator company. Also, the average prices of originator companies tended to drop. The overall bearing of generic entry is noteworthy, offering European patients enhanced access to safe, innovative and affordable medicines, as well as shrinking the weight carried by national health systems. In markets where generic medicines become available, average savings to the health system can be projected to be almost 20% one year after the first generic entry, and about 25% after two years. The inquiry highlights considerable variations

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[282] European Commission, Pharmaceutical Sector Inquiry – Preliminary Report Fact Sheet "Prices, time to generic entry and consumer savings", available at <http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html> accessed March 2019

[283] See European Commission Fact Sheet above at <http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html> accessed 19th March 2019.

[284] See European Commission Fact Sheet above at <http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html> accessed 19th March 2019

around this average in the various EU Member States and across medicines.[285] An important point from this is that market shares are affected. It follows that generic entry does not just affect price. It also affects companies' market shares. Generic companies attained about 30% market share at the end of the first year and 45% after two years. Further, it appears that the decrease in price levels allows for more consumers being able to afford the medicine.[286]

Another important aspect of this study lies in assessment of time to generic entry. It was discovered that in many instances, generic entry occurs later than could be expected on the basis of the statutory loss of exclusivity of the originator product. The average time gap between the date on which the originator medicines lost exclusivity and the date of first generic entry was more than seven months plus for the highest selling medicines, for which rapid entry matters most, it took about four months on average before market entry.[287] A further significant element which is directly relevant to access lies in the potential loss of savings. Based on a sample of medicines that faced generic entry in the period 2000 to 2007, the sector inquiry has analysed the additional savings that could have been obtained over this period had generic entry taken place earlier.

The sector inquiry has estimated that aggregate expenditure on the sample of medicines analysed, which was about € 50 billion over the period following loss would have been at least € 15 billion higher without generic entry. The potential savings attainable in case generic entry had taken place immediately upon loss of exclusivity of the originator medicine, could have led to additional savings of about € 3 billion. In

[285] See European Commission Fact Sheet above at <http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html> accessed 19th March 2019

[286] See European Commission Fact Sheet above at <http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html> accessed 19th March 2019

[287] See European Commission Fact Sheet above at <http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html> accessed 19th March 2019.

other words, the generic savings could have been 20% higher[288] which represent a conservative estimate.

A deeper analysis suggests that a number of factors may well have an influence on the observed pattern and effect the generic entry, for instance, the turnover of the originator medicines before the expiry of the patent/data exclusivity or the regulatory environment. A prime example is can be found where Member States which oblige pharmacists to dispense the cheapest generic medicines whenever possible appear to show earlier entry and greater savings for their health budgets. Likewise, generic uptake seems to be faster and ultimately generic prices seem to decrease more in Member States which do not impose a price cap, on generic companies entering the market.[289] This adds to the discourse on cost matters and demonstrates reasons for varied costs of pharmaceutical products once patent and SPC protection expires.

However, the highlight of the empirical analysis in this study finds a trade-off[290] between innovation of new medicinal products and lower prices of medicinal products through faster availability of generics. This adds tremendous value to the discussion on access matters and will be pivotal in construing means of addressing public health obligations. Such trade-off can be explained as the protection offered by the IP rights and incentives and rewards stimulate innovation in the EU but the protection delays entry of generic medicinal products and a subsequent sliding push on prices. It means that, later entry of generic medicinal inventions drives up total expenditure on these inventions, which, all else equal, pushes up overall healthcare overheads. The figures indicate that around 76% of the EU expenditure on medicinal products goes to originator products and the remaining 24% to generic products.[291] In a hypothetical scenario, the immediate was calculated, short term effect on health care expenditure of changing this split to 66% and 34%, respectively, i.e., reducing spending on originator products by 10% points and instead using that money to buy the same

[288] See European Commission Fact Sheet above at <http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html> accessed 19th March 2019.
[289] See European Commission Fact Sheet above at <http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html> accessed 19th March 2019.
[290] Copenhagen Economics Report 2018, pg. 15

[291] Copenhagen Economics Report 2018

volume of cheaper generic products. The result is a saving of less than 1% of the total EU health care expenditure.[292] Whilst this scenario may assist there may be repercussions in reducing protection in order to cement a facility for faster generic product availability which may be complex. One obvious one is that on development of future originator products. This study is supported somewhat by more updated findings from another study in the industry.[293] The W.A.I.T study provides a benchmark of the rate of availability and waiting times in European countries. The Patients W.A.I.T. Indicator shows that for new medicines the rate of availability is measured by the number of medicines available to patients in European countries and that for most countries this is the point where the product gains access to the reimbursement list.[294] The average time between marketing authorisation and patient access, measured by the number of days elapsing from the date of EU marketing authorisation to the day of completion of post-marketing authorisation administrative processes.[295] This impacts the average length of market access to the day of completion of post-marketing authorisation administrative processes.[296]

No doubt, the pertinent point to note is that the ultimate aim of the W.A.I.T. indicator is to measure the differences in time to reimbursement across European countries. Thus a medicine is available on the market if patients can receive the medicine under a reimbursement scheme. The accessibility date is the first date when doctors can prescribe or when hospitals can administer the medicine to patients in the country, who will be able to benefit from reimbursement conditions applicable in the country which may also include administrative procedures where applicable.**[297]**

Key observations, generally involve the assessment that patient access to new medicines is exceedingly diverse across Europe, with the greatest rate of availability in the geographically Northern and Western European countries and lowest in

[292] Copenhagen Economics Report 2018.
[293] EFPIA Market Access Delays Indicator 2018 Survey, (3 April 2019), which used DATA from IQVIA, accessed online on EFPIA website, 17th April 2019 and available at <https://www.efpia.eu/media/412747/efpia-patient-wait-indicator-study-2018-results-030419.pdf>, referred to as EFPIA WAIT 2019.

[294] EFPIA WAIT 2019.
[295] EFPIA WAIT 2019.
[296] EFPIA WAIT 2019., Pg. 13

[297] EFPIA WAIT 2019, Pg. 7

Southern and Eastern European countries. Interestingly, in some countries, over 30% of products are available and reimbursed but with specific conditions. The average delay between market authorisation and patient access can vary across Europe, with patients in Northern or Western Europe accessing new products 100-200 days after market authorisation and patients mainly in Southern or Eastern Europe between 600-1000 days.[298] Noteworthy, countries with more products available manage to have faster access to medicines but even within a country there is a large variation in the momentum of patient access to different products. Frequently the level of variation contained in a country is greater than between countries. There seems to be an increase in the rate of availability in that a comparison to the previous W.A.I.T. indicator shows, 65% countries have a higher rate of availability, and 58% countries have a longer delay in the 2018 study.[299]

To put this in context to drugs considered as key to public health, patient access to new Orphan and Oncology medicines as well as combination drugs, is highly varied across Europe, with the greatest rate of availability in Northern and Western European countries. For example, where Orphan drugs are concerned, in over 80% of the countries, the rate of availability is lower for orphan drugs compared to all products approved between 2015 and 2017, the average delay between market authorisation and patient access for Orphan drugs is between 4 months to 3 years.[300] Similarly for Oncology drugs, in 73% of the countries, the rate of availability is higher for Oncology products compared to all products approved between 2015 to 2017, the average delay between market authorisation and patient access for oncology products is between 2 months to over 2.5 years.[301] The observations for Combination drugs show that patient access to new combination medicines is highly varied across Europe. Over 40% of these combinations are for HIV or Hepatitis C. The average delay between market authorisation and patient access for combination products is between 2.4 months to over 2.5 years when comparing the figures in two separate studies.[302]

[298] EFPIA WAIT 2019
[299] EFPIA WAIT 2019
[300] EFPIA WAIT 2019
[301] EFPIA WAIT 2019
[302] EFPIA WAIT 2019, Pgs. 12 & 14 - In assessing the average delays per capita with information obtained from GDP per capita, PPP (current international $), 2017 -World Development Indicators, World Bank

3.4. EXPLORING COST SAVINGS FOR PHARMACEUTICALS IN THE EU GENERICS CONTEXT

Delving into the generic system for production and marketing of pharmaceuticals shows that despite obvious cost savings as a result of using generic products, there exists major hurdles in putting drugs on the market as well as general limitations on the drug patent system.[303]

Overall, the patent system appears to yield high prices for drugs, with attendant problems of access, counterfeiting, cross-border trade in pharmaceuticals of dubious quality, high levels of marketing and promotion, insurance cost-control schemes, increased costs for research and development of drugs and extensive litigation. The current system also skews priorities for research and development toward incremental improvements to existing blockbusters and away from drugs for neglected diseases and the diseases of poverty.

Current thinking about the role of patents in drug innovation can be summarized simply that research and development is very costly. This means that no firm would invest the finance required to bring a new drug to market if faced with the prospect of instantaneous competition from manufacturers of low-priced generic copies. Patent protection keeps generics at bay for a limited time, allowing the innovator to charge a price sufficiently high to recoup research and development costs. However, the current drug patent system has its drawbacks. It is widely recognised that setting high drug prices to recoup costs restricts access to people with comprehensive insurance or insufficient ability to pay. In addition, aspects of the patent system increase the cost of discovering novel therapies, decrease sales revenues and thus reduce the financial incentive to innovate.

The best place to start to unpack the generic industry appears to be from the EU perspective. A review of the pharmaceutical context in the EU suggests that the use of generic medicines appear to be the cornerstone of European healthcare policy. Without generic medicines, payers in Europe would have had to pay €100 BN more in

[303] Paul Grootendorst et.al, "New Approaches to rewarding pharmaceutical Innovation" (April 5, 2011) CMAJ 183(6) – Accessed online – March 13th 2019 @10:30 am – CMAJ 2011. DOI:10.1503/cmaj.100375

2014.[304] Generic medicines account for 67%, 29% of prescribed medicines of pharmaceutical expenditure.[305] The industry accounts for 400 manufacturing sites employing over 190, 000 direct employees. Up to 17% of turnover invested in R&D exporting to more than 100 countries outside the EU.[306]

The limitations inherent in the systems associated with patents for pharmaceuticals. Despite cost savings on R&D, generic companies are required to uphold the industry's tradition of quality, safety and efficacy. The system operates such that:

- A generic medicine enters the market once the originator's patent has expired;
- Generic medicines and originator products are authorised to the same standards of safety, quality and efficacy;
- Generic medicines are bioequivalent to the original product which means that they deliver equal medical benefits to the patient. Generic medicines are therefore interchangeable with the equivalent branded product;

According to the European generics association, the European generic industry ensures equal access to healthcare for all European patients by ensuring equal access to frontline treatments for over 500 million European citizens and providing cost effective treatments for a large range of health conditions. From their many internal reviews they have concluded that the economic benefits of generic medicines are purely based on the improvement of the figures which demonstrate that with the increased turnover invested in R&D generic medicines lead in pharmaceutical manufacturing in the Europe while creating a multi-supplier market. This has knock-on effect in that 75% of generic medicines consumed in Europe are produced in Europe. What is even more beneficial is that the emerging markets outside Europe provide EU manufacturers with major opportunities for export.[307] Datasets which indicate the heavy reliance placed on the generic industry and the split of the supply

[304] EGA Internal Survey 2014, 'The Role of Generic Medicines in Sustaining Healthcare Systems: A European perspective' IMS Institute, (2015), accessed <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> (EGA 2014)

[305] EGA 2014

[306] EGA 2014

[307] EGA 2014

between originators and generics are illustrated by the study[308] which yields that despite the cost savings, the industry strongly believes that regulatory barriers both obstruct entry and inflate costs. The generic medicines industry is accustomed to struggling with long lead times, country-specific regulatory requirements, and changing standards over time. However, if regulations are redundant between geographies or overly burdensome, it can increase the barrier to entry, resulting in too few manufacturers being willing or able to overcome that barrier. Moreover, repeated regulatory costs added on top aggravates pricing and threatens sustainability.[309]

In Europe, governments have finally embraced the opportunity of biosimilar medicines competition (which is increasing access to biological medicines by 50-200 percent depending on the country) but there are still major gaps in the system.[310] For example, southern European countries with low generic penetration appear to be slower at establishing more effective generic prescribing policies. Another example is seen in the system of hospital procurement and reference pricing which seem to lead to extreme consolidation of suppliers on the market. These provide strong impetus for unsustainability and more risks of shortages.

The generic and biosimilar medicines industries have demonstrated over decades that access to quality medicines drive sustainable healthcare and better prevention of disease but this industry can only deliver on these important public health objectives in a competitive environment that encourages and rewards a robust base of manufacturers that invests in new products and capacity. Responsive and well-crafted policy has the ability to balance innovation and access for a sustainable, healthy generic drug market. Timely and sufficient action to address unfair competitive conditions, in the U.S. and around the world, is essential to ensuring the sustained availability of affordable generic medicines.[311]

[308] See EGA 2014.
[309] IGBA, "Preserving Sustainable Competition and Preventing Medicines Shortages
Comments from The International Generic and Biosimilar Medicines Association (IGBA) regarding FDA-2018-N-3272: Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions" (2018) <www.igba.com> Accessed February 2020, (IGBA 2018)
[310] See Kyle Report, 2017
[311] IGBA 2018 pg. 5

The system is also rigged with Regulatory constraints in the EU. Despite the indication in the figures that the regulatory approval process time has been slightly decreasing, there is other evidence pointing towards an increase in the regulatory requirements for applying for marketing authorisation. Between 1999 and 2005 the median number of procedures per clinical trial protocol increased from 96 to 158. Furthermore, the length of clinical trials increased from 460 to 780 days during the same period. This points to the fact that even though the regulatory process has shortened, the regulatory requirements for approval of an application for marketing authorisation have increased, causing the development of new medicines to take a longer time.[312] This significantly impacts generic entry in that it affects the time given at the SPC stage, if one is in force and if there is none, the extra time may be added to the data exclusivity.

[312] Copenhagen Economics 2018, pg. 182

3.5. DISCUSSION ON THE DATA

The data from these studies and reports paints a clearer picture on the cost implications of SPCs and demonstrates trends in spending by payers and buyers of pharmaceutical products, not just from the SPC standpoint but also from an industry perspective. This solidifies the perceptions on massive gaps between and innovation and access and puts in contexts the actual costs associated with delays in Europe.

Despite being based on different data sets, the findings appear valid as the central theme throughout resonates the inherent systematic discrepancies that contribute to the myriad of issues which arises. A closer look at the data reveals that changes in operations are required which would certainly spur legislative amendments and industry institutional developments. All the reports highlighted functional difficulties across Europe, based on lack of harmonisation, national irregularities in implementation which hinges on varied interpretations of the legislation based on local industry standards and requirements. Whilst these reports make estimates of effect using a number of assumptions, their respective data sets and calculations were varied and appear to be not adequately explained, such reports may require additional assessments as, individually, they do not appear fit to guide policy. No wonder the Commission has taken further steps by publishing the findings and opened public consultation. Nevertheless, whatever inherent dysfunctional and impracticalities emphasised, the reports are devoid of suggestions to replace the SPC. What seemed a harmonising thread is the requirement for legislative modifications to make the system more flexible to adapt to current industry situations.

Although Meijer suggested harmonisation of the scope of SPCs across Member States, it would appear cumbersome to undertake such without gaining clarity on the scope of medicinal product protection and harmonization of grant processes within national offices.[313]

[313] Charlotte Weeks, *'European Commission Publishes Study on Options for a Unified SPC System'* Out-Law, (2022), available at https://www.pinsentmasons.com/out-law/analysis/european-commission-study-options-unified-spc-system, accessed August 2023

This would, no doubt, enhance legal certainty across Europe, particularly in the current digital environment.[314] On the other hand, The Kyle Report suggests that it would be more suited to centre harmonisation on timescales for the development of therapeutically important medicines. This is based on findings that products with SPCs normally attract more generic attention and yield higher earnings. Thus, the idea that more generic entry and lower costs associated with entry of generics would benefit from a centralised/harmonised system throughout the product development stage, would definitely be advantageous.[315]

The empirical data in the Kyle Report is significant in providing useful guidance for pharmaceutical innovation and healthcare outcomes. The use of econometric analyses data on patenting activity, drug launches, pricing, and utilization patterns to evaluate the economic implications of SPCs in practical applications, provides insightful acumen concerning the financial dynamics of pharmaceutical innovation and regulation in the European context and informs not only academic debates but adds to the discourse on intellectual property rights policy and access.

Moreover, the Charles Rivers report was deeply concerned with early working exceptions and extending the scope of the "Bolar" exemption, which would unquestionably have the effect of reducing time and costs for both originators and generic companies. Such arguments seem plausible to increase access but their findings that trading in Europe would be bolstered by increases in skilled jobs and research may prove difficult to be digested by the industry. Arguably, it is envisaged that the continued use of SPCs and reworking the system to allow stockpiling exemptions may well have substantial positive bearing on manufacturing in the EU, in particular on jobs and trade.[316] This presupposes that the EU is at the forefront of

[314] Kamil Baranik, *'Legislation on Supplementary Protection Certificates for Plant Protection products (RECAST)',* Members Research Service, Legislative Train, 2024*, available at* https://www.europarl.europa.eu/legislative-train/theme-a-europe-fit-for-the-digital-age/file-supplementary-protection-certificates, accessed March 2024.

[315] Scott et al., *'European Commission Proposes a Unitary SPC and/ or a Unified Procedure for Granting National SPCs',* 2022, available at https://www.williamfry.com/knowledge/european-commission-proposes-a-unitary-spc-and-or-a-unified-procedure-for-granting-national-spcs/ accessed August 2023.

[316] De Coninck et al, "*Assessing the Economic Impacts of Changing Exemption Provisions During Patent and SPC Protection in Europe*", (2016), Published by The Commission in October 2017, the CRA Report.

global competitiveness in both innovative products and generics and biosimilars. Nonetheless, considering the EFPIA's assessment of such findings, it is not difficult to conclude that the SPC export and stockpiling exemptions, may not achieve the right balance required. There seems to be no evidence to support the assumptions of the EU's competitiveness in global R&D for pharmaceuticals. On the matter of providing jobs and trade and future patient access to innovative medicines, more suitably, the EU might consider focusing on development, manufacture and export of innovative products, instead of generic production due to the lack of competitiveness there.[317] Moreover, it appears that introduction of the SPC Manufacturing Waiver Exemption in the EU may well see decline in export value and potentially experience losses to European originator companies.

This is partly due to the current climate among countries outside the EU which normally afford incentives for boosting local manufacturing, resulting in production costs and distribution of generics manufactured in these countries being less when compared to European cost for manufacturing generics. Consequently, whilst it may be a challenge to smaller producers, more prominent international generic manufacturers may elect to increase production locally inside the non-European market instead of Europe as a means of competing with domestic generic manufacturers. This may apply significantly to domestic companies in countries like Brazil, Russia, and Turkey which countries often emerge with gains in the majority of generic business at the outset and in long term. Consequently, with or without an SPC Manufacturing Exemption, ultimately, these dynamics do not inspire hope for increased export potential for European generic manufacturers. In essence, these elements denote that an SPC Manufacturing Exemption may very well result in switching the export value of originator products in lieu of lower value generics, potentially decreasing the export value for Europe.[318]

[317] Mestre-Ferrandiz, J., Berdud, M. and Towse, A., "*Review of CRA's Report "Assessing the Economic Impacts of Changing Exemption Provisions During Patent and SPC Protection in Europe*", OHE Consulting, (2018), pg. 6.
[318] Ramya Logendra and Per Troein, 'Assessing the Impact of Proposals for a Supplementary Protection Certificate (SPC) Manufacturing Exemption in the EU', QuintilesIMS, 2017, available at https://www.efpia.eu/media/288516/efpia-spc-report_120917_v3_10217-002.pdf, accessed July 2021.

Moreover, pharmaceuticals occupied the 8th spot among patent applications with 6,330 applications at the EPO in 2017, biotech followed in 9th place with 6,278 applications. Top 10 applicants in 2018 were electronics companies.[319] Granting patents at EPC saw a change for some European countries which previously did not grant patents for pharmaceuticals and medicines. Such introduction has brought conflict between patenting and individuals needing access to essential medicines where drugs are offered at prices most cannot afford. Competition law issues also arise as the top companies are increasingly seeing annual turnovers of 0.8 billion Euros but whose products are nearing the end of patent protection and despite increased subsidies in research and development in the industry, fewer medicines are reaching the market. The situation may become worse through the new systems being adopted in patents throughout Europe, particularly the use of the European Patent. The European Patent, as an international patent, has effects under international law but utilises the method of definition by reference and in some cases produces a fusion of reference and independent provisions.[320] In the end, this may have the result of producing more applications to the court for clarification.

Looking at products for children, legislation relating to Paediatrics in the EU seems to be motivating paediatric product development universally. It means that facilitating harmonization and global development of paediatric medicines, requires an understanding of the legislative obligations that needs to be satisfied in tandem with incentives that exist to include paediatric patients in therapeutic clinical trials. The goal of the legislation should always be geared at providing incentives and should incorporate timely, ethical, and sound scientific development of pharmaceutical products for paediatric patients whilst ensuring adequate information for using them safely and effectively.[321]

[319] Justine Pila & Paul Torremans, *European Intellectual Property Law*, 2nd Edition, (Oxford University Press, 2019)108-109

[320] Winfred Tilmann & Clemens Plassmann, Unified Patent Protection in Europe, A Commentary, (Ed), (Oxford University Press, 2018)19-20.

[321] Penkov et.al., 'Paediatric Medicine Development: An Overview and Comparison of Regulatory Processes in the European Union and United States.' Therapeutic Innovation & Regulatory Science. 2017;51(3):360-371. doi:10.1177/2168479017696265, available at https://journals.sagepub.com/doi/abs/10.1177/2168479017696265, accessed July 2020.

Assessing the various reports provides significant insights into legal challenges, policy debates, industry trends, market access, emerging technologies and of course public health considerations. Discussions on the legal challenges delving into eligibility criteria, scope of protection and duration of SPCs is what was needed to steer the discussion away from business as usual into policymaking considering amendments geared at reform which encapsulates a balance between increased innovation and access in terms of promoting generic access. Consideration of the combined effect of these studies also demonstrate that changes in the number or type of SPCs that are granted sheds light on shifts in innovation or regulatory priorities, in particular, how SPCs affect healthcare delivery and patient outcomes. Further analysis indicates that subsequent focus may well follow more profound questions and analysis into emerging technologies, such as gene therapies or advanced biologics and whether or not the existing SPC regulations can be applied to these innovative products.

Despite being in force for over 20 years and the subject of a plethora of ECJ decisions, the SPC legislation remains one of the most unpredictable and contentious aspect of European IP law. Users of the SPC system do not appear to have much confidence in it and are often dissatisfied by guidance from the ECJ, as in most instances, it seems to generate more new questions rather than responding to the previous ones. This attitude is transferable to the unitary patent system, where currently the legal framework makes provision for SPCs derived from European patents to fall under the jurisdiction of the UPC if there is no declaration of an opt out.[322] The main issue is likely to be that beyond the transitional period of seven years and a possible further seven year extension to allow the Unified Patent Court (UPC) exclusive jurisdiction, national courts will have the authority to make pronouncements on validity of SPCs.[323] The result of this may be alarming and is likely to cause more confusion.

[322] Romina Kuhnle et.al, "Obtaining Patent-Term Extensions in Europe", IAM, 2023, available at https://www.iam-media.com/guide/global-life-sciences/2023/article/obtaining-patent-term-extensions-in-europe

[323] European Patent Register, "Supplementary Protection Certificate(s)", EPO 24/01/2024, available at https://register.epo.org/help?lng=en&topic=UPcertificate

Unlike copyright law, which protects the expression of ideas, through works in fixed formats, patent law requires proof of novelty and reimburses innovators for such creative achievements. Under copyright law arrangements, compilations, listings, databases etc, are given copyright protection separately from the original material embodied in them. The patent system appears to have borrowed this ideology through the sui generis SPC regime by allowing SPCs a life of their own in what can be considered an expression of innovative pharmaceutical products. The legality of this is not what is in question but rather the viability and practicalities of the system and how it contributes to lack of access. Since the introduction SPCs in Europe various cases have made their way through the court system, purely on a legal basis, exploring validity under patent rules and the SPC Regulation. More recent cases in the UK merely delve into possible infringement and invalidity of patents despite the existence of SPC's,[324] on the issue of the right time to pay fees for extension,[325] or where errors were made on an application for extension for 2 years instead of 4 years extension,[326] and considerations on whether an active ingredient was deemed to fall under the invention covered by the patent which is a requirement under Article 3 (a) of Regulation 469/2009.[327]

A review of these cases shows that whilst they attempt to provide guidance to industry on what may be considered valid extensions, they rarely touch on matters concerning the cost implications for end users which usually fall outside the remit of the judicial system and assessed by industry. The fundamental issue with the cases is that they do not specifically address access issues. Even the Canadian reported cases post CSP are indicative of arguments on what is considered a "medicinal ingredient"[328] legal arguments surrounding single ingredient and combination drugs.[329] These cases are indicative of the types of matters anticipated to be brought through the courts which are likely to have attached delays in making generic products available for the market

[324] See *Teva UK Ltd v Janssen Pharmaceutical NA*, [2020] EWHC 3157 (Pat), [2020] 11 WLUK 293, Judgement given 16 November 2020. [2020] EWHC 3157 (Pat)

[325] *Genentech Inc. v Comptroller General of Patents,* [2020] EWCA Civ 475, 31 March 2020.
[326] *Master Data Center Inc. v Comptroller General of Patents*, [2020] EWHC 572 (Pat), 11 March 2020.

[327] *Teva UK Ltd v Gilead Sciences Inc.* [2019] EWCA Civ 2272, 19 December 2019
[328] J. Bradley White, Nathaniel Lipkus, 'Canadian court interprets CETA drug patent extensions more broadly than EU equivalent', April 2020, accessed online at Osler.com, August 2020. See further, *Glaxosmithkline Biologicals SA v Canada (Health),* 2020 FC 397
[329] ViiV Healthcare ULC v. Canada (Health), 2020 FC 756, accessed online December 2020.

and further additional cost implications for pharmaceutical companies, health authorities and ultimately the payers. At most, the cases are symbolic of a further burden on the system in the sense that patent litigation in Canada appears more complicated with the additional dimension on CSPs and SPCs, which prior to CETA were non issues, within the Canadian experience.

Despite SPCs playing a thorny role in the intellectual property terrain in Europe, impacting innovation, competition and access of medicines, balancing the interests of key players: innovators, generic manufacturers and public health concerns may remain a challenge for policymakers and regulators. Solutions for boosting patent law to deal with consequences may require a varied model of activism and advocacy.[330]

[330] Thambisetty, Siva, 'Improving access to patented medicines: are human rights getting in the way?', Intellectual Property Quarterly, I.P.Q. (2019), 4 284-305, accessed online August 2020

3.6. EU AND IMPROVED ACCESS TO PHARMACEUTICALS

This section focuses on the rising cost of pharmaceuticals and offers suggestions for collaboration on pricing structures and the effectiveness of fixing the broken SPCs.

Collaboration on Price as an attempt to lower drug prices.

It appears that countries may find some common perspective in collaboration when it comes to pricing. Some overarching principles are suggested by EFPIA. The suggestion includes: Any Member States collaboration on pricing, reimbursement and access related issues should lead to broader and/or accelerated access for patients; Since one of the aims of Member States' collaboration should be to accelerate patient access, the collective agreement should impose neither additional market access barriers nor additional price-related measures. Therefore, there should be no duplication between collective agreement and equivalent steps in participating countries; Any voluntary Member States' collaboration on price should be confined to countries of similar economic and health-related needs; Industry participation in any Member States' collaboration on pricing, reimbursement and access related issues should be voluntary; and Any Member States' collaboration on pricing, reimbursement and access related issues should guarantee confidentiality of pricing and reimbursement agreements.[331] EFPIA reports[332] on collaboration and identifies four activities common to the majority of cross-country collaborations and provides details on supra-national horizon scanning; joint Clinical Assessment (JCA) and Joint Health Technology Assessment (HTA); information sharing, purchasing and joint pricing negotiations and joint public procurement.

Assessing access in the UK Post-Brexit

Post-Brexit scenario for the UK requires an evaluation of whether the SPC Waiver will be adequate to fit the needs of the UK or whether a total distancing from the regime

[331] See updates on Beneluxa: Initiative on Pharmaceutical Policy, <https://beneluxa.org/collaboration> accessed December 2019

[332] EFPIA Patient W.A.I.T. Indicator 2018 survey, (3 April 2019) – accessed via <https://mapbiopharma.com/home/2019/04/efpia-report-highlights-patient-access-disparity-across-europe/> accessed August 2020

will be required in a post-Brexit situation. Whether or not a version of SPC exists, the UK will have to examine its future arrangements with the EU, US and Canada and other countries and determine whether a version of SPCs will exist. In considering whether to keep the SPC system, in light of CETA, the UK may want to consider a varied version of SPC which may address new terms for leaving the EU and how it will deal with SPCs in Europe. Of course, arrangements will have to be made for SPC's in force at the time of departure. New changes to the legislation are to begin operation as the UK attempts to manage its own term extension system beginning January 2021[333] however, the arrangements do not appear to address the issue of the Waiver or 1 day access as proposed. Implementation of the 1-day access appears to be the solution. The UK may be in such a position based on the post-Brexit position adopted and may require to re-visit its IP laws as well as those relating to pharmaceutical regulation with a view to fostering enhanced access.

Fixing the broken SPC for enhanced access.

Based on the foregoing data, the SPC system appears to be faulty and attempts to address access matters ought to stem from the source of the issue, the SPC itself. The EC recognised this and proposed a Waiver whilst the pharmaceutical industry determined that an over-hall of the system is what is required. This section shows how the proposals to fix the SPC system achieves some aims but more is required to realise relevant goals of better cost and availability.

As demonstrated through recent studies deep issues within the SPC system requires making adjustments internally and has spurred policy makers into immediate action adopting measures to address the SPC which has at its centre, significant support of generic pharmaceutical producers.[334]

[333] The Patents (Amendment) (EU Exit) Regulations 2019 ("the Patents Regulations 2019") will come into effect at the end of the transition period on 31 December 2020. These regulations will bring current EU legislation into UK law as far as possible, to maintain current systems and processes.

[334] Council of Europe, Press Release 359/19 May 14 (2019), accessed online, <www.consilium.europa.eu/press> March 2020

The EU took measures to foster the competitiveness of EU producers of generic medicines and biosimilar products. The Council adopted a regulation which introduces an exception to the protection granted to an original medicine by a supplementary protection certificate (SPC) for export purposes and/or for stockpiling, much like the "Bolar Exemption".

Based on this exception, EU-based manufacturers of generics and biosimilars will be entitled to manufacture a generic or biosimilar version of an SPC-protected medicine during the term of the SPC either for the purpose of exporting to a non-EU market where protection has expired or never existed or (during the six months before the SPC expires) for the purpose of creating a stock that will be put on the EU market after the SPC has expired. In May 2018 the European Commission published a proposal of Regulation amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products. Recent developments concerning the SPC system shows proactive measures through Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009. The regulation entered into force 1 July 2019 and introduced "The Waiver".

Although the Waiver came about rapidly, it did not happen suddenly and is considered timely as global demand for medicines has increased massively (spending expected to reach €1.4 trillion in 2020, an increase of 29-32% from 2015 compared to an increase of 35% in the prior years).[335] Alongside this, there is a shift towards an ever-greater market share for generics and biosimilars. Rising drug development cost, high investments needed for drug discovery, clinical research, and post-marketing surveillance are some of the key contributors to increased spending.[336]

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[335] See further information IMS Institute for Healthcare Informatics, 'Global Medicines Use in 2020, Outlook and Implications', (November 2015), available for at <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-medicines-use-in-2020> accessed May 2020

[336]Research and Markets, 'Global Medical Information Markets 2020-2027: Increasing Demand for New Drug Development with the Emergence of Technologically Advanced Healthcare Solutions', (October 13, 2020 06:49 ET) , available at <https://www.globenewswire.com/news-release/2020/10/13/2107364/0/en/Global-Medical-Information-Markets-2020-2027-Increasing-Demand-for-New-Drug-Development-with-the-Emergence-of-Technologically-Advanced-Healthcare-Solutions.html#:~:text=The%20global%20medical%20information%20market,7.4%25%20during%20the%20forecast%20period.&text=The%20market%20expansion%20is%20a,high%20prevalence%20of%20chronic%20diseases.> accessed December 2020

The SPC system, it is envisaged, was set to contribute to Europe's competitiveness as a hub for pharmaceutical R&D and manufacturing. It will help new pharmaceutical companies start up and scale up in high growth areas, and is projected to generate, over the next 10 years, additional net annual export sales of well in excess of €1 billion, which could translate into 20, 000 to 25, 000 new jobs over that period.[337]

The Kyle Report suggested that a better administration of SPC regime would add significant benefit[338] and identified several areas where the policy could be improved. As noted in the Commission's pharmaceutical sector inquiry, a unitary patent would likely reduce costs for both originator and generic firms. Similarly, a single SPC application that is valid in all member states would also simplify the complex terrain of intellectual property across Europe.[339]

Barring these changes, better information sharing across patent offices on SPC applications and outcomes would make it easier to identify cases where the rules are not evenly applied, for example. Clarification of the definition of a "basic" patent, so that there is greater uniformity across member states, would also be useful. Finally, the speed of generic competition could be increased by reducing the fixed costs of preparing applications for marketing authorizations across many countries with varying IP barriers. Generics that can make use of the centralized procedure seem to reach the market more quickly, for example. This suggestion is a bit speculative, as not all generic producers have the scale to market throughout Europe.

Harmonization of patents and SPCs across member states provides an option for assisting in the SPC system but may prove very costly. An alternative is to adjust the exclusivity policy and eliminate SPCs. A key difference is that exclusivity is independent of the time spent in development. This may reduce the incentives for firms to move products quickly through trials and for rapid launch compared to a situation with a "ticking" patent clock.[340] This method seems to be what was preferred during the Covid-19 race for a vaccine.[341]

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[337] See Kyle Report 2017
[338] Kyle Report 2017
[339] Kyle Report 2017 pg. 30
[340] Kyle report 2017 pg. 31
[341] See further *WHO Covid-19 Vaccines Update* available at <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines> accessed December 2020

Another measure is the coherence of examination outcomes which could be achieved through increased clarity on the scope of medicinal product protection and harmonization of national SPC granting procedures. Coordination across national patent offices and exchange of information on SPC applications might facilitate this process further. More coherence and transparency are expected to reduce the divergence in the scope of protection for originators as well as may improve legal certainty for generic entrants.[342] Such level of harmonisation will no doubt enhance the effectiveness of whatever changes are effected to SPCs.

Not surprisingly, further assessments yielded: the need for a unitary patent[343] and early working exceptions in the form of the SPC Waiver, both of which were given drastic push in the last 2 years which spurred consultation on amendments to the legislation to facilitate these proposals.[344] The industry welcomed such bold moves and Formycon and Janssen Biotech have even tested the efficiency of the new arrangements.[345] The case was brought against German pharma company Formycon which developed FYB202, a biosimilar of Stelara but regardless of the 2019 SPC amendment, the company was not allowed to produce the biosimilar for export, whilst the SPC was still valid.

This is indicative of a new wave of litigation and requests for clarification under these new regimes, which will no doubt involve major litigation and constant battle between originators and generic producers, the ultimate costs being born by the consumers, resulting in access difficulties. It appears however that whatever measure adopted made little sense without direct attention placed on generics entry, which is what the SPC WAIVER intended to address. Of course, there are proponents for and against

[342] Meijer 2017 pg. 16

[343]Simmons+Simmons, *'EU SPC Reform - Centralised Examination Procedure Proposed'*, 2023, available at https://www.simmonssimmons.com/en/publications/cllorhdy500w8u2s8k45d45di/eu-spc-reform-centralised-examination-procedure-proposed accessed August 2023.

[344] Regulation EC 2019/933, which since 2019 has supplemented the previous SPC regulation EC/469/2009).

[345] Konstanze Richer, *'Formycon and Jansen Biotech put EU SPC Waiver to the test in Munich*', JUVE Patent Newsletter, 2023, available at http://Formycon and Janssen Biotech put EU SPC waiver to the test in Munich - JUVE Patent (juve-patent.com)

SPC Waiver[346] and also recent study shows[347] the difficulty in finding an efficient balance.

The Charles Rivers Associates Report also supports the SPC waiver and indicates that it will be beneficial.[348] It shows that such a waiver provision would generate additional net sales for the EU pharmaceutical industry amounting to €9.5 billion; 25,000 additional jobs; €254.3 million additional net sales of EU Active Pharmaceutical Ingredients (API); 2,000 new direct jobs for the EU API industry and savings in the European healthcare system of €3.1 billion.[349]

Despite an apparent constructive way forward, not every stakeholder is confident that the new system will bring about positive change. Medicines for Europe conducted its own assessment of whether a Waiver will allow for quicker access to medication and proposes a 1-day Launch. The main argument against proposed SPC waiver[350] include the fact that it only applies to export and future SPCs and that it does not allow for Day 1 launch in Europe. Because of this it is believed that the SPC waiver, in its proposed form, will not assist access, within the European context. Medicines for Europe strongly contend that the SPC Waiver will not reduce intellectual property protection, well at least not in the EC. In fact, it is suggested that not just access will be affected negatively but commenting on jobs and competitiveness, it is estimated that 25,000 additional direct jobs and 100,000 indirectly, will be lost due to the Waiver, 9.5 billion Euros loss in net sales for EU pharmaceutical industry and 3.1 billion lost in savings to EU pharmaceutical spending.[351]

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[346] EC Commission, '*Feedback to Commission Public Consultation Supplementary Protection Certificates SPC*, (2018-01-15)

[347] Charles Rivers Associates 2018

[348] Charles Rivers Associates 2018, see also Medicines for Europe website. (The Commission published the study)

[349] Medicines for Europe, 'SPC Manufacturing Waiver: For Quicker Access to Medicines for Patients', <http://www.spcwaiver.com/en/> Accessed 13th April 2019, (SPC Waiver 2018)

[350] SPC Waiver 2018

[351] SPC Waiver 2018

It appears therefore that the best solution for the Waiver is to allow Day 1 patient access in the EU. To an extent, Day 1 measure is estimated to benefit all stakeholders in that generic companies will have an opportunity to plan, originator companies will be able to make arrangements for licensing and activate post patent expiry strategies and buyers/payers will benefit from quicker access to cheaper drugs. This may also have a knock-on effect on litigation in that the need to utilise the remedy in the courts will be diminished. Currently, the real impact on access is a bit premature since, at the time of writing, it would be just about 1 year since its implementation and a full report on progress may be forthcoming. Such analysis will require a comprehensive assessment of the number of applications for Waivers, the process, grants, delays, and economic/cost savings where applicable. Such analysis would also provide insight into the types of drugs actually benefited from the Waiver and details of exports to match applications. This process does not appear to be as simplistic as intended and requires in-depth considerations to assess its full potential in finding a fix to the SPC system. For now, the benefits of the Waiver remain speculative.

The arguments for and against the SPC Waiver regime seem sound in their own right but for now, particularly in the wake of the pandemic, it may be difficult to assess how well the Waiver will fear in terms of addressing access. Since the SPC regime is a community construct, Members are not free to pick what aspects they adopt, as such, assessment of the impact of the Waiver can only be seen from a community perspective. Countries wishing to make use of the 1- day rule for access as proposed by the Generic Industry, may well see savings, not just to facilitate in-country savings but to assist in exporting. Currently, the real impact on the SPC Waiver and access is a bit premature since, at the time of writing, it would be just about 1 year since its implementation and a full report on progress may be forthcoming. Such analysis will require a comprehensive assessment of the number of applications for Waivers, the process, grants, delays, and economic/cost savings where applicable. Such analysis would also provide insight into the types of drugs actually benefited from the Waiver and details of exports to match applications. This process does not appear to be as simplistic as intended and requires in-depth considerations to assess its full potential in finding a fix to the SPC system. For now, the benefits of the Waiver remain speculative.

Chapter summary

Consideration of the data highlighted effects of SPCs on access in terms of time and cost. What this translates to in a nutshell, is that the rate of filing of SPCs in Europe has arisen and continues to rise; that SPCS's delay an average price drop of approximately 50%; the average length of SPC is 3.5 years; the total spending on medicinal products in the EU is USD 247bn. Hence a 10% change of total spending on medicinal products from originator products to generic products would have yielded a possible saving of USD 12.4bn; Potential savings on generic entry could have been in the region of € 3 billion,[352] 20% higher. In the final analysis, attempts to address some of the regulatory problems in administering SPCs include harmonisation through the use of the Unitary Patent. Combined with the 1-day Waiver, these changes have the potential to impact time and costs, positively. Proactive measures are geared at removing major competitive disadvantage, adjusting to the current systems in an effort to achieve a balance between continued prominence of European pharmaceutical originators and providing an avenue for EU-based generics and biosimilars to compete globally.

[352] Meijer, 2017

Chapter Four

STRENGTHENED PATENT MONOPOLY Vis PHARMACUTICAL ACCESS

An analysis of the generic industry in both European and Canadian contexts as well as the projected implications on access through the new “restoration” system adds to the discourse by forging beyond arguments of increased cost and time delay to generic entry of term extensions, to explore and determine that many of the issues are inherent to the patent system, albeit outside the scope of term extensions.

The main arguments are that issues such as regulatory hindrances, trading relationships and special treatments in EU provide useful illustrations in explaining lower costs in Europe and Canada’s higher drug cost despite no extensions, which is illustrated by an anticipated significant increase in the costs for pharmaceuticals in Canada as a result of CETA. This provides an understanding of the possible reasons why the cost of pharmaceuticals is higher in Canada and adds to the overall cost and access dynamics. This requires a viewing from the angle of the generics industry and issues that seem to obstruct seamless access to the markets in Europe and Canada, the limitations of the patent system as it pertains to pharmaceuticals, as well as the potential impact of the Trade Agreement.

At over US$700 per person per year, Canada spends more per capita on pharmaceuticals than any other country in the world except the US. When measured against comparator countries in the OECD, Canada’s growth in drug spending per capita between 2009 and 2011 was 43% per year compared to the OECD average of 35%.[353] Despite not having SPCs Canada’s drug cost remained higher in Canada than most European countries which may appear to support a conclusion that SPCs do not automatically result in extensions and or higher prices and consequently hinder access as is made out in the literature.

Further exploration of the data indicates however that other IP matters affect the cost and availability of medicines in Canada as well as non-IP/patent developments.

[353] OECD 2019 and PMRB.

4.1. DISSECTING PHARMACEUTICAL SPENDING FROM A CANADIAN STANDPOINT.

A scrutiny of the Canadian drug spending based on data and analysis reveals that although the system of law and industry varies, at over US$700 per person per year, Canada spends more per capita on pharmaceuticals than any other country in the world except the US.[354]

Significantly, this information is useful to illustrate the similarities and differences in drug prices in the relevant jurisdictions and to add context to trends based on varied legal underpinnings, in this instance the addition or not of term extensions. Key to understanding this section is to bear in mind that at the time of research there were no effective extensions yet as products caught by the new CSP's would not have reached maturity and data was not available. Hence the information associated with the Canadian context is purely to understand the state of law and industry prior to the new system taking effect and provides explanations on trends in Canadian spending. Importantly, it should be noted that no direct comparisons are made with the European context based on previous numbers on access, however the data indicates that in comparison to the OECD average of 35%, Canada's growth in spending for pharmaceuticals between 2009 and 2011 was 43% annually, per capita, registering a drop in the rate to 0.3% per annum during that period but 0.9% drop in the OECD average.[355]

Spending costs for pharmaceuticals show further increases and although various cost drivers can claim responsibility for such increases,[356] the substitution of newer but more costly drugs for older, less expensive versions, seemed to have had the biggest impact on spending. A classic example is seen in Ontario's policy changes for altorvastatin (Lipitor), treatment for high cholesterol. Before the patent expired,

354 Canadian Institute for Health Information, National Health Expenditure Trends, 1995 to 2012, (CHI: 2013) and Canadian Institute for Health Information, Drug Expenditure in Canada, 1995 to 2011, Ottawa, (CHI:2012) accessed via <https://www.cihi.ca/en> March 2019

355 CHI: 2013 and Lexchin and Gagnon, 'CETA and pharmaceuticals: The Impact of the Trade Agreement Between Europe and Canada on the Cost of Prescription Drugs', (2014) Globalization and Health 2014.

356 CHI: 2013, above

providing Lipitor cost Ontario $316 million[357] and on expiry, with available generic versions, the cost of fell to US$133 million registering total savings of $183 million.[358]

Understanding Canada's spending on drugs is best understood through comparisons made with other countries in the Western world where sophisticated patent systems exists and research and development as well as manufacturing are suitable established. The OECD data sets on pharmaceutical spending[359] combined with findings from the PMPRB Report of 2017 provides balanced reporting on the issues.[360] These findings are given below and are used in conjunction as the PMRB utilises OECD datasets and normally make their own comparisons. Pharmaceutical spending covers expenditure on prescription medicines and self-medication, or over-the-counter products. Pharmaceuticals consumed in hospitals and other health care settings are excluded. Financial expenditure on pharmaceuticals includes wholesale and retail margins and value added tax.

The OECD figures represent net spending, that is, adjusted for possible rebates payable by manufacturers, wholesalers or pharmacies. This indicator is measured as a share of the total health spending in USD per capita and as a share of GDP which represents the data for the period 2014 to 2017 and compares overall health information for Canada and five major European countries.[361]Interestingly, the PMPRB shows that the average generic medicine prices in Canada have been reduced to half of what they were a decade ago. While this decrease exceeded the overall price reductions in most PMPRB7 markets, the rate of decline has slowed in

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[357] CHI: 2013, above

[358] Lexchin and Gagnon, 'CETA and pharmaceuticals: The Impact of the Trade Agreement Between Europe and Canada on the Cost of Prescription Drugs', (2014) Globalization and Health 2014

[359] Pharmaceutical spending (indicator), OECD (2019), doi:10.1787/998febf6-en available at <https://www.oecd-ilibrary.org/docserver/4dd50c09-en.pdf?expires=1606756249&id=id&accname=guest&checksum=A2E74874B254D2BBBFF4CA0B9664A23A> Accessed on 19 March 2019

[360] Appendix 3: Pharmaceutical Trends – Sales, Table 19. Sales of Patented Medicines, 1990-2017 available at <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1380&lang=en#app3> accessed March 20th 2019

[361] OECD (2019), "Health expenditure and financing: Health expenditure indicators", (2019) *OECD Health Statistics* (database), <https://www.oecd-ilibrary.org/social-issues-migration-health/data/oecd-health-statistics/system-of-health-accounts-health-expenditure-by-function_data-00349-en> accessed on 30 May 2019. (later referred to as OECD 2019)

recent years. Generic price reductions coupled with a weakening Canadian dollar have gradually reduced the sizable gap between Canadian and foreign generic price levels over the past several years.

Despite this, average prices in the PMPRB7 countries are still substantially less than Canadian levels, with the gap being slightly wider for the OECD countries. Canada has the seventh highest generic prices in the OECD, just below the US.[362] Direct comparisons can be made to some European countries in the EC which shows Foreign-to-Canadian Price Ratios for Generic Medicines, OECD, Q4-2016 calculated at medicine level for medicines with prices available in at least three foreign markets.[363] Bilateral comparisons show that consumption costs were higher in Canada for pharmaceuticals under patent purchased in 2017, than for France, Sweden, Switzerland and the UK.[364]

In sum, both the PMRB and OECD figures show that Canadian drug prices, although once some of the lowest, are slowly climbing and in some instances are on par with European countries. Reasons for this is explained in the next chapter but the cost of medication in Canada may be more complex and may be outside the remit of this research. In the meantime, re-analysis from DrugCost drug-database[365] represents an indication on where the cost of medication in Canada may be heading. The information from orders placed between April and June 2018 from various countries including European, US, Canada and other countries show that Canada did not register a significantly lower rate for drugs than other countries in Europe. The data did not reveal whether SPCs were attached to any of the products and was only concerned with the actual cost to purchase of certain types of drugs and to offer a direct price comparison.

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362 Price Indices for Generic Medicines, Canada and the PMPRB7, Q4-2007 to Q4-2016 Group of generic medicines set to 18% of the brand price through pan-Canadian Pharmaceutical Alliance negotiations.

363 See further OECD 2019

364 See further, https://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2018/2017_Annual_Report_Final_EN.pdf

365 Original data published on their website and can be found <http://drugdatabase.info/drug-prices/.> Dataset made available from the institution and all necessary permissions given.

The data indicates that just 46% of the drugs analysed showed lower prices for Canada. The importance of this information to this Research is that it demonstrates the actual price comparisons for individual pharmaceuticals which originates from a single distributor to both EC and Canadian buyers. The cost of the pharmaceuticals which are all on the EML, is instrumental in showing the pre 2017 environment which will add to the overall discussion on the impact of added time through the new CSP.

4.2. EXPLAINING COST SAVINGS FOR PHARMACEUTICALS IN THE CANADIAN GENERICS CONTEXT

Canadian system of generic production of pharmaceuticals reveals that despite an active, pro-generic structure and more integrated legislative system, Canadian costs for pharmaceuticals continue to soar.

Summary of Canadian laws protecting pharmaceutical intellectual property ultimately begins with an understanding of the system of operation in Canada, which is somewhat different to what obtains in the EU. The federal government uses three sets of regulations that attempt to "balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower-priced generic competitors."[366] In the first instance, the Patent Act:[367] Pharmaceutical firms can apply for patents to obtain 20 years of exclusivity for an invention disclosed in a patent. Examiners at the Canadian Intellectual Property Office, a division of Industry Canada, decide which innovations are worthy of patent protection on the basis of several legal criteria, most notably novelty, utility, and non-obviousness to a person "skilled in the art." Typically, commercially successful drugs have numerous patents disclosing the active ingredient, coatings, therapeutic indications, dosing, manufacturing methods and other aspects of the drug.

Additionally, there is the Patented Medicines (Notice of Compliance) Regulations:[368] In short, a firm wishing to sell a generic drug must address patents asserted to be relevant by the patent owner before it can be sold. For any given patent, a generic drug firm can either await expiry or allege that the patent is invalid or not infringed. If it chooses the latter path, the brand drug firm can trigger a judicial proceeding in which the merits of the allegations are assessed in federal court. Health Canada is prohibited

[366] Deloitte, '*Ensuring a Consistent Supply of Safe, Effective and High-Quality Generic Medicines for Canadians*', Canadian Generic Pharmaceutical Association, (October 2016)

[367] Patent Act R.S.C., [1985, c. P-4] full text available at <ttps://laws-lois.justice.gc.ca/eng/acts/p-4/FullText.html>

[368] Government of Canada, Guidance Document: Patented Medicines (Notice of Compliance) Regulations, (2000), last updated (2018), available at Guidance Document: Patented Medicines (Notice of Compliance) Regulations - Canada.ca, accessed March 2020.

from granting market approval to the generic drug until after the matter is adjudicated, or 24 months elapse, whichever comes first. Canada's unique pharmaceutical patent system means that generic drug companies may have to litigate a single branded patent twice. First, they may face litigation over their allegation of patent invalidity under the Notice of Compliance regulations. Second, after launching the generic drug, they risk being sued for infringement under the Patent Act. Similarly, a branded drug firm that wins under the Notice of Compliance regulations may be forced to defend a patent's validity again in an impeachment action.

Further, the data protection regulations:[369] These regulations essentially guarantee branded drugs a minimum period of market exclusivity. A generic drug company is not allowed to apply for regulatory approval, by establishing its bioequivalence to the reference brand drug, until the brand drug has been on the market for six years. It cannot receive regulatory approval until the brand drug has been on the market for at least eight years. Additionally, a six-month extension granted for drugs that have undergone clinical trials in paediatric cases. The rationale for the data protection regulations is that the clinical trials mandated by Health Canada can consume much of a brand drug's patent life. In these cases, the period of effective market exclusivity may be too short. Data protection privileges are restricted to "innovative drugs," defined as, "A drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph."[370]

Exploring cost savings in using generic products

The Canadian Generic Pharmaceutical Association estimates that:

The availability and use of generic prescription medicines saved Canada's health-care system more than $84.3-billion over the past five years, based on figures between

[369] See Health Canada, Guidance Document 'Management of Drug Submissions and Applications' (January 2018) Revised date: 2019/02/15 Effective date: 2019/07/25 available at <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/management-drug-submissions/industry/document.html> accessed January 2018 (Health Canada 2018)

[370] Section C.08.004.1(1) of the Food and Drug Regulations

2013 and 2017;[371] Generic prescription medicines play a key role in controlling health-care costs in Canada. Generic prescription medicines are used to fill 70.6-percent of all prescriptions, yet account for only 21.8-percent of the $27.5-billion dollars spent annually on prescription drugs in Canada;[372] Generic prescription medicines are essential for the sustainability of public, employer and union-sponsored healthcare benefit plans upon which the vast majority of Canadians rely.[373]

The data shows that within a five-year period, 2013—2017, the use of generic prescription medicines saved Canada's health-care system both public and private sector drug purchasers a total of $84.3-billion 2013 - $13.0B, 2014 - $14.1B, 2015 - $15.0B, 2016 - $20.0B, 2017- $22.2B.[374]

The ongoing sustainability of benefit plans in Canada depends on the use of generic prescription medicines. Canada faces demographic changes that will amplify the pressure on both publicly and privately funded healthcare services. Therefore, policies to increase the use of generic prescriptions are key to ensuring the ongoing sustainability of drug benefit plans and broader healthcare services. These policies include: Intellectual property regimes that are fair and balanced for all stakeholders, including payers and generic pharmaceutical manufacturers; timely national Health Canada review and approval of new generic pharmaceutical products; timely listing of generic pharmaceutical products on provincial drug plan formularies following Health Canada approval; changes to the design of both public and private sector drug benefit plans to ensure maximization of cost-saving generic medicines; careful, unbiased, clinical evaluation of the cost-effectiveness of new, patented medicines to ensure they provide therapeutic improvement to patients and not just higher costs.

[371] CGPA "Generic Medicine Saves $84.3-billion CGPA Generic Medicine Saves $84.3-billion" Five-year savings 2013-2017- <http://www.canadiangenerics.ca> Accessed 29th April 2019 @13:14
[372] CGPA, "The Value of Generic Prescription Medicines: Every time you use high quality medicines you support sustainable health care", available at <https://canadiangenerics.ca/get-the-facts/generic-medicine/> Accessed April 2019
[373] See above CGPA "Generic Medicine Saves $84.3-billion CGPA Generic Medicine Saves $84.3-billion" Five-year savings 2013-2017- <http://www.canadiangenerics.ca> Accessed 29th April 2019 @13:14
[374] CGPA "Generic Medicine Saves $84.3-billion CGPA Generic Medicine Saves $84.3-billion" Five-year savings 2013-2017- <http://www.canadiangenerics.ca> Accessed 29th April 2019 @13:14

4.3. INVESTIGATING WHY DRUGS ARE MORE COSTLY IN CANADA

An evaluation of the drug costs in Canada makes direct linkages between the patent system, internal system and other factors which impacts access. It is significant to understand that medicines play a key role in healthcare and access to pharmacotherapy as a crucial human right and despite not having term extensions provisions, until 2017, Canada remains at the top for price of pharmaceuticals and growth in cost.[375] From a generics standpoint the problems faced in reaching the market are paramount.[376]

Although the issues raised fall outside of term extensions, they ought to be given some relevance in an attempt to understand the factors outside extensions, both patents related and otherwise. These include but are not limited to: licence costs; fluctuating Canadian Dollar; possible infringement provisions under the PA; lack of harmonisation; trade agreements with other countries; and special pricing in the EU.

Understanding how Licence Costs and Fluctuating Canadian Dollar affect the cost of pharmaceuticals.

Licencing costs added to instability of the Canadian currency play a major role in the cost of pharmaceuticals in Canada.

Canada is the 10th largest market for pharmaceutical drugs in the world. In 2013, total pharmaceutical sales in Canada represented 2.3% of the global market, while generic sales in Canada represented less than 2% of the global market.[377] The top 5 pharmaceutical sales countries in 2013 were the U.S., Japan, China, Germany and

[375] See OECD Reports mentioned in Chapter 3.

[376] Amir Attaran, 'Why Canada's Access to Medicines Regime Can Never Succeed' (2010) 60 UNBLJ 150 - accessed via <https://heinonline-org> March 2020

[377] Generics360, *Generic Drugs in Canada* (2018), Report available online at <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1469&lang=en>, accessed online August 28th 2019, (Generics 360 2018)

France accounting for 62% or $615B in sales [378] from this data the breakdown in sales and growth rate can be scrutinised further.

Notably, the U.S. (population of 324M), is the largest market for pharmaceutical drugs and accounts for 34.4% of the global market. The EU is the second largest market in the world with the top 5 markets in the EU, collectively known as EU5, consisting of Germany (population 82M), France (population 67M), Italy (population 61M), UK (population 65M) and Spain (population 46M) accounting for 15.8% of the market. As the market in Canada (population 36M) is significantly smaller than the U.S and the EU5, generic drug manufacturers may determine that it is not economically viable to launch a generic in Canada if they are required to conduct product development and/or manufacture product batches specifically for the Canadian market, even though the product may already have been approved in a similar regulatory jurisdiction.

The costs for bioequivalence studies and clinical trials are significant and, given the limited market size in Canada, it may not always be the best investment for a generic manufacturer to introduce the drug into the Canadian market. Generic manufacturers in, in Spain, for example, the country with a population closest to Canada, can access the entire European market with approval based on a single drug dossier making the return on investment worthwhile. The ability for Canadian generic manufacturers to take advantage of global product development and introduce drugs from other markets, such as the U.S. or EU, can result in an increased number of generic drugs becoming available in the Canadian market. In 2015, over 700 generic approvals were issued by the United States Food and Drug Administration[379] compared to 128 generic approvals by Health Canada.[380] According to one commentator, "*The bioequivalence standards we use in Canada have been in place for 20 years and are among the most rigorous in the world.*"[381]

[378] Deloitte LLP and affiliated entities, *Canadian Generic Pharmaceutical Association 4* - (IMS Institute for Healthcare Informatics, 2014).

[379] U.S. Food and Drug Administration, 2015

[380] Health Canada, 2015.

[381] Eugenia Palylyk-Colwell, BSc Pharm, PhD; Member, Scientific Advisory Committee on Bioavailability and Bioequivalence, Health Canada, taken from Canadian Generic Pharmaceutical Association, "Bioavailability and Bioequivalence – What do they mean?" <<http:www.canadiangenerics.ca> accessed 27th April 2019

Additionally, from a business perspective, the compound annual growth rate (CAGR) in Canada has been relatively modest at 1.4% over a 5-year period, compared to the growth rates in the U.S. 3.6%, EU 5 2.2% and emerging markets 13.6%.[382] This, added that to the fluctuating value of the Canadian dollar and the business case becomes troublesome.

A demonstration of how possible infringement with the Patents Act impacts generic entry

In addition to product licensing costs, Canada's unique patent regime, whereby brand name manufacturers have two sequential tracks of litigation for the same patents, places generic companies at significant and often catastrophic risk when entering the Canadian market. Companies can be sued for patent infringement under the Patent Act even after they have successfully challenged the same patents under the Patented Medicines Notice of Compliance Regulations.[383]

Once Health Canada issues a Notice of Compliance, the generic drug can be sold anywhere in Canada; however, in order to maximize sales and revenue the drug must be listed on the provincial formularies, in order for it to be eligible for reimbursement by the provincial government. The formulary specifies which drugs can be reimbursed and to what extent. For a generic drug to be added to a province's formulary, in addition to having a Notice of Compliance with a Declaration of Equivalence from Health Canada, it must meet the regulatory requirements of each individual province.[384] Some provinces may require additional data and/or clinical trials even after the drug has been approved by Health Canada, which increases the cost of introducing a generic drug to the market, delaying patient access and savings to the province. In many cases, this can result in a generic manufacturer deciding not to

[382] Ibid

[383] See further Mary Atkinson, 'Patent Protection for Pharmaceuticals: A Comparative Study of the Law in the United States and Canada' (2002) 11 Pac Rim L & Pol'y J 181 – accessed via <https://heinonline-org> March 2020

[384] Health Canada 2018

introduce their generic drug in one or more provinces, or in some cases, not even filing for approval of the generic drug in Canada.[385]

There has also been increased pressure on generic manufacturers to reduce the costs of generic drugs. The pan-Canadian Pharmaceutical Alliance (pCPA), established in 2010, utilizes the combined purchasing power of the provinces to achieve lower prices for both generic and branded drugs.[386] The average price of a generic drug prescription in Canada has decreased from $26.23 in 2010 to $20.92 in 2015 while the cost of a brand name drug prescription has increased from $71.91 to $91.92 in the same timeframe.[387] Collaborative efforts on pharmaceuticals through the pCPA showed major in price reductions on 18 generic drugs and negotiated agreements for 95 brand name drugs. It is estimated that this work results in approximately $712 million in combined savings annually.[388]

Understanding the possibility of the lack of harmonization and its impact on generic entry

The lack of harmonisation across Canada's system impacts negatively on generic entry of mediations.

Harmonization would appear to be a problem for the EU with numerous member states from various legal systems however, it no doubt unique to the EU.[389] Canada, it seems is plagued with its version of harmonization issues which, is seen as equally damaging to the industry. The situation is summed up by a commentator who asserts that: "Due to the lack of regulatory harmonization between the different provincial, territorial and federal governments, Canada and its current health care system is one of the more

[385]Generics 360 2018

[386] The pan-Canadian Pharmaceutical Alliance, 2016 available at <https://www.pcpacanada.ca/> accessed August 2019

[387] The pan-Canadian Pharmaceutical Alliance, 2016 available at <https://www.pcpacanada.ca/> accessed August 2019

[388] pCPA Report, *Leadership in Health Care Report to Canada's Premiers on the Achievements of the Health Care Innovation Working Group 2013-2016* (2016), - <https://www.canadaspremiers.ca/wpcontent/uploads/2017/09/july_2016_hciwg_report.pdf>

[389] Sarah R Wasserman, 'The Harmonization Myth in International Intellectual Property Law' (2020) 62 Ariz L Rev 735 – accessed via <https://heinonline-org> August 2020

difficult countries for the generic industry to operate in because of the complexity and costs of market access. Harmonizing regulations and working towards a more sustainable and predictable environment would be critical elements for the supply chain to deliver consistency, quality and dependability and ultimately better serve Canadian patients.[390]

For a better understanding of this point, the system is dissected by Zhang et al[391] comparing the Approval and Coverage Decisions of New Oncology Drugs in the United States and Other Selected Countries. Health Canada's drug review process begins with its Therapeutic Products Directorate, a board of scientists that assesses the quality, safety, and efficacy of a drug and decides whether the benefits outweigh the risks of allowing the drug to enter and continue to be on the market.

The Canadian Agency for Drugs and Technologies in Health runs a Common Drug Review to rate the clinical and cost effectiveness of drugs for the purpose of recommending drugs to be covered by the provinces, but each province can make its own decision. The pan-Canadian Oncology Drug Review evaluates oncology drugs based on clinical evidence and cost-effectiveness, recommends funding decisions, and includes suggested dosage and place in therapy. Then, the provinces make their respective coverage decisions independently on the basis of the information provided by the pan-Canadian Oncology Drug Review.[392]

Explaining how trade agreements with other countries affect access in Canada

Canada's relationship with its trading partners appears to be harmful to its pharmaceutical industry.

[390]Larry MacGirr, *News Release* (Pharmascience Inc, Toronto, February 27, 2017) available at <https://canadiangenerics.ca/news-release6/feb-27-2016/> accessed March 2019

[391] Youtang Zhang, Hanna Chantel Heuser, Inmaculada Hernandez, 'Comparing the Approval and Coverage Decisions of New Oncology Drugs in the United States and Other Selected Countries', (Feb 2017) 23(2 J Manag 247-254, <https://www.jmcp.org/doi/abs/10.18553/jmcp.2017.23.2.247> - Accessed April 11th 2019

[392] Statcan.gc.ca, 'Population Projections for Canada, Provinces and Territories: Highlights' (2015) Available at, <https://www150.statcan.gc.ca/n1/pub/91-520-x/2010001/aftertoc-aprestdm1-eng.htm> accessed April 2019

The USMCA pharmaceutical intellectual property concessions are the latest hit for access to affordable prescription medicines for Canadians.[393] In Addition, Canada's intellectual property regime for pharmaceuticals was amended in September 2017 as a result of the Comprehensive Economic and Trade Agreement (CETA) with the European Union.

The Canadian Generic Pharmaceutical Association (CGPA), does not appear to find favour with new arrangements regarding the pharmaceutical intellectual property aspects of the United States-Mexico-Canada Agreement (USMCA):[394] The Association's view is that the pharmaceutical provisions in USMCA will delay access to competition from biosimilar biologic drugs in Canada, extending the period of market exclusivity for these products to 10 years from the current period of 8 years. Biologic medicines represent the fastest growing cost segment of health-care spending, and it is anticipated that these delays will be costly to patients, businesses that sponsor employee drug plans, private payers and the generic medication industry.[395]

The view is strongly held that agreeing to concessions that reduce access to essential medicines and increase cost for those who pay for it will not assist the Government of Canada in its endeavours to improving access to necessary prescription medication and reducing the amounts Canadian governments pay for these drugs.

Exploring the Special Pricing Systems in the EU which contributes to lower prices

Pricing structure in EU countries contribute to lower prices in Europe despite the SPC system and explains how the interplay between protection and price negotiations in a country[396]provides a different matter of concern to the cost of pharmaceuticals.

[393]Cherie O Taylor, 'Twenty-First Century Trade Policy: What the U.S. Has Done & What It Might Do' (2016) 23 Currents: J Int'l Econ L 49 – accessed via <https://heinonline-org> March 2020

[394] News Release 2018 » CGPA Statement on Pharmaceutical Concessions in United States-Mexico-Canada Agreement, (October 1st 2018) – Accessed online 27/04/2019

[395] Thomas J. Schoenbaum, 'The Art of the Deal and North American Free Trade: Advantage for the United States?' (2020) 14 Ohio St Bus LJ 100 – accessed via <https://heinonline-org> March 2020

[396] Copenhagen Economics 2018, pg. 298

There are generally two sides to the pricing of medicinal products and hence to the effect on healthcare budgets. One side is governed by the protection schemes granted to new medicinal products.[397] As has been shown and discussed at length earlier, the longer the protection period, the later the time at which generic companies can enter the market. At face value, longer protection thus alleviates some of the competitive pressure on pharmaceutical companies.

Another element having an effect on the prices obtained by the pharmaceutical companies is the reimbursement side.[398] After products have been granted marketing approval, in many countries companies must negotiate a price with a central authority responsible for the reimbursement of pharmaceutical expenses in the given country. The competitive situation in the market is an important factor in determining the bargaining power of the companies and the reimbursement authorities in these price negotiations, and hence there may be a connection between the protection schemes and the negotiable prices. In the case of protection schemes granted include both the IP protection systems such as patents and SPCs, and the regulatory protection schemes such as data protection and market protection.

These protection structures protect originator medicinal products against competition, albeit in different ways and to varying degrees. The competition landscape is one element of chief importance when setting prices in any industry. As such, through their effect on the competitive situation, the protection schemes for medicinal products influence the pricing possibilities of pharmaceutical companies.

As far as reimbursements go, in most EU countries, the people receiving treatment with medicinal products do not directly pay for their treatment themselves. In most

[397] Health Canada 2018

[398] Conference Board Research, '*Health Care Cost Drivers in Canada Pre-and Post-COVID-19'*, Impact Paper, September 2020, available at https://www.canadaspremiers.ca/health-care-cost-drivers-in-canada-pre-and-post-covid-19/

countries, either a private or a public insurance/reimbursement system is in place.[399] From an economic point of view, the fact that the people receiving treatment do not directly pay for it themselves is a so-called market failure.[400] It creates an incentive for patients to always demand the novel medicine, regardless of the price and perhaps more importantly, regardless of the relationship between price and clinical benefit, compared to the second-best medicinal product.

The reimbursement authorities in many European Member States are responsible for negotiating prices with the pharmaceutical companies based on an assessment of clinical value and willingness to pay.[401] As such, the final decision on whether or not to reimburse a new medicinal product lies with the reimbursement authorities in the various Member States. However, as the protection schemes, possibly granted at an EU level, influence the competitive situation surrounding a product, there is an interplay between the protection schemes and the bargaining position of the companies and reimbursement authorities, respectively.[402] This means that it might be pertinent to see the two systems as interconnected components rather than completely independent ones. However, there are many other factors determining the bargaining power of the various players, and the degree to which the protection period is important might vary based on the interplay with these other factors.

[399] F. Schulenburg, S. Vandoros, P. Kanavos, 'The Effects of Drug Market Regulation on Pharmaceutical Prices in Europe: Overview and Evidence from the Market of ACE Inhibitors' (2011) 1 Health Econ Rev 18, doi: 10.1186/2191-1991-1-18 PMID: 22828053

[400] S. Vogler, C. Habl, M. Bogut, L. Voncina, 'Comparing Pharmaceutical Pricing and Reimbursement Policies in Croatia to the European Union Member States' (2011) 52(2) Croat Med J 183–197, doi: 10.3325/cmj. 2011.52.183 PMID: 21495202

[401] World Health Organization, *WHO Guideline on Country Pharmaceutical Pricing Policies*, Geneva, Switzerland: (WHO, 2013)

[402] P. Kanavos, W. Schurer, S. Vogler, *Pharmaceutical Distribution Chain in the European Union: Structure and Impact on Pharmaceutical Prices* London/Vienna: Eminet/London School of Economics/Gesundheit O¨ sterreich GmbH, (2011)

4.4. CETA AND ITS PROJECTED IMPACT ON COST AND AVAILABILITY OF PHARMACEUTICALS IN CANADA

Canada's drug pricing system will be impacted significantly based on the effect that the new term extensions will have on costs of pharmaceuticals in Canada. Although, at the time of writing, data was not available to make direct pronouncements on the cost of Certificates of Supplementary Protection, CSPs, in Canada, it is possible to project on its possible future impact on prices. These projections demonstrate that prices for pharmaceuticals are destined to elevate when the full operation of CSPs are realised but a more comprehensive assessment will, no doubt, be more explicit once the first set of pharmaceuticals caught by CSPs become eligible for generic entry.

Understanding how the CSP system in Canada works

The Office of Patented Medicines and Liaison, within the Office of Submissions and Intellectual Property, TPD, Health Canada, is administering the CSP provisions of the Patent Act and the Certificate of Supplementary Protection Regulations.[403] The CSP regime is substantially defined in the amendments to the Patent Act introduced in 2017 in the Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act (in force on September 21, 2017). However, various related timelines, requirements and procedures that are needed to administer the regime are provided for in the Certificate of Supplementary Protection Regulations. In light of the requirements of the Patent Act and Certificate of Supplementary Protection Regulations, a CSP can be issued only in respect of an eligible medicinal ingredient or combination of medicinal ingredients and an eligible patent.[404]

[403] Guidance Document: Certificate of Supplementary Protection Regulations
Date adopted: 2017/09/21, Revised Date: 2018/06/26 Effective date: 2018/09/04 Provisions 2017-2018 - Amendment of the Patent Act, CSP Regulations 2017 - These are miscellaneous amendments that are needed as a result of the substantive amendments to the Patent Act that received royal assent on May 16, 2017.

[404] Consolidated Patent Act, R.S.C., [1985], c. P-4, Current to March 27, 2019
Last amended on December 13, 2018, Published by the Minister of Justice at the following address: <http://laws-lois.justice.gc.ca> accessed March 2018

Exploring the potential impact of CETA's CSP on drug prices in Canada

Using information from projected analysis made from Canadian studies, this section demonstrates the potential impact of CETA on drug prices on Canada with the introduction of the CSPs. The section mainly addresses the projected cost to buyers of pharmaceutical products, which includes local consumers, insurers, Provinces and Federal Government.

Results from the data from OECD indicates that drug prices are higher in Canada than most EU countries even without term extensions. It is anticipated that the full extent of term restoration in Canada will manifest itself by 2023 and that in effect it may impact the Canadian drug pricing system with the requirement to adopt a term restoration system that which will operate to delay entry of generics for another 2 years. Additionally, it is anticipated that CETA will prolong generic entry by instituting a new right of appeal under the patent linkage system. In money terms, it is estimated that Canada's drug cost may see increases by 6.2% to 12.9% in 2023.[405] It is estimated that the two-year patent term extension included in CETA will cost Canadians more $500 million annually.[406] Since the Administration of CETA the potential impact of CETA on drug prices in Canada is illustrated by a more detailed assessment, conducted under the auspices of the Canadian Parliament:[407] The 2018 Report provides data analysed by office of the Parliamentary Budget Officer, (PBO).

This report estimates additional drug costs to Canadian consumers from changes to the Patent Law as negotiated under the CETA resulting from the two-year CSP elsewhere termed patent restoration, and used synonymously here since CSP provides patent-like protection. It is projected that the CSP system will delay the introduction of generic alternatives, and likely keep prices higher than they otherwise would be. The report also estimates the fiscal cost to the federal government of compensating provinces for increased expenditure.

[405] Lexchin and Gagnon, 'CETA and pharmaceuticals: The Impact of the Trade Agreement Between Europe and Canada on the Cost of Prescription Drugs', (2014) Globalization and Health 2014, <http://www.globalizationandhealth.com/content/10/1/30> accessed March 2018

[406] The Canadian Generic Pharmaceutical Association (CGPA), News Release, October 1st 2018.

[407] Office of the Parliamentary Budget Officer Ottawa, 'Patent Restoration and the Cost of Pharmaceuticals' (April 2018), <www.pbo-dpb.gc.ca> accessed online 20 February 2020, (PBO 2018 Report)

CETA included two provisions geared at making changes to Canada's patent laws for pharmaceuticals with the direct result being up to two additional years to the 20-year protection afforded to drugs containing a new medicinal ingredient or novel combinations.[408] Consequently delays are anticipated in introducing more affordable versions of pharmaceuticals, (generics), to consumers although, unlike five years[409] which exists for European countries.

Understanding how the CSP is intended to work depends on how the time is calculated. The CSP term is calculated in conjunction with the NOC and operates by calculating five years from the original filing date up to date of issue of the NOC, with a two-year maximum. Importantly, CSP does not affect drugs that receive a NOC before September 21, 2017.[410] The significance of this is that the effect will not be manifested immediately but since the availability of generics has proven to lower drug costs, direct implications for payers are embedded in delaying market entry of generic versions to patented pharmaceuticals, particularly, as drugs under patent protection usually keep the high prices long after patent expiry.[411] Early utilisation of generic pharmaceuticals would yield savings based on the calculations between the cost of the generic versus the patented version, however, savings are lost by extending the sale at patented prices for any period outside the 20 year patented term,[412] thus the delay in generic entry will, no doubt, increase costs for consumers and insurers.

An examination of the fiscal cost to the federal government shows that In 2015, Canada's spending was $15.2 billion for patented medicines.[413] Further, national increases in expenditures are projected to show uphill movement had CSP system been implemented in its entirety by 2015 and the direct cost for provincial public

[408] Guidance Document Certificates of Supplementary Protection Date adopted: 2017/09/21 Revised Date: 2019/03/28 Effective date: 2019/05/15 available at https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/certificate-supplementary-protection-regulations.pdf

[409] See Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 and Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585 (codified at 21 U.S.C. 355(b), (j), (l); 35 U.S.C. 156, 271, 282)(Hatch-Waxman Act), respectfully.

[410] PBO 2018 Report, Pg.10
[411] PBO 2018 Report Pg.11 and Table B-1 in Appendix B.
[412] PBO 2018 Report, Pg.11(see simplified illustration in Figure 3-1)
[413] PMRB Report, 2016

programs would have been $214 million.[414] Anticipating the general costs of CSPs, between 2015 and 2024,[415] an average of $211 million of sales of innovative drugs would lose protection under patents.[416] This, no doubt affects the application of the discount factor as patented innovative drugs can cost up to 17 times more than generic versions.[417] Considering the average annual worth of patents due to expire during the period 2015 to 2024, without the discount factor, it is estimated that lost annual savings from a two-year CSP may be around $392. [418, 419] Projections aside, the effects on costs have already manifested in the government's spending which in the period 2018-2019, was about $4,656 per person on health care which is predicted to increase to around $7,039 by 2040/41.[420]

Implications for the Provinces and consumers will definitely see increased costs as the utilisation of generics was instrumental in keeping expenditures on public health plans low.[421] It is projected that implementation of CSP will have the result of undermining many cost reduction measures by Provinces.[422] Most provinces, under the previous system, had begun replacing innovator products with generic versions which lowered generic prices. The CSP system limits the latitude for additional savings from generics, leaving Provinces at a loss with solutions to overcome increased prices.[423]

For the Federal Government the effect is anticipated to be felt in the compensation of deficits to Provinces, in the form of reimbursements to federal plans. In keeping with CETA negotiation commitments, the Federal Government pledged to provide compensation to public plans for losses which occurred as a result of any extra time

[414] PBO 2018 Report
[415] PBO 2018 Report, Pg. 14 and: Health Canada Patent Register (2017), Innovative Drug database (2017), IQVIA Canada, GPM data (2017), NPDUIS (2017).
[416] PBO 2018 Report, See Section 4.2.,
[417] PBO 2018 Report, See Section 4.3.,
[418] PBO 2018 Report, Pg.22 and further Appendix A
[419] PBO 2018 Report, Pg.23 and further Table 5-1
[420] Conference Board Research, 'Health Care Cost Drivers in Canada Pre-and Post-COVID-19, Impact Paper', (September 2020) available at <https://www.canadaspremiers.ca/health-care-cost-drivers-in-canada-pre-and-post-covid-19/> accessed December 2020

[421] See Further Canadian Parliament Report, Pg.12 and Figure 3-2; see Appendix B for more discussion concerning the dynamics of Canada's drug market.
[422] PBO 2018 Report, Pg.12
[423] PBO 2018 Report, Pg.25

of market exclusivity which affects drug costs under federal responsibility.[424] Providing the Federal Government upholds these assurances, it is estimated that the cost will include an extra 25% in the region of $270 million yearly,[425] to maintain hospitals and public healthcare facilities.

PBO's projection of cost raises concerns of price dynamics after patent expiration which may have an impact on other aspects of pharmaceutical delivery[426] but recent projections for long-term health care spending, conducted by The Conference Board of Canada indicated that expenditures would increase at an average annual pace of 5.4 % out to 2030-31.[427]

Of particular interest is the provision on export which shows similarity with the Bolar exemption and the newly instituted SPC Waiver in Europe. CSP protection is not given to innovators attempting to bar export of generic drugs in the sense that although the sale of drugs under protection by a CSP will not be allowed, production for export will not be prohibited.[428]

The legitimacy of the data sheds a futuristic appraisal of the best-case scenario but the findings appear to be concrete and independent. Support for this is that the PBO supports Parliament by providing analysis, including analysis of macro-economic and fiscal policy, for the purposes of raising the quality of parliamentary debate and promoting greater budget transparency and accountability. The PBO's report is profoundly comprehensive and is indicative of the most reliable assessment at the time of writing, despite being anticipatory or speculative. The estimates provide an elaborate starting point in understanding what may unfold which can quite possibly act

[424] PBO 2018 Report, Pg. 3 see also Canadian Institute for Health Information (CIHI), 'Larger Portion of Canada's Public Drug Dollars Spent on High-Cost Drugs' <https://www.cihi.ca/en/larger-portion-of-canadaspublic-drug-dollars-spent-on-high-cost-drugs> Accessed July 29, 2020.

[425] PBO 2018 Report, Pg.24

[426] See further, Hema Mistry, Hyeladzria Garnvwa, and Raymond Oppong, 'Critical Appraisal of Published Systematic Reviews Assessing the Cost-Effectiveness of Telemedicine Studies' (May 2014) 20 (7) Telemedicine and e-Health 609–618 <https://doi.org/10.1089/ tmj.2013.0259 > accessed July 2020.

[427] Conference Board Research, 'Health Care Cost Drivers in Canada Pre-and Post-COVID-19, Impact Paper', (September 2020) available at <https://www.canadaspremiers.ca/health-care-cost-drivers-in-canada-pre-and-post-covid-19/> accessed December 2020, (Impact Paper 2020)

[428] PBO 2018 Report, Pg.11

as a useful reference resource for other countries contemplating such inclusion into their patent legislation or even entering trade agreements. What is even more plausible about the report is that it did not originate from industry, thus, issues such as bias and ulterior motives are negated. At the cut-off time for this research no other report with this depth was uncovered although the Conference Board Research has attempted to show a pre and post Covid-19 assessment and cost implications but is based on a general scale and not specifically related to CSP.[429] [430]

[429] Impact Paper 2020

[430] Canadian Medical Association, The College of Family Physicians of Canada, and Royal College of Physicians and Surgeons of Canada, 'Virtual Care Recommendations for Scaling Up Virtual Medical Services: Report of the Virtual Care Task Force' (Ottawa February 2020) Accessed via <https://www.cma.ca/sites/default/files/pdf/virtualcare/ReportoftheVirtualCareTaskForce.pdf.> accessed July 2020

4.5. CANADA AND IMPROVED ACCESS TO PHARMACEUTICALS

This section offers conclusions on the Canadian system in assisting to lower cost of pharmaceuticals and making generics more accessible and is focused on incorporating a system of re-assessing obligations under CETA, looking into an enhancement in the cannabis industry as "Value Added", checking into pricing strategies to address availability and accessibility, adopting a dynamic approach based on the SPC Waiver.

Re-assessment of CETA as a pro-active measure

A re-assessment of CETA may seem premature but it is strongly recommended that Canada reviews its arrangement under that Agreement. Although the exact extent of CETA is not fully assessed, the speculative figures pertaining to the cost of pharmaceuticals and the knock-on effect of the new "restoration" seems enough to require a review of trade agreements. Despite utilizing prowess in drafting the Agreement to include many of the pro-access terms, a post CETA check may discover instances of access blockers in the Agreement. Such arrangements usually require constant supervision of its impact on access as this level of scrutiny can operate to inform amendments and provide guidance on dealing with future agreements.

Adopting a dynamic approach based on the SPC Waiver

In light of EC introduction of SPC Waiver, Canada's access issues may benefit from adopting a dynamic approach to the proposed SPC Waiver, with a view to an early amendment. A term which resembles the SPC Waiver would facilitate more flexibility in addressing the needs of persons who need medication the most. Such scrutiny should consider the legal arrangements for value added medicines which would definitely assist Canada with working out its pro-access strategies which no doubt will consider bringing generics to the market sooner. Coupled with the "for export" terms, bringing the Restoration in line with the SPC Waiver, it is suggested, will allow for more wriggle room for generics entering the market sooner and ensuring access.

Boost Cannabis industry as "Value Added"

Boosting the cannabis industry as value added may prove instrumental in Canada's efforts to advance access. As discussed previously, Canada's cannabis is advanced

in many ways. Without rehashing the section in the previous chapter, it is strongly recommended that Canada boosts its cannabis industry as a value-added product. The significance of this is that it will benefit the local pharmaceutical production and operate as a supply hub exporting to countries with less sophisticated cannabis systems. This would place Canada on a firm negotiating footing in terms of facilitating access and become the form norm setter where cannabis legislation, patenting and pharmaceuticals are concerned.

Checking into pricing strategies to address availability and accessibility.

For decreased costs pricing strategies can be re-configured. As of April 2018, under an agreement between drug manufacturers and public drug plans, Canadian prices of 69 generic drugs were predicted to fall by 25%–40% at community pharmacies.[431] As a reward, governments have indicated that they would hold back from the introduction of competitive tendering processes for five years, despite having previously committed to putting such pricing policies in place five years ago.[432] The recommendation is that that failure to implement tendering for generic drugs keeps prices unnecessarily high and, paradoxically, increases the risk of drug shortages. Therefore, a timelier structure for implementing the tendering of such drugs is encouraged which would have both short- and long-term savings.

However as early as 2012 it was predicted that a necessary solution to the rising cost of pharmaceuticals would be to offer fixed periods of market exclusivity to innovative drugs, thereby enhancing investment certainty for brand drug firms and reducing litigation. This came about as scholars and researchers deduced that the protection laws governing pharmaceutical intellectual property in Canada have led to costly litigation between brand and generic drug companies, with costs estimated at over $100 million annually.[433] This issue came to light from legal uncertainty created by the

[431] Steven G. Morgan, Nav Persaud "New Generic Pricing Scheme Maintains High Prices and Risks of Shortages" (2018) CMAJ 190: E410-1. doi: 10.1503/cmaj.180197 accessed online 11th April 2019

[432] See further, *From Innovation to Action: The First Report of the Health Care Innovation Working Group* (Ottawa: Council of the Federation Secretariat 2012) <https://www.canadaspremiers.ca/wp-content/uploads/2017/09/health_innovation_report-e-web.pdf> accessed April 2019

[433] Paul Grootendorst, Ron Bouchard, Aidan Hollis, "Canada's Laws on Pharmaceutical Intellectual Property: The Case for Fundamental Reform", (2012) 184(5) CMAJ 543, accessed online 11th April, 2019, (Grootendorst et.al, 2012).

somewhat complicated regulations and the legal rights of brand and generic drug companies to contest the period of market exclusivity. Decisions by provincial drug plans to lower generic drug prices may reduce the incentives for generic drug firms to contest market exclusivity, possibly resulting in longer exclusivity periods and higher costs to payers.

In this regard policy-makers can consider reform of the legal and regulatory framework governing the privileges of market exclusivity afforded to brand drugs. This may be achieved through several measures. Firstly, a repeal of the existing regulations and simply guarantee innovative drugs exclusivity for a fixed/limited period, say 10 years. The advantage this would create is that investment certainty would be enhanced to brand drug firms and significantly reduce litigation because both sides of the industry would be less able to contest market exclusivity. The idea of fixed terms of exclusivity may represent a trade-off in the sense that some brand drugs would be given longer periods of exclusivity under such a system while others would have a shorter period however through this system, the nominal period of exclusivity would cease to have much value. All public drug plans, and an increasing number of private plans, now negotiate with brand firms over the prices to be paid for new drugs that are being considered for formulary listing. Drug plans currently use evidence of cost-effectiveness and forecasted budget impact in these negotiations. Common knowledge of the term of exclusivity could just as easily be incorporated into negotiations over the price paid and would reduce the uncertainty over the budget impact of listing a new drug.

Repealing the Notice of Compliance regulations and sole reliance on the Patent Act and the data protection regulations presents yet another measure for adoption. It is anticipated that litigation costs would be decreased as patents could be litigated only once. Such removal would provide Health Canada with the responsibility of deciding which patents should be listed on the Patent Register, a job that critics suggest it lacks the legal analysis.[434]

[434] See Grootendorst et.al, 2012 pg. 547

Since this extra compliance is not required by Canada's obligations under TRIPS.[435] The government's stated rationale for the Notice of Compliance regulations was to prevent abuse of the patent system by generic drug firms. Apparently, there was a concern that generic drug firms found to have infringed a patent would declare bankruptcy or otherwise fail to provide compensation. This concern, however, can be addressed much more effectively by requiring firms that launch a generic before the expiry of all relevant patents to post a performance bond that is relinquished in the event that the drug is found to have infringed on the patents. As long as Notice of Compliance regulations continue to operate it suggests that generic drug firms will ultimately be financing the cost of patent vetting. What is recommended is a pre-specified, time-limited royalty payable to litigating generic by all sellers of bioequivalent products for each unit they sell.[436] This type of measure, it is anticipated, would directly provide an incentive to generic manufacturers that achieve gains in patent litigation by enabling competition.

Additionally, much can be achieved through expediting the Notice of Compliance proceedings. Federal court judges have little or no expertise in the complex technical issues that arise during patent litigation. Expert witnesses hired by the respective sides educate them. But this escalates costs because the advantage is with the party that can afford to have the most authoritative witnesses on its side.[437] Even then, federal court judges have felt overwhelmed at the job of "assimilating masses of purportedly expert opinions, predominantly on scientific matters, all in written form, often

[435] Christopher Scott Harrison, 'Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91' (2001) 26 NCJ Int'l L & Com Reg 457 – accessed online <https://heinonline-org> September 2020

See also RS Tancer 'Foreign investment in North America and the pharmaceutical industry in Canada' (2007) 39 Int Exec 283-97 – accessed online via <https://heinonline-org> September 2020

[436] A. Hollis, 'Generic Drug Pricing and Procurement: A Policy for Alberta, Calgary (AB): University of Calgary' (2009), Available: http://policyschool.ucalgary.ca/files/publicpolicy/Hollis%20 ONLINE%20(Feb%2009).pdf – accessed from <https://heinonline-org> December 2020

[437] W. Kingston, 'Reducing the Cost of Resolving Intellectual Property Disputes', (1995) 2 Eur J Law Econ 85-92 accessed online via <https://heinonline-org> December 2020

comprising several volumes."[438] One option is to use court-appointed experts who could help the judge quickly get to the core of a dispute. Because such experts would be paid by the court, they would have no allegiance to either party.

Altering the Notice of Compliance will no doubt, require a restructure of the legislation. Other countries are facing the same challenges as Canada, have attempted fundamental reform of their laws on pharmaceutical intellectual property. Canada may use this opportunity to show leadership.

Chapter summary

Explanations on the reasons for higher drug prices were explored and the discussion unearthed that quite possibly the biggest threat lies in patent legislation and Canada's relationship through trading agreements with other countries, in particular, the EU. Moreover, special pricing schemes in the EU seem to favour a lower cost situation than what obtains in Canada, thus despite cost savings due to the efficient workings of the generics system, prices continue to sour.

Possible added cost to Canada's pharmaceutical system once the CSP system goes live with certain active ingredients in patents and based on projections the restoration is likely to see prices continue a steady incline.

Whilst Canada is awaiting the experience to adequately assess the full impact of CSPs, it seems that its dealings with other countries appear to be the major determinant in the country being able to afford pharmaceuticals. Conclusions are based on utilising legal, industry and technical solutions to create equitable co-existence of the systems, fostering a balance between regulation and access and enabling enhanced performance in the global pharmaceutical context, post pandemic.

[438] *Eli Lilly Canada Inc. v. Novopharm Ltd* [1998] 2 SCR, 129 accessed - <https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/1641/index.do> April 2019

See further J McNish, 'As Patent Cases Clog Courts, Drugs are a Lawyer's Best Friend', Globe and Mail [Toronto] March 12, 2008) <https://www.theglobeandmail.com/report-on-business/as-patent-cases-clog-courts-drugs-are-a-lawyers-best-friend/article718533/> accessed April 2019

Chapter Five

THE BALANCING ACT: COPING MECHANISMS/ALTERNATIVES FOR INPROVED ACCESS

Considerations in fostering a system that simultaneously nurtures access and innovation remains the central element of attempting to foster better access to pharmaceuticals. Various measures previously employed by countries and organisations in their efforts to promote access, albeit, within the current IP frameworks indicate that their impact have had varied results.

The main argument is that whilst many schemes are utilised, outside the scope of SPC system, they show that most, if not all, are linked, in some way, to intellectual property systems and although they present workable alternatives to improvement of access, it is possible for these schemes to foster healthy competition in the pharmaceutical patent climate.[439]

Analysis of measures focused on: International efforts/perspective on addressing access issues, The SPC Waiver; Patent Pools; Trade secrets, Partnerships and some Canadian experiences and shows that the legality and cost effectiveness of the measures interfere in their responsiveness in addressing respect for patent owners' rights and allowing access, simultaneously. This brings into perspective the global approach to tackling the issue of access, and demonstrates how countries with varying levels of development cope and what options are available for LDCs.

5.1. EXPLORING THE EFFECTIVENESS OF THE INTERNATIONAL MEASURES ON ACCESS

An assessment of the effectiveness of international measures instituted to address access concludes that theoretically, while they provide strategic avenues for improved access, their implementation proves troublesome, mainly due to inherent organisational hindrances.

[439] See Matthews & Zech, (2017), pgs.304-334

5.1.1. World Health Organization, WHO, Road Map in fostering access.

WHO's Road Map which in itself promises to address access from a global perspective focusses its work on developing countries. An initial assessment of WHO's initiative shows that the very nature of the system creates its own hurdles in addressing access.

WHO acknowledges that access to medication is a global concern and that high prices of new pharmaceuticals added to rapidly changing markets for health products place increasing pressure on all health systems' ability to provide full and affordable access to quality healthcare. The WHO determines that the high percentage of health spending on medicines, 20–60% as demonstrated in various studies in selected low and middle-income countries, impedes progress for the many countries that have committed to the attainment of universal health coverage.[440] Furthermore, it is known that a large proportion of the population in low-income countries do pay out-of-pocket for medicines. Thus, the combination of the rise in non-communicable diseases and the fact that many of them are chronic conditions that require long-term treatment and the financial burden on both governments and patients will become even greater.

The WHO has outlined a comprehensive plan for addressing access to medication, albeit from an international perspective. The all-encompassing plan is contained in the special report by the Director-General with strategic goals and detailed plans for implementation. The Report stresses that acceptability and affordability of health products of assured quality is required to be addressed in order to achieve the Sustainable Development Goals, in particular the target concerning disease management strategy that encompasses the requirement for access to health products for prevention, diagnosis, treatment, palliative care and rehabilitation.

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[440] World Health Organisation, '*Medicines, Vaccines and health products, Access to medicines and Vaccines*', Report by the Director-General, EXECUTIVE BOARD EB144/17 144th session 5 December 2018, Revised (9 April 2020), Geneva, The 146th session of WHO's Executive Board, meeting in February 2020 requested the Director-General to develop, in consultations with Member States and stakeholders, the new road map for neglected tropical diseases for the period 2021–2030 – Revision adding a different dimension, available at <https://www.who.int/neglected_diseases/resources/who-ucn-ntd-2020.01/en/> Accessed July 2020, (WHO 2018 Road Map)

The strategies consider that improving access to health products is a multi-dimensional challenge which requires comprehensive national policies and strategies. The WHO suggests an alignment of public health needs with economic and social development objectives and promote collaboration with other sectors, partners and stakeholders; they also need to be aligned with legal and regulatory frameworks and cover the entire product life cycle, from research and development to quality assurance, supply chain management and use.

WHO's comprehensive health systems approach to increasing access to health products is guided by a series of Health Assembly and Regional Committee resolutions. These resolutions, nearly 100 in number formed the basis for the previous report by the Director-General on this topic. The present document responds to the Health Assembly's subsequent request for WHO to develop a road map describing its activities, actions and deliverables for improving access to medicines and vaccines, for the period 2019 to 2023.[441]

The health systems approach to improving access to health products informs the road map which encapsulates work on access to health products, including essential health system components and is structured around two interlinked strategic areas that are necessary to support access to health products. This includes ensuring the quality, safety and efficacy of health products which activities supporting countries to deliver regulation that protects the public while enabling timely access to, and innovation of, quality products. Activities focus on regulatory system strengthening, assessment of the quality, safety and efficacy of health products through prequalification, and market surveillance of quality, safety and efficacy.

The second strategic area is particularly concerned with improving equitable access to health products and covers: Research and development that meets public health needs; Application and management of intellectual property; Evidence-based selection and fair and affordable pricing; Procurement and supply chain management; Appropriate prescribing, dispensing and rational use of medicines.

While these measures appear to have some thrust in that they provide a detailed assessment of the situation and promises to address many aspects of health services, the measures represent more of a proposal than effective hands-on focus for

[441] See WHO 2018 Road Map.

addressing access. WHO is an international institution and as such is limited to a purely advisory role in many of these areas and is constrained by a lack of flexibility to address matters in the commercial private sphere outside of industrial action brought by countries to the various legal avenues, much, unlike WIPO or WTO.[442] Momentarily, how these efforts will address access issues can only be speculative since the plan is over a 3 or 4 year period and in any event contains major limitations on reaching countries or the industry directly. The WHO can suggest changes and propose international instruments for ratification by countries but in practicality, WHO is estopped from directly implementing projects on the ground. It is left to be seen how this plan, which, for now, seems ultimately far-fetched, unfolds in actuality. This project suggests that for implementation, the activities will have to be more than an encouragement, which, ultimately, may not come from WHO within the specified timeframe suggested. The suggestion here is that WHO liaise directly with country specific projects on the issues and designate specific tasks to other agencies which can actually conduct work on the ground in terms of making effective change where it is most needed.

5.1.2 Medicines Patent Pool, (MPP), system for managing access.

Another important organization which has attempted to alleviate and or address cost of medication includes the Medicines Patent Pool, (MPP), which in the real sense operates like a patent pool but can be considered more of a public-private partnership. Since inception, the MPP has been working to increase access to and facilitate the development of, life-saving medicines for low and middle-income countries,[443] however, its effectiveness on access remains uncertain.

Through its innovative business model, MPP partners with civil society, governments, international organisations, industry, patient groups and other stakeholders, to

[442] See WIPO's ADR at <https://www.wipo.int/amc/en/center/wipo-adr.html> and the WTO's <https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c6s1p1_e.htm#:~:text=There%20are%20two%20main%20ways,Appellate%20Body%20reports%2C%20which%20are> both accessed February 2019

[443] Lauren Ulrich, 'Trips and Compulsory Licensing: Increasing Participation in the Medicines Patent Pool in the wake of an HIV/AIDS Treatment Timebomb' (2015) 30 Emory Int'l L Rev 51 - <https://heinonline-org> accessed July 2020

prioritise and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations.[444]

The MPP provides an example of measures adopted which considers public health needs and engages flexible structures. The MPP was created in 2010 by UNITAID[445] arm of WHO and is guided by its mission which is to aggregate patents, clinical trials data and other IP relating to HIV/AIDS, Tuberculosis and Hepatitis-C medications and make them available at low or no cost to manufacturers that commit to produce and sell drugs to users in low-income countries with all of its funding coming from UNITAID.[446]

The name appears to be misleading in that the MPP is not considered a patent pool,[447] in the general sense but mainly operates as a clearinghouse or intermediary which secures licenses from consenting IP holders and then sublicenses those rights to generic drug manufacturers operating in developing countries. Most of the licences are royalty-bearing or royalty-free, are generally available *a-la-carte*, and do not necessarily aggregate all of the rights licensed to MPP which also assists in avoiding antitrust issues and up-front costs. To date, several significant patent holders,[448] including AbbVie, Bristol-Myers Squibb, Gilead Sciences, Pfizer, ViiV Healthcare and Johns Hopkins University, have licensed IP to the MPP, which has in turn

[444] Access to Medicines Tracker, MPP website available, <https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker/> accessed July 2020, (MPP Tracker)

[445] See further UNITAID, 'Innovation for Global Health' (Geneva, 2016), available at <https://www.who.int/global-coordination-mechanism/working-groups/unitaid.pdf> accessed July 2020

[446] Michael Mattioli, 'Communities of Innovation' (2012) 106 NW U L Rev 103, available at <https://heinonline-org> accessed March 2020

[447] Jorge Contreras, 'Patents and Coronavirus – A role for Patent Pools?' (Apr 13, 2020) Info Justice, <https://infojustice.org/archives/42242> accessed at March 2020

[448] Licences published online on the MPP website and are available at <https://medicinespatentpool.org/progress-achievements/licences/> accessed

granted twenty-two sublicenses to generic drug manufacturers for distribution of products in the developing world.[449]

The work of MPP cannot go unnoticed and in fact it has contributed significantly to addressing access matters in low-income countries. As of July 2020, the MPP has signed agreements with ten patent holders for thirteen HIV antiretroviral, one HIV technology platform, three hepatitis C direct-acting antivirals and a tuberculosis treatment.[450]

Part of the reason for much success is attributed to the unique business model as it comprises partners such as: Originators and health technology developers, as well as patent holders who want to place their licence with MPP. The terms of each licence are bespoke and take into account the specific characteristics of each product and the public health needs in LMICs. Generic producers also form part of the partnership, to which group, MPP offers a range of services and technical advice, including support in the development, registration and supply of the medicines in LMICs. Biotech and new actors as new products are developed, MPP works with partners on access strategies and explores partnering options. Global health stakeholders work with WHO and other international organisations, foundations, NGOs, civil society and patient groups and conducts information sharing on patents in a transparent fashion. MPP partners with groups to understand public health priorities, identify access gaps and explore opportunities to increase access through MPP licenses. Thus, MPP licences make it possible for many LMICs to affordably treat people with quality products.

Due to its dedicated and streamlined process MPP has signed agreements with ten patent holders for 13 HIV antiretrovirals, one HIV technology platform, a tuberculosis

[449] MPP Tracker

[450] MPP Tracker

treatment and three hepatitis C direct-acting antivirals 22 generic manufacturers and product developers have now signed MPP sublicensing agreements.[451]

The major benefit or upside the MPP system is that it incorporates the use of generic companies. Generic competition is making a difference in fostering lower prices and improving treatment coverage. Generic partners have distributed 31.4 million patient-years of HIV and hepatitis C products, saving international procurers USD 1.44 billion (January 2012-December 2019).[452]

The Medicines Patent Pool is designed to address the fact that patent-holders are not producing either the fixed-dose combinations or the new formulations required by developing countries and that anti-retroviral and the other combinations are not affordable in those countries.[453] Despite the successes there is insufficient scrutiny of the MPP, being a UN Organisation thus it is not conclusive whether MPP is especially well adapted to addressing the production problem in LMICs. The capacity of the pool to address the issue of affordability is also not a given. The numbers show the successes of the MPP however there is no assessment of what actually obtains on the ground and what the real impact is in the countries where the MPP serve. What is the actual cost saving? What percentage of needed drugs are supplied by MPP and how is the effect measured on the ground? While the MPP pool lessens the costs of medicines through increased competition, it is unclear how significant those cost reductions actually are which will require a data on actual cost reductions from countries who benefit.

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[451]The Medicines Patent Pool Signs First Sub-licences for Hepatitis C Medicine Daclatasvir, (20 January 2016), available at <https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-signs-first-sub-licences-for-hepatitis-c-medicine-daclatasvir/> accessed March 2020.

[452] See Overview of all licences and sub-licences of MPP available at <https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker/ > Slide decks highlighting progress of MPP's generic partners in developing, manufacturing and supplying MPP-licensed medicines, are available for: all MPP's sublicenses, dolutegravir (DTG)-based regimens, daclatasvir (DAC)-based regimens, (Last update: July 2020 – data as of March 2020)

[453] Richard E. Gold, Tina Piper, Jean-Frédéric Morin, Karen L. Durrell, Julia Carbone and Elisa Henry, *Preliminary Legal Review of Proposed Medicines Patent Pool,* UNITAID, July 26, (2007)

Further, a pool based on voluntary licences raises very little significant international or national legal issues. In addition, it offers numerous practical advantages to patent holders, generic producers, governmental authorities in exporting and importing countries, and more importantly, for people in need of medicines. A pool based on non-voluntary licensees' and or compulsory licences may have had different outcomes. The latter may have become more complicated to administer and would have been problematic for keeping within the ambit of TRIPS. While TRIPs offer significant flexibility in establishing a pool through compulsory licences, national laws can limit that flexibility significantly. The manner in which the MPP has succeeded in overcoming these obstacles adds to the lack of clarity on what actually obtains on the ground. How has the issue of voluntary licences and the whole model of the MPP affected the legal climate of the countries where the MPP operates? It would be rather impractical for legislation changes and regulatory amendments to be effected solely for the purpose of facilitating the MPP's imports and not tackle matters of access generally such that other agencies or private organisations can participate without having to carve out their own exceptions. Being a quasi-international organisation, this leaves the behind-the-scenes operations covered as international organisations may carry a lot of weight in the LMICs.[454]

5.1.3. UNITAID's efforts in addressing access.

Considering the limitations highlighted in the previous measures, the UNITAID efforts are now analysed but also reveals internal weaknesses which compromises its effectiveness.

UNITAID is engaged in finding new ways to prevent, treat and diagnose HIV/AIDS, tuberculosis (TB) and malaria more quickly,[455] more cheaply and more effectively. It takes game-changing ideas and helps to turn them into practical solutions that can help accelerate the end of the three diseases. By helping to fast-track access and

[454] Stefano Barazza, 'The Draft Trans-Pacific Partnership Agreement and Its Implications for Public Health and Access to Medicines: The UNITAID Report' (2014) 5 Eur J Risk Reg 366 - accessed <https://heinonline-org> March 2020

[455] David Gartner, 'Innovative Financing and Sustainable Development: Lessons from Global Health' (2015) 24 Wash Int'l LJ 495 <https://heinonline-org. March 2020

reduce costs of new, more effective medicines and diagnostics, UNITAID aims to maximize the impact of every dollar spent to overcome these diseases. The Organization recognises that the patent system is designed to support innovation and, at the same time, offer a mechanism to ensure that such innovations are accessible to society. But while patents can stimulate innovation, they can also limit competition; as a result of the latter, prices of patented medicines may remain a barrier to broad access.[456]

UNITAID has attempted to and has achieved some level of success in its priorities in assisting access but taking a look at its system is important in understanding the limitations of that system. The successes include that in 2017 some intellectual property barriers were overcome by cutting the cost of antiretroviral medicines from $10,000 to $100 for a year's treatment. Expanding access to new malaria drugs and diagnostics, contributing to 50% reduction in deaths since 2000. The measures adopted in order to achieve such seemed instrumental in what it hails as a success. It is estimated that 60% of health R&D is funded by the private sector, 30-35% is funded by the public sector, and the remainder from other sources, including private non-profit organizations.[457] In 2009, total investment in health R&D was estimated at US$ 240 billion.[458] It has been estimated that roughly 8-15% of global turnover on pharmaceuticals is reinvested into R&D by the private sector.[459]

The effects of IPR barriers may be tricky, for instance via a compulsory license or by opposing patents or patent applications. For many countries, in accessing these remedies present an even further barrier as their use would require significant legal and technical expertise and the process tends to be lengthy. More favourably buyers eventually decide to either buy originator products, opt for a clinically inferior alternative product, or forego the purchase altogether. Technical expertise is important in dealing with know-how with regard to IPR and public health and play an active role in safeguarding access to medicines but many of these countries lack sufficient human and financial resources to work on a large scale. Additionally, the situation in many

[456] UNITAID 2016 IP Report
[457] See UNITAID 2018 Report
[458] See UNITAID 2018 Report
[459] See UNITAID 2018 Report

low and middle-income countries is that the legal and technical expertise on IPR is somewhat limited.

Interestingly, in the UN system various organizations undertake work on intellectual property rights which sometimes focus on national, and sometimes regional, intellectual property offices. WTO focuses on implementation of health systems for administration of TRIPS, for instance, added to that are UNAIDS, UNCTAD, UNDP, WHO, WIPO and WTO undertake analysis and/or provide guidance on intellectual property issues that interface with their area(s) of work; which, no doubt includes medical innovation and/or access to medicines. The difficulty with the organisations is that they are hardly concerned with dealing with intellectual property barriers and appear to leave that to the countries as they consider this an internal country issue.[460]

The organisations hardly get involved in implementing solutions to overcome specific IPR barriers at a large scale which would be instrumental in ensuring that people in low and middle-income countries will have timely access to innovative products. For this reason, UNITAID appears to be the saviour in that it enjoys a vantage, unique position. As its main aim constitutes explicit focus on intellectual property barriers, it is no surprise that buyers rely on UNITAID to address IPR barriers.[461]

UNITAID, through its work, has conducted major studies in the area of access to medication and as such is in a pivotal position to identify IP issues in bringing medication to people who need it most.[462] Although much of its work concerns AIDS, tuberculosis, malaria and hepatitis, which are maladies affecting low income countries particularly in Africa, UNITAID has identified that Long-acting (LA) platform technologies could contribute to removing some of these challenges; approved and new, investigational drugs could be developed into oral, parenteral or implantable depots. Such LA products could offer extended drug release, thereby enabling less frequent administration. Recent years saw an increase in the number of innovative LA

[460] See UNITAID, 'The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good', (2010) 4 Open AIDS J. 37–40, published online 2010 Jan 19. doi: 10.2174/1874613601004020037, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842943/#R9> accessed August 2019

[461] See UNITAID 2016 Report.

[462] Ann Weilbaecher, 'Diseases Endemic in Developing Countries: How to Incentive Innovation' (2009) 18 Annals Health L 281 - <https://heinonline-org> Accessed March 2020

products being developed for a variety of diseases.[463] LA products are typically technologically intensive to manufacture, and also relatively complex in terms of patent protection as they may involve multi-layered patent protection: on the molecule, the formulation of the drug, the device, and the process of manufacturing each component.

UNITAID identified patent barriers to accessing cheaper medications and have attempted to put measures in place to address those. Such barriers may include: added years of exclusivity beyond the expiry of the compound patents; patenting landscapes appear particularly complex with potential for multiple overlapping patents which are usually owned by drug formulation firms that develop new formulations that incorporate such technologies under contract. These types of patent holders often grant a licence specific to a given product which also involves the proprietary technology, but not to the technology platform as a whole. The technology platforms most often are being applied to multiple products and are most probably covered by extensive intellectual property protection. The above complexity may present some challenges to the freedom-to-operate of future LA products, be it generic or originating from the patent holders themselves. Further, the geographical scope of patent protection may vary by product and technology. In most high-income countries and certain middle-income countries, where many of the leading generic manufacturers are based, are often covered in patent filings. For example, smaller corporations and academic institutions often file in less LMICs compared with the big pharma companies. However, key manufacturing countries such as China and India are generally covered in the patenting strategy.

UNITAID has attempted to adopt a methodology compiled by the MPP and UNITAID, for the purpose of illustrating the complexities of IP protection for select LA products marketed or under development for HIV, Hepatitis C Virus (HCV), TB, malaria and

[463] UNITAID, 'How UNITAID deals with IP, Intellectual Property Report on Long-Acting Technologies', (November 2018), <https://unitaid.org/assets/MPP-Unitaid_Intellectual-property-report-on-long-acting-technologies.pdf> - accessed online, October 20th 2019

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opioid substitution therapy[464] however, implementation issues arise casting limitations on UNITAID's work. Although UNITAID has direct access to initiatives in-country, the limitations suggest massive delays in achieving its objectives and in terms of the commercial side of pharmaceuticals, the measures hardly touch on that.

In concluding this section, the international bodies have seen tremendous positive outcomes in their efforts however it is suggested that measures that fail to address the root of the expense of pharmaceutical products and or healthcare services, will no doubt be inadequate in achieving access goals and objectives. The next section considers the patent strategies and an attempt to fix the SPC system itself.

[464] Jay Purcell, 'Adverse Clinical and Public Health Consequences of Limited Anti-Retroviral Licensing' (2010) 25 Berkeley Tech LJ 103 - Accessed via <https://heinonline-org> October 2019

5.2. THE VIABILITY OF PATENT POOLS IN ADDRESSING ACCESS

This section assesses the viability of patent pools in facilitating access and although such pools have facilitated licencing and commercialisation through the merging of patents, it is unsettled as to how much this system has achieved in terms of access to pharmaceuticals. Patent pools[465] consist of arrangements in the private sector which facilitates participants to operate under others' patent rights, to manage and administer the pooled rights on a centralized basis, which most time includes the granting of licenses of the pooled patents to third parties and splitting the proceeds among the pool members according to the arrangement.

There is no precise definition of a patent pool but generally, a patent pool involves collecting a series of patents that relate to the use of a particular technology so that they can be efficiently licensed to those making, using or selling that technology.[466] Historically patent pools have been established to build airplanes, sewing machines and radios. These pools, particularly those created in the first half of the 20th century, arose from the need to overcome strategic behaviour from patent-holders that blocked the development and sale of a new product. For example, in the airplane industry, the two main competing patent-holders, Curtiss Company and the Wright Company, could not agree on how to license one another so that somebody could build an airplane.[467] Under government pressure, the pool (the Manufacturer's Aircraft Association) was established comprising the companies with important patents related to the airplane. Similarly, in the radio industry, the Associated Radio Manufacturers was created to pool, by corporate merger rather than by licence, all patents related to the radio industry.[468] This pool was later dismantled for being anti- competitive, but in the early

[465]Richard E. Gold, Tina Piper, Jean-Frédéric Morin, Karen L. Durrell, Julia Carbone, and Elisa Henry, *Preliminary Legal Review of Proposed Medicines Patent Pool,* UNITAID, (July 26, 2007), pg.16

[466] See Geetrui Van Overwalle, Esther Van Zimmerman, Birgit Esther Verbeure, and Gert Matthijs, "Models for Facilitating Access to Patents on Genetic Inventions" (2006) 7 Nature Reviews Genetics 143 for a discussion of various modes of collaboration. See also Jeanne Clark, Joe Piccolo, Brian Stanton, Karin Tyson, "Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?" USPTO (December 5, 2000).

[467] See further H.A. Toulmin Jr, 'Patent Pools and Cross Licenses' (1935-1936) 22 VA L Rev 119 - Accessed via <https://heinonline-org> March 2020

[468] David L. Podell , and Benjamin S. Kirsti, 'Patent Pools and the Anti-Trust Laws' (1927) 13 ABA J 430 - Accessed via <https://heinonline-org> March 2020

years, it provided a means to overcome the problem of patents blocking commercialization.

Modern patent pools arise where companies wish to establish a common technological standard for an industry. For example, DVD player manufacturers wished to assure that all DVD manufacturers and DVD reader and recorder manufacturers used the same standard. These pools are pro-competitive in that they create the possibility of producing new technologies, such as DVDs and MPEGs that, absent the pool, would have been difficult. Despite the obvious benefits of pooling, it becomes intrinsically more complicated when transferring the business model to essential items such as pharmaceuticals.

Patent pools have also been suggested as mechanisms to address more critical public health crises such as disease outbreaks. This is even more evident in the wake of the Covid-19 pandemic where pools have been developed to address many issues relating to access to education, technology and health care. Previously patent pooling structures were actively discussed and considered in response to the SARS outbreak of 2002-03, the H5N1 influenza outbreak of 2005, and the H1N1 influenza pandemic of 2009.[469] Yet despite the perceived need for aggregation of distributed patent rights in order to combat these diseases, patent pools were never formed.[470] The use of patent pools may have been the more practical way forward however the legal system itself places challenges on how these pools are to operate. One reason that may have impacted the forming of patent pools in these areas may relate to antitrust law. A patent pool necessarily includes a variety of patents held by different owners. But when a pool aggregates rights covering technologies that may be substitutes for one another, such as patents covering different types of vaccines, innovation could be reduced in the sense that there will be no haste to improve vaccines where such vaccines are already under licensed in the pool. From a different perspective, when

[469]Hilary Greene, 'Patent Pooling behind the Veil of Uncertainty: Antitrust, Competitive Policy, and the Vaccine Industry' (2010) 90 BU L Rev 1397 - Accessed via <https://heinonline-org> March 2020 and Sloan, Arielle., 'IP Neutrality and Benefit Sharing for Seasonal Flu: An Argument in Favour of WHO PIP Framework Expansion' (2018) 17 Chi-Kent J Intell Prop 296 -- Accessed via <https://heinonline-org> March 2020

[470]Contreras Jorge, 'Patents and Coronavirus – A role for Patent Pools? (Apr 13, 2020) Info Justice, accessed <http://infojustice.org/archives/42242> March 2020

pooled patents are complementary (e.g., several patents covering aspects of the same vaccine), pools are viewed as increasing efficiency and enhancing innovation. Consequently, most antitrust enforcement agencies generally agree that the patents included in a pool are better off being complementary and not substitutes for one another.[471] The very model of pooling itself creates difficulty in applying it to access to medicines. Once patents are brought into the pool, they are licensed out to others in pre-defined packages. For example, the DVD 6C pool suggests 14 packages covering different uses of the technology such as DVD players, DVD recorders and so on. That is, anyone wishing to access the technology represented by the pool can purchase a non-exclusive licence to use all of the patents within the package at a given royalty rate.

Taking into consideration the pharmaceutical process, such model would best work with medical devices as opposed to actual medicines. Regulatory and patenting rules require the pharmaceutical product to be registered and referred to as an active ingredient. These systems are primarily concerned with the main ingredient and so unless a drug contains different major ingredients then it will be difficult to apply these principles. Although there have been calls for pooling during the Covid-19 pandemic, such may not prove practical in a sense which may also have been the reasons why pools were not the chosen system in previous times.[472] The major question for the proponents of pooling to foster access during Covid-19 is: how does one pool the active ingredients for a vaccine for treating the symptoms? Or what symptoms? Additionally, how is it going to work in terms of splitting the proceeds or even licensing to begin with?

The Medicines Patent Pool as discussed previously, differs in important respects from previous or existing patent pools. In particular, to the extent that the Medicines Patent

[471]U.S. Department Of Justice And The Federal Trade Commission, 'Antitrust Enforcement And Intellectual Property Rights: Promoting Innovation And Competition' (April 2007), <https://www.ftc.gov/sites/default/files/documents/reports/antitrust-enforcement-and-intellectual-property-rights-promoting-innovation-and-competition-report.s.department-justice-and-federal-trade-commission/p040101promotinginnovationandcompetitionrpt0704.pdf> accessed online August 1st 2020

[472]Richard E. Gold, 'SARS Genome Patent: symptom or disease?' (2003) 361 The Lancet 2002 <http://www.dvd6cla.com/list.html> accessed August 2020

Pool aims at licensing products that, despite being expensive, are available in the relevant markets, it does not follow past or current trends. Based on its business model and international organisational model, the MPP type system may present a more logical solution where access is concerned. On the other hand, while this aspect of the Medicines Patent Pool differs from both the older airplane-type pools and the newer DVD pool, it bears some similarity to the SARS pool in that it aims at serving the public interest through social entrepreneurship rather than through strictly furthering commercial interests.

Contreras suggests that an IP clearinghouse or pool administered by a United Nations agency, particularly if it is truly global in scope, could alleviate many patent-related impediments to the development, production and distribution of vaccines, diagnostics, therapeutics and equipment in the fight against Covid-19, which, would complement existing efforts such as voluntary IP pledges[473] that have already freed thousands of patents for use in this public health crisis. Contreras also suggests that to ensure that such a pooling effort is effective, however, the WHO must act quickly and decisively in defining the details of the proposed arrangement and in persuading patent holders in both the public and private sectors to join this worthwhile effort. While this may be beneficial in creating a quick fix to address the current Covid-19 situation, the idea appears simplistic at best as this may very well boil down to what patent applications are made, what type of licenses to be used, domestic legislation of various countries and an adherence to international law principles in terms of guarding against unilateral laws for domestic or commercial enterprise.[474] For now, it all seems more futuristic and speculative and much more work is required to devise a pooling system that balances fostering innovation and access.

In sum, it is evident that patent pools, although they represent an excellent measure in facilitating commercialisation of medicines, they may not be the ultimate in addressing access matters in that their use would only assist in strengthening the monopolistic behaviour among originators. The main difficulty is presented in addressing access matters is that they are pro-originators. If a pool seeks to regulate

[473] Further information at <https://opencovidpledge.org/> Accessed December 2020

[474] Dana Beldiman, 'Patent Choke Points in the Influenza-Related Medicines Industry: Can Patent Pools Provide Balanced Access' (2012) 15 Tul J Tech & Intell Prop 31 - Accessed via <https://heinonline-org> August 2020

transaction costs or strategic behaviour with an aim, instead, at encouraging competition in the market through generic competition, this would assist in furthering access. Accordingly, prices would fall to a level at which most required medicines are more accessible.

5.3. EXPLORING TRADE SECRETS AS A TACTICAL IP MEASURE IN PHARMACEUTICALS

Consideration of the use of trade secrets as an alternative system of IP protection for fostering access to pharmaceuticals is imperative to the discourse.[475] Delving into the legal underpinnings at utilising trade secrets as an alternative to patents, it is understood that while the TRIPS Agreement might be interpreted to allow trade secrets in access matters, the benefits can be regarded as speculative in the context of pharmaceuticals and may prove impractical in framing policy on access.

Trade secrets have been utilised by major branded companies in pursuit of increased commercialisation and is an advanced intellectual property right recognised by international organisations including TRIPS. Anti-patent proponents have always looked outside the patent system for more sustainable ways of maintaining their commercial activity and transferring such to pharmaceuticals is not entirely novel. During emergencies, there have been calls to utilise trade secrets to facilitate access to medication, particularly, during the Covid-19 season.

Much dissimilar to patents, regulatory entities do not grant or confirm trade secrets and in simplistic terms a trade secret exists by keeping valuable information secret.[476] Trade secrets are not meant to be shared unless the owner authorizes it and then, usually, under a requirement of secrecy by the authorized party. It means that the main trade secret legal action would be misappropriation of it by a former employee/competitor through commercial espionage or inadequate trade secret management.[477]

[475] Copenhagen Economics, 2018, pg. 282.
[476] KFC/COCOA COLA are prime examples.
[477] David Levine, 'Covid-19 Trade Secrets And Information Access: An Overview, (Jul 10, 2020) Academic Resources, AI, Coronavirus accessed through <http://www.injustice.org>, 25th July 2020

To date no codified legislative systems, exist neither is there any attempt requiring non-registration and non-clinical trial trade secrets to be shared with competitors, civil society groups, or other "watchdog" or advocacy entities. Additionally, while voluntarily licensing of trade secrets is permissible, the decision to license is determined by the owner's discretion which can prove cost-prohibitive or denied outright. Use of compulsory licensing, common in other forms of IP, may not be practical for a trade secret, especially with respect to biological resources and manufacturing information. It is important to recognize that trade secrets are often used to secure countries national security interests which is promoted by TRIPS.[478] It means that national security is usually the most powerful basis for preventing access to information held by governments, so using it to encourage sharing of information, to foster access, as is seen is required during a pandemic, would be novel.

TRIPS[479] requires some degree of protection for trade secrets against unauthorized acquisition or use. Unlike patents, there is no involuntary use exception. Worthy of note is that both TRIPS Agreement and the WTO's Doha Declaration on the TRIPS Agreement and Public Health, (Doha Declaration), raise possible avenues for limited trade secret access. The legal basis for trade secrets in the European Union provides a definition as information meeting the following requirements: It is a secret in the sense that it is not generally known or readily accessible to people within the circles that normally deal with the kind of information in question; It has commercial value because of its secrecy; The person in control of the secret has taken reasonable steps to keep it secret. As such, trade secrets are an alternative to other intellectual property protection schemes.[480]

Nonetheless, a reasonable interpretation of certain TRIPS Agreement provision suggests that trade secrets might be made accessible to ensure access to medicine.[481] This language might offer support for trade secret access to foster the faster production of generic equivalents of medicines. Further, the Doha Declaration's paragraph 4 provides that the TRIPS Agreement can and should be interpreted and

[478] TRIPS Agreement, Article 73
[479] TRIPS Agreement, Article 39
[480] Directive 2016/943, 1 Article 2
[481] TRIPS Agreement, Articles 7 and 8 outline "objectives" and "principles," respectively, for "social and economic welfare" (Article 7) and "public health" (Article 8).

implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. This may appear to reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

This is indicative that the TRIPS Agreement provides a welcome avenue towards expanding trade secret access, as it has built-in recognition of concerns about which trade secret law is seemingly unresponsive. The key benefit of trade secrets as opposed to patents is that they offer potentially indefinite market protection. If competitors do not discover the information necessary to manufacture the medicine, they cannot enter the market. Additionally, producers are likely to benefit in that some costs related to the process of patenting the product are avoided. For illustration the case of Premarin by Pfizer Premarin, a hormone replacement therapy product used to treat the negative symptoms of menopause, was first marketed in 1942 by Wyeth.[482] A series of patents were filed in the years surrounding the initial marketing of the product. However, long after the expiry of these patents, Wyeth (acquired by Pfizer in 2009) continued to be the only supplier of the medicine. This was due to the fact that competitors had been unable to discover the extraction process, which Wyeth had kept as a trade secret rather than patent it. This is one example of how trade secrets can be an effective alternative to patenting in certain cases, also in the pharmaceutical sector.

Further, a key feature of the patent system is that other companies can make use of the information covered by the patent to produce generic products or to build new research. As such, while patents may make the use of certain information strictly exclusive, it does so for a finite period of time. As the information becomes public, other agents may build on this information to create new innovations. This facilitates a continual accumulation of knowledge, while ensuring the necessary incentives for private innovation. With trade secrets, this is not the case. Information can stay private

[482] See further, Andrew A. Schwartz, 'The Corporate Preference for Trade Secret' (2013) 74 Ohio St LJ 623 - Accessed via <https://heinonline-org> July 2020

for an indefinite period, which potentially hampers the process of innovation in society.[483]

Despite the apparent benefits of trade secrets, it is difficult to determine how the use of trade secrets would assist access matters. It is suggested that matters concerning pharmaceutical regulation may operate to negate access. In-depth analysis of the logistics in terms of pharmaceuticals, using the EC legislation and TRIPS, suggests that the primary question is whether a genuine trade secret exists to be shared. A positive response to this will lead to the "how" and the "when" in terms of sharing. Alternatively, a negative response ends the conversation and reverts to other IPRs.

The main obstacle to a positive response would be the regulatory situation concerning pharmaceuticals. Due to the nature of assessing the efficacy and sustainability of pharmaceutical product, it is highly unlikely, if not impossible, for pharmaceutical processes to be kept secret. The rules require transfer of the information and publication at some stage which negates the "secret". Notably, the acquisition of a trade secret is considered lawful if it is obtained by observation, study or disassembly of a product or object that has been made available to the public or is in the lawful possession of the acquirer of the information who is free from any legally valid duty to limit the acquisition of the trade secret.[484]

Put simply, reverse-engineering a medicine is a lawful way for potential competitors to obtain information of its composition. Nonetheless because of the legality of acquiring information through reverse-engineering, the option of using trade secrets to protect a product might be of limited applicability for pharmaceutical companies. This does not mean that the final composition cannot be reverse-engineered however, the process with which a medicinal product is produced may not be obvious or possible to reverse-engineer from the final product, and it might therefore be more likely to be protected as a trade secret. It follows that if the innovation is not in some way embedded in the final product or detectable from the final product, trade secrets are an option for pharmaceutical companies seeking to protect their market.[485]

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[483] See further <http://press.pfizer.com/press-release/pfizer-completes-acquisition-wyeth> accessed July 2020

[484] Directive 2016/943, Article 3(b)

[485] See further Price W. Nicholson, 'Expired Patents, Trade Secrets, and Stymied Competition' (2017) 92 Notre Dame L Rev 1611 - Accessed via <https://heinonline-org> July 2020

This in itself presents a drawback of trade secrets in that they do not prevent independent discovery by other companies. This means that if a competing company can discover the information necessary to manufacture the medicine, it can then proceed to bring it to market. While a patent only lasts a set number of years, it ensures that competitors cannot enter the market with the same product during this period. This is likely to raise a situation where many different reversed-engineered products being available on the market, but not one has been tested for safety and efficacy. This in itself may present its own pandemic since clinical trials and labelling and other marketing rules may have to be dispensed with and is likely to cause more harm than access.

Moreover, trade secrets are pro-originator and if used for pharmaceuticals, will delay generic entry in perpetuity. The whole idea of trade secrets is conducive to achieving a competitive advantage in the market and may operate worse than patents in terms of access. Patents at least expire after 20/25.5 years but trade secrets exist in perpetuity. It means that generic companies would have to go through their own process of reverse-engineering which will add cost and run counter-productive to access. Further, it is difficult to see how a government can make use of trade secrets through compulsory licenses and so use of flexibilities also disappear when dealing with trade secrets for pharmaceuticals.

In sum, trade secrets are a complicated and body of law, with significant variations in international and national law, but some possible scope for limitations and exceptions.[486] Moreover, its application is extremely fact and sector specific, and the existence of a trade secrets must be assessed individually against its value in the industry sector in which it operates as a piece of information.[487] It is suggested that the pharmaceutical sector is not a right fit for trade secrets based on the foregoing. The Covid-19 situation presents an opportunity to plunge ahead and be creative in

[486] Mark R. Halligan and Scott T Piering, 'Trade Secrets and Interference with Contracts' (2005-2006) 2005 ABA Sec Intell Prop L Ann Rep 1 - Accessed via <https://heinonline-org> July 2020

[487] David S Levine and Ted Sichelman, 'Why Do Start-ups Use Trade Secrets' (2018) 94 Notre Dame L Rev 751 - Accessed via <https://heinonline-org> accessed July 2020

finding solutions because it can literally be life-or-death decisions, however, safety and effectiveness will be required to be balanced against the interests of the patent owners, trade secret owners and the public. While the TRIPS Agreement might be interpreted to allow trade secret access in ways heretofore unseen purely as this is untested waters, for now, the benefits of trade secrets on access can also be regarded as speculative where pharmaceuticals are concerned and strongly recommends against its use in framing policy on access.

5.4. LESSONS FROM THE CANADIAN CANNABIS EXPERIENCE IN FOSTERING LOCAL PRODUCTION

Although the Canadian cannabis industry is not strictly related to direct pharmaceutical and access matters, it presents a proactive approach to fostering local production and in turn economic growth which may have a domino effect on access. The Canadian cannabis industry shows that Canada's attempts to address production and manufacturing appears to be more sophisticated than other countries which puts it in a key position to steer the narrative and conduct norm setting in cannabis as value added drugs.

In 2001, the country started a medical marijuana program, managed by Health Canada.[488] The program originally offered people access to home grown cannabis or sales directly from Health Canada. This was replaced with new regulations that set up a more traditional commercial sector for cannabis cultivation and distribution in 2013.[489] To provide some context, sometime around the 1960s, cannabis began to rapidly increase in Canada. For the entire period of 1930–1946, the RCMP recorded only 25 cannabis arrests, but this rose to 2,300 cases in 1968, and to 12,000 cases in

[488] More information on this is available at <http://www.hc-sc.gc.ca/> accessed August 2020

[489] The Canadian Press, CTV News-London, 'A timeline of some significant events in the history of medical marijuana in Canada'*, (2018)*. Accessed 3 August 2020. See also Leafy, 'A Guide to Canada's Medical Marijuana Program'*, (*28 June 2017) Accessed 3 August 2020

1972.[490] To date Cannabis in Canada is legal for both recreational and medicinal purposes. Medicinal use of cannabis was legalized nationwide on 30 July 2001 under conditions outlined in the Marihuana for Medical Purposes Regulations, later superseded by the Access to Cannabis for Medical Purposes Regulations,[491] issued by Health Canada and seed, grain, and fiber production was permitted under license by Health Canada.[492] The Federal *Cannabis Act* came into effect on 17 October 2018 and made Canada the second country in the world, after Uruguay, to formally legalize the cultivation, possession, acquisition and consumption of cannabis and its by-products.[493] Canada is the first G7 and G20 nation to do so[494] and considering figures from the sale of cannabis up to the end of 2018, the availability of cannabis for recreational purposes appeared to be widespread and retailed across most provinces, via varied outlets.[495] Despite such bold steps, it is anticipated that potential problems in sourcing raw materials from legally licensed growers may interrupt growth in retailing of end products.[496]

The benefits of taking a more proactive approach to Cannabis is that cannabidiol (CBD) is being used widely more and more by health, beauty and wellness companies for its use in new over the counter, OTC drugs, cosmetics and food supplements. It is highly controversial because while CBD has many natural health benefits for treating a variety of conditions and symptoms, it is the active ingredient extracted from

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[490] Colin Kenny and Pierre Claude Nolin, 'Cannabis: Report of the Senate Special Committee on Illegal Drugs', (2003) Canada Parliament Senate Special Committee on Illegal Drugs, University of Toronto Press. Pg. 59 ISBN 978-0-8020-8630-3. Accessed 1 August 2020.

[491] 'Access to Cannabis for Medical Purposes Regulations' <http://laws-lois.justice.gc.ca/.> Accessed 20 March 2020

[492] Health Canada, 'Industrial Hemp Regulation Program FAQ', (November 2012), Accessed *20* March 2020

[493] Bani Sapra, 'Canada Becomes Second Nation in the World to Legalize Marijuana, *CNN*, (20 June 2018), Accessed online 1 August 2020.

[494] Selena Ross, 'All eyes on Canada as first G7 Nation Prepares to make Marijuana Legal', The Guardian, (6 June 2018), accessed online 10 July 2018.

[495] See further, https://mycaribbeanscoop.com/jamaica/a-jamaican-entrepreneur-giving-voice-to-her-community

[496] 'Ontario is holding a lottery for cannabis stores on Friday. Here's what the rest of the country tried and how it turned out', Toronto Star, (10 January 2019), Accessed online 3 August 2020

cannabis which comes from hemp plants, and therefore has a number of regulatory and legal challenges for its use, but also offers some new market opportunities. It seems the rest of the world is now playing catch up with legalisation of cannabis. The UK for instance legalised cannabis on 1 November 2018.[497] This began with an announcement by the Health Secretary on 20 June 2018, where he pledged his support for the medical use of cannabis and that a review would be undertaken to study changes to the law.[498] A license is available from the home office to import prescribed medicinal cannabis.[499] However, as of mid-February 2019, virtually no-one has been able to access medical cannabis.[500] HBW Insight has been closely monitoring and reporting on the developments of CBD across the global consumer healthcare industry and can provide data on the worldwide use of CBD oil in particular as key to cancer treatment and pain management.

Consequent to Canada's sophisticated cannabis system, it appears miles ahead of the other countries in the world and is in a pivotal position to steer the narrative and conduct norm setting in terms of cannabis as value added drugs. In fact, the norm setting appears to have begun but this requires a fundamental change to patenting structures to accommodate whatever complications may arise. At this juncture Canada appears to have a handle of this and is best placed to move this forward in an economically viable fashion that benefits local producers and industry and boost access overall.

[497] Home Office Circular 2018, 'Rescheduling of cannabis-based products for medicinal use in humans' Crime, Policing and Fire Group (CPFG) – Drugs and Alcohol Unit, A*ssets* Publishing Service.gov.uk, (1 November 2018), *Accessed* 3 August 2020

[498] Ned Simons, 'Jeremy Hunt Reveals He Backs Legalising Use of Medicinal Cannabis Oil', HuffPost, (18 June 2018), Accessed 3 August 2020.

[499] United Kingdom Home Office 'Guidance Controlled drugs: licences, fees and returns', Accessed 3 August 2020

[500] 'Medicinal cannabis: Why has it taken so long to get to patients?' BBC News, (16 February 2019), Accessed 3 August 2020.

5.5. MIXED ATTEMPTS/EFFORTS AT ADDRESSING ACCESS

This section is illustrative of collaborations in the context of pharmaceuticals being utilised to foster lower prices and make much needed drugs available sooner. These, constructs take the form of partnerships, merged procurement systems and other collective modes of operations.

It would appear prudent that countries would attempt to fix access matters using the TRIPS and the WTO systems as a starting guide based on the flexibilities. Japan, apparently, has adopted its own system in attempting to deal with access[501] but other African countries appeared to favour attempting to use the WTO system since the ability of LMICs to act as a block was key to the Doha Declaration on TRIPS and Public Health (2001), which came about through LMICs working on a shared position, supported by international advocacy groups. A group of African states led by Zimbabwe and supported by Latin American and Asia-Pacific countries called on other countries to agree in the World Trade Organization that "nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health".[502] As Peter Drahos notes, "the Doha Declaration was about the weak networking networks that surrounded and eventually isolated the US and in the final instance its pharmaceutical industry."[503]

Meanwhile, a better fit seemed an orchestration of movement away from TRIPS and have attempted to not utilise the flexibilities offered by TRIPs. Instead, these countries have opted for their own system, for example the Peruvian Deregulation[504] however the main thrust of the measure is that deregulation over a five-year period did not increase access. It caused a distrust in the system of local production and a demand

[501] Belinda Townsend, Deborah Gleeson, Ruth Lopert, 'Japan's Emerging Role in the Global Pharmaceutical Intellectual Property Regime: A Tale of Two Trade Agreements' (2018) 21 J World Intellect Prop. 88–103. Accessed online, <http://wileyonlinelibrary.com/journal/jwip> accessed August 2020

[502] World Trade Organization, 2001b.

[503] Drahos 2007.

[504] Joan Costa Font, 'Field Report Deregulation and access to Medicines: The Peruvian Experience' (2016) 28 Journal of International Development J. Int. Dev. 997–1005 Published online 10 April 2015 in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/jid.3096, accessed 22 October 2019.

for branded, overseas products as well as market fragmentation; quasi-generics by originator companies.[505] It appears that lack of success using data exclusivity and flexibilities under TRIPS spurred such steer away from the WTO system.[506]

Efforts at devising ways of dealing with access have given rise to major developments in cooperation. Consequently, countries have so far maintained poise in their ventures and fostered collaborative working systems geared at minimising cost and accelerating availability. In so doing many have engaged futuristic all-inclusive holistic approaches as they strive for better value in terms of pharmaceutical spending. The association of the British Pharmaceutical Industry strongly suggests incorporating joint working ventures and increased R&D endeavours in an attempt to strengthen its pharmaceutical base.[507] Joint working involves the NHS and industry organisations pooled skills, experience and/or resources for joint development. No doubt it is anticipated that these efforts will assist the UK in is post Brexit endeavours as it aims to make access to not just pharmaceuticals but patient care, more sustainable. Whatever the outcome, it seems that in the long term if these policies yield cost savings to patients and government spending, they would be considered beneficial.

Pooled procurement, provides another system of access adopted. Not to be confused with patent pools, pooled procurement systems, PPS, considers the regional pooling of resources for medicines procurement creates economies of scale for suppliers, enabling them to offer lower prices.[508] It is suggested that countries that share similar health problems should therefore consider the establishment of a regional drugs procurement policy and even a regional procurement entity. For instance, the West

[505] Lauren Kuehn, 'Do Desperate Times Really Call for Desperate Measures: The Ethical Dilemma behind the Regulation and Use of Experimental Drugs' (2017) 7 Notre Dame J Int'l Comp L 134- Accessed via <https://heinonline-org> accessed July 2019

[506] Lisa Diependaele, Julian Cockbain, and Sigrid Sterckx, 'Data Exclusivity', (2016) The Authors Developing World Bioethics Published by John Wiley & Sons Ltd, see also Muhammad Z. Abbas, 'WTO "Paragraph 6" System for Affordable Access to Medicines: Relief or Regulatory Ritualism?' for details on why use of the flexibilities do not work.

[507] APBI News Release, (29th June 2018), accessed online, <www.abpi.org.uk>, 4th July 2019

[508] Peter K Yu, 'Access to Medicines, BRICS Alliances, and Collective Action', (2008) 3 American Journal of Law and Medicine 345-94, Last revised: 18 Jul 2014 – accesses online August 2020

African Health Organization (WAHO)[509] procures on a regional scale from producers based in member states of the Economic Community of West African States (ECOWAS).[510] Member States of the Southern African Development Community (SADC)[511] have identified pooled procurement as a means to rationalize expenses and obtain lower prices for greater volumes of medicines.[512] The OECS Pooled Procurement System provides a more practical example of how this works in real time.[513] By that system 9 States are able to order drugs in bulk and are able to participate in a system that enables joint procurement, financials, quality assurance, pharmacovigilance, HIV/AIDS management, medicines utilisation review, country support and international collaboration. Essentially the body operates as a pooled procurement agency that provides excellent pharmaceutical and medical supplies management service to the OECS.

Supposedly financial gains are top of the list of benefits for these states however such systems come with their own set of complications however it appears that so far, it has mainly been gains for these countries. Similar systems exist in Europe[514] where Iceland has joined the Denmark-Norway pricing alliance while Denmark could soon

[509] See further information at West African Health Organisation, (WAHA) website <https://www.wahooas.org/web-ooas/> accessed December 2020

[510] Economic Community of West African States (ECOWAS) website available at <https://www.ecowas.int/ecowas-law/treaties/#:~:text=The%20Economic%20Community%20of%20West,in%201975%20in%20Lagos%2C%20Nigeria.> accessed December 2020

[511] Further information available at South African Development Community, (SADC), available at <https://www.sadc.int/> accessed December 2020

[512] Poku Adusei, 'Exploiting Patent Regulatory Flexibilities to Promote Access to Antiretroviral Medicines in Sub-Saharan Africa' (2011) 14 J World Intell Prop 1

[513] See Francis Burnette, '30th OECS/PPS Policy', Board Meeting, (12 October 2016) <https://www.oecs.org/our-work/knowledge/library/pps-annual-report-2016/viewdocument/680> accessed online July 26 2019

[514] See Beneluxa: Initiative on Pharmaceutical Policy, <https://beneluxa.org/collaboration> accessed December 2020

join the BeNeLuxAI collaboration[515] which is a cross-country collaboration made up of Belgium, the Netherlands, Luxembourg, Austria and, most recently, Ireland. This is the most advanced of Europe's joint pricing initiatives and has already secured access in Belgium and the Netherlands to Biogen's spinal muscular atrophy treatment Spinraza (nusinersen) following a joint health technology assessment and pricing talks.[516] Whilst there have been major gains there is speculation that such may be short lived for many reasons including lack of transparency.

[515] Pink Sheet, 'The Drug Pricing Debate Article Pack', Informa UK Ltd, (2019), pg.13, (Pink Sheet 2019)

[516] See Pink Sheet, 2019.

5.6. LDCS AND IMPROVED ACCESS TO PHARMACEUTICALS

As a follow-up to assessing the various efforts at enhancing access compounded with the hurdles encountered, conclusions are drawn on legislative avenues and trading adherence for the least developed of developing countries for increased access. These are focused on addressing production, cost and availability of pharmaceuticals. Such are no doubt based on the level of development not just from an economic standpoint but also in terms of legislative arrangements and lack of pharmaceutical manufacturing and hinges on boosting local production of pharmaceuticals, re-assessment of existing trade agreements and taking proactive actions in trade agreements as a means of deterring hindrances to access and participating in healthy global trade where pharmaceuticals are concerned.

5.6.1. Boosting Local Production of Pharmaceuticals for enhanced access.

Development of local manufacturing of pharmaceuticals in developing countries appears key to success on access. Countries such as India[517] and Brazil[518] have recorded benefits of local production, which are mainly generics through reverse engineering mechanisms.

Carlos Correa recognises the strategic importance of a local pharmaceutical industry has been as a result of the COVID-19 crisis.[519] This would present a huge leap for developing countries with the aim of strengthening their pharmaceutical industry, including biological medicines. However, it appears that not many developing countries may be in a position to take advantage of such opportunities. For some, industrial policies would need to undergo some kind of restructuring to incorporate value-added medicines and create jobs while addressing public health needs. This

[517] See further explanation of India's version of pharmaceutical regulation – Armouti Wal and F A Mohammad Nsour, 'Test Data Protection: Different Approaches and Implementation in Pharmaceuticals' (2016) 20 Marq Intell Prop L Rev 267 - accessed online via <https://heinonline-org> September 2020

[518] Karen Walsh, 'Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries' (2014) 11 Scripted 332 - accessed online via <https://heinonline-org> September 2020

[519] Carlos M. Correa, 'Lessons from COVID-19: Pharmaceutical Production as a Strategic Goal', (July 2020) South Centre No. 2020, <www.southcentre.int> Accessed online July 24th 2020

can be assisted by South-South cooperation which has the potential to increase the contribution of developing countries to the global production of pharmaceuticals.

As seen in Europe, the pharmaceutical industry can be structured to provide a pivot for local production. This would not just assist in industry restructuring but can make contribution to local added value and employment, especially of technical and professional staff and foreign exchange, as well as an instrument for achieving health autonomy to address public health needs. No doubt such approach will require sophisticated legislative arrangements on the ground and instruments that are tailored to incorporate fiscal measures, access to financing, support for R&D, a regulatory framework which does not create undue obstacles to registration an intellectual property regime that uses TRIPS flexibilities such as compulsory licensing, and a policy of government procurement that provides predictability to local demand.

Cognizant of the fact that some developing countries may not be in a position to adopt manufacturing processes just yet, Correa's views are pertinent as one of the lessons of COVID-19 for developing countries is that they can put in place comprehensive industrial policies to enhance their manufacturing capacity in pharmaceuticals which will be indeed indispensable to supply products and required medication, which may ensure that shortages do not become a constant. IGBA suggests that shortages are primarily due to high regulatory requirements and that addressing such would involve a global take. This approach appears to be taken on board in the preliminary talks during the negotiations for the India-EU FTA.[520]

5.6.2. Reconsideration of existing Trade Agreements

Avoiding certain legal transplants through trade agreements is significant in access discussions.

[520] Yvan Decreux and Cristina Mitaritonna, 'Economic Impact of a Potential Free Trade Agreement (FTA) between the European Union and India' (2007) Report by CEPII/CEMIN to the DG Trade of the European Commission, Trade Specific Contract No: SI2.434.087, (2007), available at <http://trade.ec.europa.eu/doclib/html/134682.htm> accessed September 2020

International trade agreements regulate the way in which markets are opened to competition from imported goods. In this context, generics, like all goods, are affected by the obligations and concessions negotiated and reflected in trade agreements. The multilateral trading rules are set forth by member countries within the framework of the WTO. In addition, rules affecting pharmaceutical products are increasingly being set by preferential FTAs.

Developing countries must address access matters, and more so, least developed countries which rely on international organisations and international charities, which in turn rely on the cost and availability of drugs being low. Discussions on access for developing countries must consider the varying degrees of development and the availability of resources, in particular, whether or not there is manufacturing capacity locally.

It has long been the advice that the use of TRIPS flexibilities may be a fix for developing countries however the literature suggests that this is an uphill battle, if not an almost impossible climb. Just like developed countries, developing countries are urged to look internally at their legislation in finding solutions based on local legislation but taking advantage of the opportunities presented and required under international rules and obligations. Although the impact of patents on access to affordable medicines predated the TRIPS Agreement, the introduction and requirements of the international IP system have generated controversy around the implications for price and access to essential medicines.[521]

WHO'S 2019 TO 2023 plan comprises 3 main priorities and shifts: Achieving universal health coverage; addressing health emergencies; promoting healthier populations. This is on the backdrop that access is seen as a global concern, given the high prices of new pharmaceuticals and rapidly changing markets for health products that place increasing pressure on all health systems' ability to provide full and affordable access to quality health care. The high percentage of health spending on medicines (20–60%

[521]Jennifer H. Mike, 'A Re-Evaluation of the Framework for the Protection of Patents, Women's Health in Nigeria and the Issue of Accessing Pharmaceutical Innovation in Africa: Designing Strategies for Medicines, (2019) The Journal of World Intellectual Property, (23 March 2019) DOI: 10.1111/jwip.12123, accessed online January 2020.

as demonstrated in a series of studies in selected low- and middle-income countries) impedes progress for the many countries that have committed to the attainment of universal health coverage.[522] Furthermore, it is known that a large proportion of the population in low-income countries who spend for health do pay out-of-pocket for medicines. With the rise in non-communicable diseases, many of which are chronic conditions that require long-term treatment, the financial burden on both governments and patients will become even greater.

Addressing the problem of access in an era when increasing demands are being made on the world's healthcare services, generic and biosimilar medicines provide a major benefit to society by ensuring patient access to quality, safe and effective medicines while reducing the cost of pharmaceutical care.[523] For this reason trade agreements ought not to operate in a way that add hurdles to importation or transit of generic drugs.

Regulating IPR's in Trade Agreements.

Consideration of the international IP legal framework when developing national legislation and policies, which sets the standards and general principles should no doubt, be key to informing national IP systems. Although international framework is defined by the Paris Convention and TRIPS which incorporates the substantive provisions of the Paris Convention, more and more, standards concerning IPR protection are increasingly being set as a result of the negotiation and conclusion of FTAs.[524]

[522]Mr Reich, J Harris, N Ikegami, A Maeda, C Cashin, EC Araujo, et al, 'Moving Towards Universal Health Coverage: Lessons from 11 Country Studies, (2016) The Lancet 2016; 387:811-16 <https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)60002-2.pdf> accessed January 2020

[523] The International Generic and Biosimilar Medicines Association (IGBA), 'Fostering International Trade in Generic and Biosimilar Medicines' (2015), <www.igpagenerics.com> accessed online – January 2020

[524] As is seen in the CETA and other Trade Agreements

TRIPs required WTO members to make available for inventions in all areas of technology, including pharmaceutical products,[525] and the requirement to protect clinical trial data submitted to obtain marketing approval against unfair commercial use, *inter alia*. The protection of test data is required for regulatory approval of the pharmaceutical product. The terms of test data protection are defined by pharmaceutical legislation; at the same time, test data protection is part of intellectual property frameworks in that it represents a form of protection against unfair competition.[526]

In the same vein these standards set by the TRIPs Agreement provided extensive liberty for implementation, and WTO members remain free to determine the appropriate method of implementing the provisions TRIPs within their domestic legal systems. WTO members may also implement in their laws more extensive protection than is required by the TRIPs Agreement, provided that they comply with the provisions set forth therein.[527]

The inclusion of 'TRIPs-plus provisions in the IP Chapters of FTAs has been championed by the countries and territories that are home to originator companies, with the clear objective of ensuring that FTA partners would implement, in their domestic legislation, a level of IP protection similar to that which is applied nationally. This trend appears to be leading to the creation of new international standards of IP established through bilateral rather than multilateral negotiations and to the adoption of domestic laws providing for higher levels of IP protection[528] which as is seen in the

[525] The TRIPs Agreement requires patents to be available for any inventions, whether products or processes. The protection for process patents would not prevent the manufacture of patented by a process of reverse engineering, where a different process or method from that which has been patented is used. Therefore, in countries where national legislation required only process patent protection, before the TRIPs Agreement entered into force (and subject to transition periods) generic manufacturers were able to make generic versions of patented products.

[526] A. Tauban, H. Wager and J. Watal, (Eds), *WTO, A Handbook on the WTO TRIPs Agreement*, Cambridge University Press, (2012) p. 96.

[527] See relevant section on TRIPS at Chapter 1

[528] See R. Valdés and R Tavengwa, 'WTO, Economic Research and Statistics Division, Staff working Paper ERSD', (2012) p.40. The authors argue that the non-discrimination requirement of the TRIPs Agreement, together with the distinct 'hub-and-spoke' architecture of IP provisions, leads to a 'ratchet-like' process whose effect is

case of Canada, has a potential effect on the generic and biosimilar sector where such tighter IP protection is aimed at, or has the effect of, preventing generic and biosimilar competition and delaying the entry of generic and biosimilar products into the market.

The recently negotiated U.S. - Mexico-Canada Agreement is a prime example of this kind of anti-competitive increase in IP standards, which will have a significant detrimental impact on the generic and biosimilar medicines industries in those three countries and in all other countries where the affected companies do business. There are currently three trade agreement negotiations underway by the U.S., six by the European Union, and three by the European Free Trade Association.[529] In each of these agreements, brand drug and biologic companies will seek to increase their monopolies, detrimentally impacting generic and biosimilar companies and the patients who need access to high quality affordable medicines, and further increasing the likelihood and number of shortages.[530]

The conclusion is that the system in some way alters the balance between the encouragement of investment and the need to ensure competition and technology transfer that must inform IP systems and central to the balanced approach.[531] It is also recommended that negotiations concerning IPRs should not seek to harmonise IPR frameworks, but recognise the different approaches taken by the negotiating parties with respect to IPR protection. Certain provisions that are frequently found in trade agreements and/or that have been identified as bearing particular importance to the generic industry and which presents a bar to access include: term extensions; patentability; 'best mode' requirements; patent linkage; regulatory review, "Bolar" clause; data exclusivity; and enforcement of IPRs, must be addressed.

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to incrementally tighten countries' domestic IP regulations, and which feeds back into the international arena (as countries would want to include in future FTAs the standards resulting from commitments that they made under previous agreements).

[529] This includes Brazil, see Neto, Abrão., Hyatt, Ken., Godinho, Daniel., Schineller, Lisa., and Braga, Roberta., Deepening US-Brazil Trade and Investment Report Title: US-BRAZIL TRADE AND FDI: Enhancing the Bilateral Economic Relationship Report, Atlantic Council (2020), available at <https://www.jstor.org/stable/resrep26647.6> See also reports on the FTA -India and EU – Khaona, 2020

[530] IGBA 2018, pg. 4

[531] See support given by the Industry in IGBA 2015, pg. 12.

Addressing Term Extensions in Trade Agreements

Provisions addressing the extension of the duration of patent rights seem to be the new normal and a standard feature in FTAs concluded by the EU and the US. Under the TRIPs Agreement it is not a requirement for WTO members to provide for additional extension of patent rights to compensate for the time lost in the regulatory stage.

In fact, what is required is protection granted by patents be available for 20 years from the filing date. Patent term extensions were discussed in a case involving Canada Pharmaceutical Patents at the WTO.[532] In that dispute, the panel stated that extensions due to regulatory delays should not be considered as part of the rights derived from patent law.[533]

It is evident that patent term extensions is a major cause of delay of entry of generic medicines into the market beyond the term of the patent. In light of this, it is important to guard against such inclusion in trade agreements and that they specifically do not contain patent term extensions. Where term extensions exist, the provisions should be formulated in non-mandatory terms and in a way that allows governments implementing such provisions to retain flexibilities and limit the scope of the extended protection. To foster access, term extensions provisions should ensure that provisions on patent term extensions allow generic manufacturers to export during the period of additional protection. Enabling generic manufacturers to export pending the extended patent protection term would enhance competition by creating a level playing field with manufacturers in countries where patent term extensions do not apply. In recognition

[532] Gregory Shaffer, 'Recognizing Public Goods in WTO Dispute Settlement: Who Participates - Who Decides: The Case of TRIPS and Pharmaceutical Patent Protection, Part II: Mini-Symposium: International Public Goods and the Transfer of Technology under a Globalized Intellectual Property Regime', (June 2004) 7(2) Oxford Journal of International Economic Law, 459-482 - accessed online via <https://heinonline-org> September 2020

[533] Canada-Patent Protection of Pharmaceutical Products, (Dec. 19, 1997), WT/DS 114/1 (1997) (E.C. brought complaint against Canada); Complaint by the United States, Canada-Patent Protection of Pharmaceutical Products, May 6, 1999, WTIDS 170/1 (1999) (complaint by United States against Canada, after compliance by India); Complaint by the European Communities, India-Patent Protection of Pharmaceutical Products, Apr. 28, 1997, WT/DS79/1 (1997).

of the importance that this provision stands to have for trade in generic pharmaceuticals, the export exception has been expressly included in the CETA.[534]

Exactly how this will benefit Canada is yet to be seen since the implementation is still new however, countries who import from Canada would appear best placed to take advantage of these provisions.[535] For example, the OECS Sub Region, with no manufacturing capacity and imports much of their pharmaceuticals from Canada. On the one hand, developing countries may benefit from this arrangement but on the other hand, only in the circumstances where there are no other FTA's or arrangements with other countries.

Patentability requirements can be tailor-made to assist in access.

Requirements for patentability which are reflected in the TRIPs Agreement as well as certain flexibilities, in the form of permissible exclusions from patentability.[536] FTAs appear to often seek to alter these standards in a manner that would distort the competitive relationship between generic medicines and originators' products. A number of FTAs covering patentability contain provisions limiting the permissible exclusions from patentability. In other FTAs, the standards of patentability appear more relaxed, which may lead to an increased number of patents being granted for not-so-innovative products.[537]

[534] See Armand de Mestrel, 'When Does the Exception Become the Rule? Conserving Regulatory Space under CETA' (2015) 18 Oxford Journal of International Economic Law, 641–654 doi: 10.1093/jiel/jgv033 - accessed online via <https://heinonline-org> accessed September 2020

[535] Dolle Tobias and Bruno G. Simoes, 'Mixed Feelings about Mixed Agreements and CETA's Provisional Application' (2016) 7 Eur J Risk Reg 617 <https://heinonline-org> accessed September 2020

[536] Article 27 of the TRIPs Agreement which also allows Members to exclude inventions from being granted a patent (that otherwise complies with other substantive requirements) on three grounds: (i) ordre public or morality; (ii) methods of treatment; and (iii) plants and animals.

[537] Sufian Jusoh, 'Free Trade Agreements and Implications on Public Health - An Analysis of FTA of Selected ASEAN Member States' (2009) 4 Asian J WTO & Int'l Health L & Pol'y 187 - <https://heinonline-org> accessed September 2020

Thus, standards on patentable subject matter, novelty, inventive step, and industrial applicability, as well as disclosure, as reflected in the TRIPs Agreement, are instrumental to ensure the proper functioning of the patent system, and contribute to the achievement of the overall balance between the various interests at stake, preventing instances of misuse/abuse. In this regard it is recommended that provisions on patentability[538] should appropriately reflect the language set forth in the TRIPs Agreement in relation to the criteria that apply to patentable subject matter and the permitted exclusions from patentability, and should not seek to modify the standards set by the TRIPs Agreement in relation to patents and term extensions.

Activating "Best Mode" may be beneficial to access efforts.

Initiating the "best mode" provides another avenue in addressing access and it is recommended that systematic inclusion of best mode requirements in trade agreements be evident.

TRIPs require WTO members to oblige patent applicants to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. In addition, patent authorities may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date (or, where priority is claimed, at the priority date of the application).[539] Therefore, under the so-called best mode requirement, if there are several ways in which the invention may be put into practice, the applicant can be required to disclose the one that is most practicable. Best mode requirements are not a common feature of trade agreements. Nonetheless it is recommended that the best mode requirement would make a significant contribution to enhancing knowledge dissemination and would play a

[538]Provisions addressing issues related to patentable subject matter are found in a number of FTAs and appear a standard feature of agreements concluded by the US; EU FTAs, on the other hand, do not normally cover such areas.

[539]Andrew R. Shores, 'Changes to the Best Mode Requirement in the Leahy-Smith America Invents Act: Why Congress Got It Right' (2012) 34 Campbell L Rev 733 <https://heinonline-org> accessed September 2020

decisive role in establishing the level of inventiveness legally required for a patent, with clear effects on innovation and competition.

Making Appropriate Provisions for Patent Linkage.

Appropriate use of patent linkage provisions can assist in making the legislation pro-access.

Patent linkage operate to link regulatory approval of pharmaceutical products to the patent status of the products. Patents on pharmaceutical inventions and regulatory approval for pharmaceutical products are normally granted by separate agencies. However, certain jurisdictions' domestic laws facilitate a link to regulatory approval to the patent status of the pharmaceutical product. Therefore, under a patent linkage mechanism, the marketing authorisation will not be granted to a generic medicinal product until the patent expired or is shown to be invalid irrelevant to the generic version. As a consequence, this may cause considerably delay of market entry of generic products. In jurisdictions where patent linkage is applied, the regulatory authority is effectively the patent enforcement agency, since patent linkage prevents that authority from granting marketing authorisation to a generic medicine where it appears that there is a valid patent still in existence.[540]

Patent linkage requirements are utilised in Canada, the US, and Japan, as well as in a few other jurisdictions as a result of the conclusion of FTAs, notwithstanding the fact that patent linkage is not a requirement of the TRIPs Agreement. In Canada and in the US, for example, the mechanism provides for an automatic injunction of up to 24 and 30 months, respectively, subject to the patentee's filing of a suit within a specified time frame of receiving the notice. On the other hand, patent linkage requirements are not allowed in the EU, where they are considered by the European Commission to be contrary to EU competition law.[541]

[540]Stefano Barazza, 'The Draft Trans-Pacific Partnership Agreement and Its Implications for Public Health and Access to Medicines: The UNITAID Report' (2014) 5 Eur J Risk Reg 366 <https://heinonline-org> accessed online September 2020

[541] In its Pharmaceutical Sector Inquiry (Final Report adopted on 8 July 2009), the European Commission recognised that the EU's regulatory frame- work for approval of pharmaceutical products does not allow

It is recommended that in the instances where patent linkage provisions are part of trade negotiations, negotiators should ensure that such provisions are not formulated in strict terms, be limited to the scope of the patents covered and include adequate balance by using appropriate 'safeguards' to prevent abuse.

For instance, one of such safeguards concerns the provision of clear incentives for generic manufacturers to challenge patents. This could be done through a requirement to provide a period of marketing exclusivity for the first generic applicant that challenges a patent which, in some form, may exist, with other appropriate safeguards to accompany patent linkage provisions.[542] Whilst it is suggested that this may still not compensate for the added complexity and cost of patent linkage requirements to domestic health systems, where patent linkage requirements are included in trade agreements, they should be clearly non-mandatory and allow for flexibility with respect to implementation of both the linkage mechanism and the 'safeguards' at the domestic level.

Provisions requiring countries to implement patent linkage clauses in their local legislation are often found in trade agreements, however, if they create a barrier to the registration and authorisation of generic medicines until a patent has been found to be invalid by the competent authority or in fact not relevant to the generic medicine, patent linkage requirements will considerably delay market entry of non-originator products.

Requirements for patent linkages appear more particularly problematic in negotiating frameworks involving countries with almost no IPR enforcement experience and no linkage requirements of their own in place. Functioning of the patent linkage system relies on the efficiency of local systems to quickly assess the existence or validity of a patent prior to granting regulatory approval. It follows that patent linkage requirements imposed on countries whose systems which does not currently meet such standards

authorities to take the patent status of the originator medicine into account when deciding on marketing authorisations of generic medicines. Therefore, patent linkage is considered by the Commission to be an anti-competitive instrument to delay generic and biosimilar medicines' entry into the market and, as such, subject to EU competition rules. As result, EU trade agreements do not contain patent linkage requirements.

[542] The United States – Colombia Trade Promotion Agreement (US-Colombia FTA), signed 22 November 2006 (entered into force on 15 May 2012), the United States – Panama Trade Promotion Agreement, signed 28 June 2007 (entered into force on 31 October 2012) and the United States – Peru Trade Promotion Agreement, signed 12 April 2006, entered into force on (1 February 2009).

may pose significant challenges and ultimately result in additional burdens, further delays and impediments on trade in pharmaceutical products.

Because of this inclusion of patent linkage provisions in trade agreements ought not to be included but where linkage cannot be avoided, trade agreements can include clear provisions that show patent linkage requirements not being made applicable to pharmaceuticals/generics.

Utilising the Bolar Clause for Enhancing Access

The regulatory review clause, "Bolar" or "early working" exception[543] provides for the utilisation of patented invention during the period of patent term without the consent of the patent holder, for the purpose of developing information, to obtain marketing approval from health regulatory authorities. This is may be considered an infringement of a related patent but by allowing generic producers the ability to market their versions as soon as the patent expires, the exception fosters market entry by competitors immediately after the end of the patent term and ensures timely access to generic medicines.

In the case of Canada, the regulatory review clause contained in Section 55.2(1) of the Canadian Patent Act was held to be in accordance with the requirements of Article 30 of the TRIPs Agreement by the WTO Dispute Settlement Body in the dispute Canada Pharmaceutical Patents.[544] The Canadian version of the regulatory review clause covers activities seeking product approvals under both domestic and foreign regulatory procedures. However, the scope of the regulatory review clause varies according to relevant national legislation. A number of countries explicitly provide for the regulatory review clause in their legislation.[545] The conformity of the regulatory

[543] The name "Bolar" comes from the US court case *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc*., 733 F.2d 858 (1984), concerning the manufacturing of generic medicines. In that case, the court held that US law did not allow for the experimental use of a patented chemical. Shortly after the ruling, the US Congress enacted the Hatch-Waxman Act, permitting the use of patented products in experiments for the purpose of obtaining FDA approval.

[544] Canada — Patent Protection of Pharmaceutical Products, DS114.

[545] The WIPO established that, up to 2010, 48 countries provided for the regulatory review clause, while in other countries the regulatory review clause is considered to fall within the scope of the general research exemption and, in other cases, it has been developed through case law (see WIPO Secretariat, "Patent Related

review clause with WTO obligations has also been upheld in the dispute Canada Pharmaceutical Patents.

To date, only a few FTAs include regulatory review clauses, mainly for purposes of restricting the scope of the exception. For instance, a number of agreements contain provisions that requires that the exportation of a product covered by the regulatory review clause only be permissible for the purpose of obtaining marketing approval in the country from which the export originates.

For improved access, such provisions should be avoided and instead instigates the inclusion of a liberal regulatory review clause considering focused precepts such as clauses that accommodate the manufacture, construction, use, or sale of the patented invention all associated with the development and submission of information required in the country where the generic manufacturer will use the patented invention; certain limitations operating to nullify the regulatory review clause should definitely be not be included and TRIPS flexibilities triggering automatic operation of without consent of the patent holder should apply to the regulatory review clause.

Excluding Data Exclusivity for Improved Access

Addressing the inter-play of regulatory data and patents rights can prove useful in improving the legislation to foster access.

Data protection operates to delay market entry of non-originator products, as it will not be possible to rely on the data produced for purposes of obtaining marketing authorisation for the same medicinal product. Data exclusivity may run in parallel to patent protection for approved pharmaceutical products which often results in effectively delaying the entry of generic medicinal products into the market because manufacturers of such products are required to wait until the protection period expires before submitting their application for marketing authorisation for their products.

Compounded to data exclusivity is the concept of “market exclusivity,” which refers to a period of exclusivity during which generic manufacturers may not market their

Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels”, Committee on Development and Intellectual Property (CDIP), Fifth Session, Geneva, April 26 to 30, 2010, CDIP/5/4 REV, p. 23).

products. The combined period, as seen in previous Chapter, allows for an application for marketing authorisation may be submitted and processed if data exclusivity has expired. The language in certain TAs does not make this distinction, as such, are not consistently reflected in trade agreements and can be broad as referring to protection of data for purposes of obtaining a marketing authorisation by some and the ability to market the product by others.

Article 39.3 of TRIPs requires WTO members to protect clinical data submitted for regulatory approval against disclosure and “unfair commercial use,” which refers to acts of unfair competition. Various members have interpreted this requirement as an obligation to establish data exclusivity regimes, and are advocating and ensuring that data exclusivity provisions appear in FTAs, in an attempt to bind FTA parties to institute similar frameworks in domestic laws. It must be made clear that data exclusivity is not a requirement of the TRIPs Agreement, and any interpretation that justifies the introduction of data exclusivity requirements on the basis of the TRIPs Agreement ought to be out rightly refused. The TRIPs Agreement simply requires a form of test data protection so as to prevent “unfair commercial use” of the data by third parties, a concept that refers to acts of unfair competition, and not to create a form of exclusivity.

Therefore, it is prudent that trade agreements should not contain provisions concerning the protection of test or other data that go outside of the requirements of the TRIPs Agreement, or should defer the regulation of such matter in the domestic legislation of the parties. The trend seems to be that developed countries systematically requiring the inclusion of data exclusivity obligations in their international trade agreements. In cases like this it is strongly recommended that the re-assessment of incorporation of such provisions that would obstruct the scope and length of data exclusivity requirements.

Ultimately TAs should not be concerned with addressing data exclusivity requirements for pharmaceuticals, this removes the possibility of providing for any special or additional requirement leading to longer data exclusivity periods.

Ensuring Adequate Provisions for Enforcement of IPRs

Adequate provisions for IPR enforcement in local legislation for addressing importing standards under multilateral provisions on enforcement of IPRs can improve access.

WTO members are required to ensure that IPRs are effectively enforced under their laws, and that penalties punish and deter violations.[546] The provisions on enforcement are informed by the two-fold objective of safeguarding the rights of IP owners while avoiding barriers to legitimate trade. With respect to trade in pharmaceutical products, this objective is reflected in the need to ensure that free trade in legitimate medical products is not subject to unnecessary legal barriers preventing movements of medicines among countries. The enforcement standards established by TRIPs cover civil and administrative procedures and remedies, provisional measures, special requirements related to border measures, and criminal procedures. In particular, TRIPs require WTO members to make civil procedures available and remedies with respect to all IPRs which incidentally encompasses patents and test data.[547] TRIPs further mandates Members to ensure that judicial authorities have the authority to order provisional measures to prevent infringements from occurring for example by preventing the entry into the channels of commerce in their jurisdiction of imported goods suspected of infringing IPRs and to preserve evidence.

The earlier discussion on border measures show that they substantially enable customs authorities to suspend the release into free circulation of the goods suspected of infringing IPRs. TRIPs requires that border measures be available at least for counterfeit trademark and pirated copyright goods, that criminal procedures be available in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Therefore, when it comes to patents, Border Measures were merely

[546] Peter K Yu, 'TRIPS Enforcement and Developing Countries' (2011) 26 Am U Int'l L Rev 727 <https://heinonline-org> accessed September 2020

[547] Aminesh Sharma, 'Data Exclusivity with Regard to Clinical Data' (2007) 3 Indian J L & Tech 82 <https://heinonline-org> accessed September 2020

optional and there is no requirement that criminal procedures be applied to patent or test data infringements.

However, this had not stopped negotiators from prioritising and ensuring that FTAs contain onerous mandatory disciplines on IPR enforcement, which go beyond what TRIPs requires. From the generic pharmaceutical industry standpoint, provisions on IPR enforcement are crucial to ensure that instances of IPR infringements are properly addressed and sanctioned. However, it is equally important to ensure that IPR enforcement does not create unnecessary barriers to legitimate trade in generic medicines.

Therefore, agreements which encourage excessive significance on patents can only result on offsetting the balancing Act that TRIPs are meant to foster and counteracts the objectives that need to inform IPR enforcement action. It is for this reason it is recommended to maintain the flexibilities provided in the TRIPs Agreement with respect where enforcement is concerned and that patents should not be made subject to border measures and criminal enforcement, particularly in FTA provisions.

Additionally, the application of border measures to goods in transit should be revisited. Border measures applicable to transit goods could threaten legitimate trade in generic medicines, especially where claims are based on alleged trademark violations. Further, a safeguard against abuse of enforcement should be considered in FTAs in the event that a generic company suffers damage due to enforcement procedures wrongly being commenced against its pharmaceutical products.

5.6.3. Taking Positive Proactive Actions in Trade Agreements as a means of Deterring Hindrances to Access

Having considered what ought not to be included in trade agreements, it is important to look at what should be included in FTA's. Negotiators and stakeholders should pay particular attention to drafting and ensure that treaty language includes a concerted effort to include provisions in TAs that may operate to prevent anti-competitive behaviour and or hindrance to generic entry.

The inclusion of provisions to prevent misuse/ abuse of IPRs and anti-competitive practices in international trade agreements.

Competition policy plays a key role in the legal framework for intellectual property protection in providing "checks and balances" in international agreements and national laws. Legal provisions on competition, no doubt, form an integral and complementary part of IP frameworks. The importance of competition law and policy can be seen as operating as a balance which is reflected in the IP Chapters of a number of FTAs.[548]

Healthy competition, particularly between originators and competing generic medicines manufacturers, is essential in order to keep public health spending in check and to increase access to medicines to the benefit of patients. Notwithstanding this, a number of anti-competitive and abusive practices have been identified as being harmful to the generic and biosimilar sector. As recognised by the European Commission in its Pharmaceutical Sector Inquiry Report, they include strategic patenting, patent litigation, interventions before national regulatory authorities and life-cycle strategies for follow-on products. The overall effect of such practices is to delay generic entry into relevant markets.

TRIPs contain a number of provisions on competition law and policy that reflect the concerns regarding potential abuse of IPRs protected by the agreement. Article 8.2 encourages appropriate measures may be needed to prevent abuse of IPRs by right holders or the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology. This provision is not strictly applicable to competition law violations but can be applied generally to abuse of IPRs, which is directly relevant to the generic entry.

Various FTAs contain such provisions that guard against abuse by right holders. IP-specific competition provisions vary among FTAs but inclusion of these provisions is certainly useful to restate the general principle that countries/parties may act to avoid

[548] See further – Patricia Anne D Sta Maria, 'Life, Death, and Data: Examining the Human Rights Implications of Introducing Data Exclusivity to India's Pharmaceutical System, in Light of the Global Situation of Diseases Such as HIV/AIDs in the Philippines and Other Developing Countries' (2017) 61(4) Ateneo Law Journal 1128-1207 - accessed online via <https://heinonline-org> September 2020

IPR misuse/abuse, and this should systematically be established in trade agreements. However, they are formulated in broad terms, leaving important issues to be decided at the national level.[549]

To address the anti-competitive and abusive practices that are most harmful to the generic industry, trade agreements should include a set of binding provisions on competitive safeguards. One particular way in which binding provisions against anti-competitive and abusive practices can be included in FTAs is through the insertion of a competitive safeguard provision, with a list of the practices that constitute misuse/abuse of IPRs that are most harmful to the generic medicines. Additionally, TAs can consider inclusion of provisions that specifically speak to patent revocability on a determination of anti-competitive behaviour, to be issued by relevant local judicial and administrative authorities.

The inclusion of appropriate frameworks on incentives for generic medicines

It is important that countries include frameworks to incentivise the access of generic medicines in their markets by giving appropriate incentives to generic competition and ensuring their inclusion in trade agreements. Such framework must take stock of the divergences among IPR systems and the different negotiating contexts that are relevant to the pharmaceutical sector and be adaptable and sufficiently flexible to suit all relevant systems.[550]

Such incentives may be implemented in a way that encourages challenges to weak or invalid patents, stimulate competition and innovation, as well as increase savings for national health care systems and facilitate access to affordable medicines. This is

[549]Annmarie Elijah, Karen Hussy Kenyon and Pierre van der Eng, 'Chapter Title: Korea–EU FTA: Breaking New Ground Chapter Author(s): Yoo-Duk Kang Book Title: Australia, the European Union and the New Trade Agenda, Book Editor(s), Published by: ANU Press, available at <https://www.jstor.org/stable/j.ctt1sq5ttx.7?seq=1#metadata_info_tab_contents> accessed December 2020

[550]Sangeeta Khoana, 'The FTA: A Strategic call for the EU and India? India's Foreign Policy, European Council on Foreign Relations', (October 2020), available at <https://ecfr.eu/special/what_does_india_think//analysis/the_fta_a_strategic_call_for_the_eu_and_india> accessed October 2020

more likely to work best in countries where there is little or no manufacturing capabilities and rely totally on imports from developed countries.

The US introduced provisions establishing a legal incentive to promote generic competition through the Hatch-Waxman Act, under which the first company that files a generic application containing a patent challenge certification may be rewarded with 180 days of generic market exclusivity. The US experience, therefore, provides an example as to why incentives for generics to challenge weak or invalid patents should be part of a balanced IPR regime. A similar mechanism was recently introduced in South Korea.[551] There are several features of the US market that explain the success of the Hatch-Waxman exclusivity system of incentivisation. These features are not present in other countries, so that generic incentivisation needs to be provided in different forms. Market exclusivity periods are most suitable for countries with a patent linkage system. Incentivisation through pricing and reimbursement policies could apply in countries without patent linkage systems such as the EU.[552]

A framework that encourages timely generic entry will work well in countries where both patent linkage and long data protection exist because it would act in a manner that balances protection granted through patents and other IPRs and stimulate challenges of weak patents. This initiative can be entertained by Canada as it tries to grapple with the loss of some of its provisions which fostered generic entry in exchange for CETA and the rising cost of medication it has imposed. Most definitely, the ultimate concern for stake-holders rests on price and availability. The fear of drug shortages also poses severe anxiety as it is quite possible that this may take various forms.

The generic medicines industry depends on policymakers who respond to a dynamic environment with polices that protect competition so that affordable medicines can continue to benefit society. When an imbalance occurs between innovation and access, policy must be swift and effective to correct course.

[551]See, for example, Agence Europe, Council's Green Light to Launch of Negotiations for Bilateral Free Trade Agreements with ASEAN, South Korea and India, (2007);

[552]Steven G. Morgan and Nav Persaud, 'New Generic Pricing Scheme Maintains High Prices and Risks of Shortages' (2018) 190 CMAJ E410-1- accessed online via <https://heinonline-org> accessed October 2020

The generics pharmaceutical industry is clearly experiencing where the originator industry is using highly questionable strategies to delay competition from generics. These strategies, no doubt, undermine the competitiveness of the industry's massive investments in complex follow-on competition and limits the ability to keep older products on the market. Governments should take clear corrective action against all forms of anti-competitive behaviour and restore healthy competition.

More importantly, Governments should also resist increasing intellectual property standards in international trade agreements. These provisions delay or prevent market entry of generics and biosimilars around the globe, further damaging the viability of the generic and biosimilars medicines industries.

In the final analysis,

Countries in the WTO are increasingly becoming parties to trade agreements which appears to push the protection for originators as they are home to the pharmaceutical giants. Arguably, many of these agreements appear to be self-serving and developing countries are falling prey to these agreements by failing to adequately scrutinise the provisions that relate to patent protection for pharmaceuticals. Based on CETA and in light of UK's exit of the EU and further the recent conclusion of trade agreements between the US and small Arabic and African states,[553] these conclusions shed light on legislative arrangements which can assist in addressing access of pharmaceuticals.

The increasing recognition by industry and government of the current situation spurs a sentiment that major changes are required. Moreover, changes may involve country specific, global perspective to foster in-country activity that enables growth and development which will directly impact access. Localised, proactive, legislative arrangements, with a view of enabling the co-existence of adequate flexibilities for generic companies to thrive simultaneously fostering innovation into new pharmaceutical technologies, will place countries in an offensive position which will no doubt contribute to ensuring resilience whenever priorities shift. This may have

[553] Riad Al Khouri, 'EU and U.S. Free Trade Agreements in the Middle East and North Africa', (2008) Carnegie Endowment for International Peace (2008), available at http://www.jstor.com/stable/resrep12819 accessed October 2020

tremendous impact on patenting, generally and will no doubt make in-roads in fostering and achieving greater access to pharmaceuticals from a local/national standpoint whilst having global reach. Novel approaches ought to encompass foundational and structural measures, geared at setting grounded pillars that will be capable of withstanding global changes in legislation and industry, particularly in pandemic times.

Chapter summary

It is evident that countries have encountered major difficulties where choosing appropriate measures for access are concerned. Addressing public health matters, simultaneously adhering to international obligations presents many challenges where some measures seem positive, others present work in progress opportunities that if explored fully may prove beneficial in addressing access, while other avenues prove unsatisfactory.

Based on the foregoing, pooled procurement systems combined with the international schemes have assisted in making cheaper drugs available and may prove beneficial in future arrangements but they are limited in their reach. Patent pools and trade secrets seem not to be practical in terms of access but based on the previous chapter, the amendments to the SPC system, by far, seems the more practical solution in reaching both decreased cost and increased availability.

It appears therefore that access matters must be considered holistically with LDCs and countries with no manufacturing requiring a major paradigm shift and are encouraged to look to their internal trading systems for enhanced access mechanisms, in particular utilisation of the Bolar exception and scrutinization of trading arrangements.

Chapter Six

OPTIMISATION OF LEGAL FRAMEWORKS FOR INCREASED ACCESS AND CONCLUSIONS

This research illustrated the impact on the increased cost of pharmaceuticals by patents and term extensions specifically and assessed what efforts/measures were successful and which ones proved least practical for countries attempting to gain increased access in the ever-changing environment of balancing public health obligations and respect for IP. This Chapter offers conclusions on the optimization of legal infrastructure for increased access and general conclusions which supports a paradigm shift based on Drahos' suggestions on utilising lessons from Doha for LMICs and is apt, considering the current climate, particularly, in a post Covid-19 era," …. *they must have strategies for realizing the gains of negotiation, acting where they can on the basis of self-help and unilateral action. They have to avoid concessions that are encased in rule complexity. Most importantly, they have to find ways to develop a joint bargaining strategy on at least some intellectual property issues that will counter forum shifting……"*[554].

Whilst tackling policy matters and associated workable solutions to access are outside the scope of this research, it must be appreciated that indeed significant leaps are required based on not just theoretical presumptions but practical application resulting in increased access. The reality is that people have died during the pandemic[555] and although not solely attributable to intellectual property, making the wrong decision on these matters definitely exacerbates the difficulty level in making pharmaceuticals available, at all times.

The current climate, no doubt, increases the urgency of access in that the Covid-19 crisis revealed several blind spots in the system which shows disregard for access and serious shortcomings in policy driven by technocrats. Attempts by the American

[554] Drahos 2007 pg. 39.

[555] The total of deaths worldwide was over 3,000,000 – See historical data (to 14 December 2020) on the daily number of new reported Covid-19 deaths worldwide, European Centre for Disease Prevention and Control, available at <https://www.ecdc.europa.eu/en/publications-data/download-todays-data-geographic-distribution-covid-19-cases-worldwide> accessed December 2020

President to make patent rules more flexible where the Covid-19 vaccines are concerned[556] is an indication that high level policy making no doubt, has to take centre stage.

Notwithstanding the efforts previously utilised, it appears that what works best incorporates dynamic shifts to create hybrid systems which are focussed on local public health requirements simultaneously maintaining compliance with international obligations. Such encompasses gymnastic manoeuvring of sorts but ultimately resulting in practical alternatives that actually yield real access and not access in a theoretical sense or jurisprudential basis.

In this vein, this research discovered that the lack of utilisation of legal structures and lack of manufacturing contributes to access difficulties in not just Developing Countries but also countries with little manufacturing and production based on generics industry as opposed to originators.

6.1. LEGAL AND INDUSTRY CONSIDERATIONS TO ACCESS.

Bearing in mind the positivist approach and Posner's recommendation for a fusion of law and economics, this research takes the view that a holistic approach to achieving a balanced system is what is required. In addressing access, it is not difficult to calculate that a human rights approach would be posited. Consideration is given to the views of E. Richard Gold who warns against taking a purely human rights view in addressing patents in pharmaceuticals and who contends that taking the heterodox view, despite both rhetorical and real wins in the short term, in framing patent law as opposed to human rights, has negative medium- and long-term consequences.[557]

Another argument is that one of the unintended and perhaps paradoxical consequences of those invoking a human rights paradigm to counter an expansionist patent agenda has been the entrenchment of the very frame that they opposed. This

[556] Patsy Widakuswara, 'Covid-19 Pandemic, Biden Agrees to Waive Covid-19 Vaccine Patents, but it's Still Complicated', VOA Online, (May 05, 2021), available at <https://www.voanews.com/covid-19-pandemic/biden-agrees-waive-covid-19-vaccine-patents-its-still-complicated> accessed June 2021

[557] Richard E Gold, 'Patents and Human Rights: A Heterodox Analysis', (2013) Spring Global Health and the Law 185

frame, which equates patents with the rights of innovators against the State, diminishes not only the ability of States to shape patent law to their internal needs, but also constrains the potential for patent theory, policy, and law to engage in a substantive domestic debate about innovation, education, health, and well-being.

Approaches to access have always followed dividing lines between human rights law and patent protection. What these approaches miss is that the normative and legal orders underlying international human rights law and patent law are radically different. International human rights law focuses on the dignity of individual people and is a discourse carried out at the international level. On the other hand, patents aim at increasing prosperity and well-being at the domestic level. Both are instantiations of the liberal goals of protecting fundamental political rights while increasing the well-being of the least well off. The resemblance, however, ends there.

International human rights law speaks directly to how States exercise their power while patent law does so only indirectly. One way to improve patent law and policy is to free it from the artificial constraints imposed by both patent expansionists and human rights advocates. Put simply, patent law needs to escape singular, international solutions in favour of domestic discourse. This discourse should aim at developing an “intellectual architecture” for the country. Such intellectual architecture includes not only the rules about the kinds of intangible assets inventions, works of art and theatre, logos, trademarks and brands that are protected, but also the mechanisms to ensure the creation and free flow of those assets, such as licensing arrangements, government grants and tax rules, technology clustering, universities and training of technology-related business managers without public law rules over the relations between individuals within a State. It is based on these principles; resilient patent systems can thrive.

The OECD provided a synopsis of the world pharmaceutical climate but is optimistic that pharmaceutical spending can represent good value for money in health systems. Beyond the therapeutic value of new products, many relatively inexpensive medicines delay or prevent disease complications and reduce the use of costlier health

services.[558] Considering the OECD's challenges, recalling the attempts made at addressing access, combined with the myriad of issues surrounding use of term extensions, legal systems will no doubt require to utilise resilient and dynamic approaches in addressing access.

Thus, policy considerations which includes inherent facilities for equitable balance emerges triumphant.[559] Ultimately systems with such balance generally utilises a shift away from the norm but encompasses a profound focus on access. Whatever theoretical base or jurisprudential analysis adopted some basic principles are apparent. Such include and are not limited to: Increased value of spending on medicines; Ensuring access in countries at different levels of development; Supporting a rules-based system; Fostering competition in both on-patent and off-patent markets; Promoting better communication and dialogue between payers, policy makers, pharmaceutical companies, and the general public which, ultimately, may impact parallel trade and innovation, simultaneously.[560]

Based on the foregoing, it appears that systems which are flexible in adopting new approaches whilst utilising inherent legal structures, offer more concrete solutions for access. Given the dual complexity of the patent/SPC and pharmaceutical systems, it is evident that quick fixes are not feasible in addressing access across the board particularly for LDCs, taking into account their lack of manufacturing capabilities.

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[558] OECD, *Pharmaceutical Innovation and Access to Medicines*, OECD Health Policy Studies, OECD Publishing, Paris, (2018) <https://doi.org/10.1787/9789264307391-en> - accessed 8th April, 2019, (OECD 2018)

[559] OECD 2018. Pg. 20

[560] James Love, "Policies that Ensure Access to Medicine and Promote Innovation, with Special Attention to Issues Concerning the Impact of Parallel Trade on the Competitive Sector, and a Trade Framework to Support Global R&D on new Health Care Inventions: Presented at the WHO/WTO Joint Secretariat Workshop on Differential Pricing and Financing of Essential Drugs, , Hosbjor, Norway, (April 11, 2001) - available at <https://www.wto.org/search/search_e.aspx?search=basic&searchText=Canada+pharma+case&method=pagination&pag=0&roles=%2Cpublic%2C> accessed July 2020

6.2. INCORPORATION OF EXISTING LEGAL FRAMEWORKS FOR IMPROVED ACCESS.

This section explores the impact of utilising certain legal structures for access and includes use of flexibilities, identifying gaps in existing Trade Agreements and use of patent pools to address emergency access and increased use of partnerships to facilitate access.

Utilising the International Legal Framework with a view to Legislative changes and TRIPS Compliance

The use of TRIPS as a precursor to improved access depends on understanding that International focuses on the law between countries and therefore, except for some rare cases, has no direct effect on individuals. Individuals, including patent-holders, patients, manufacturers and distributors are therefore directly subject to *national* and not *international* law. On the other hand, international law is beneficial as it indicates boundaries within which countries can create and enforce their laws. This is particularly relevant because often countries impose obligations on themselves that are not required under international law. This is a frequent occurrence in the realm of patent law where countries do not use all of the flexibilities offered by international law to customise their patent system to internal economic and social goals.

While patent law is national in scope TRIPs sets minimum requirements with which all WTO member countries' patent laws must comply. Thus use the TRIPS agreement for fostering local legislative frameworks that are suitable to economic growth have always been beneficial.

States which have adjusted their conformity with TRIPS obligations have benefited from boosting their competitiveness in terms of attracting Direct Foreign Investment. It may seem obvious however it may be enlightening to discover how many countries are not in compliance. What this does is that it allows countries to participate fully in the international trading environment and to take advantage of the various flexibilities under the TRIPS Agreement. This may be particularly important when dealing with matters like the "Bolar Clause", infringement and border measures. Whilst many doubt the effectiveness of being TRIPS compliant, it appears that countries can no longer

deflect from such as compliant or not, the rules affect these countries, but the downside to being non-compliant is that a country finds it more difficult to bargain internationally and to respond to the hostile IP climate that is emerging.

Taking advantage of the TRIPS flexibilities remains an important first step in defending one's legal system which may affect many aspects of trading. One creative example would be to address the issues with trade agreements, in tandem with TRIPS Flexibilities. Whilst this may require expertise beyond the capabilities of some countries, such measure can provide a hybrid situation, which is what is required in order to deal with the rising gymnastics and power play being exhibited by certain countries. Such may be effective in delving into aspects of the legislation that may be open for penetration, in the event of actions being brought and would have a knock-on effect on ensuring that particular clauses are enshrined in Agreements, which match the legislative arrangements, which are beneficial to the country's best interest. Such would also assist in uncovering the legislative gaps and language in the Agreements that may affect the bargaining power negatively.

Dealing with "Orphan drugs" provide yet another benefit that legislative creativity can address. Some patent laws, particularly in developing countries, fail to distinguish between new drugs for rare diseases and older established orphan drugs, whose indications, safety and efficacy are well-researched. For example, in January 2014, the cost of "trientine" an "old" orphan drug that is essential for treating Wilson disease in a subgroup of patients, increased by about 13-fold. In future, as high-priced treatments for rare diseases are developed, regulations should facilitate competitive access to older, unpatented drugs. Failure to do so puts the effective availability of the drugs at risk.[561]

Some countries, particularly in the developing world, still have not made themselves TRIPS compliant and others have done so in crafty ways including legislating around various types of IP but not addressing the TRIPS issues directly in an all-encompassing patents act. For countries that are in the process of making TRIPs compliant legislation, the hybrid approach will be beneficial in that it offers an

[561]Eve A. Roberts, Matthew Herder, Aiden Hollis, "Fair pricing of "old" orphan drugs: considerations for Canada's Orphan Drug Policy", (2015) 187(6) CMAJ, 422 – accessed online the 11th April, 2019

opportunity to craft a piece of legislation which is modern, compliant with international standards and is equipped with in-built measures and solutions that are forward thinking in nature and can stand up to future developments.

Re-analysis of existing Trade Agreements which may identify gaps posing a hindrance to access

Based on the foregoing, it may be quite necessary for countries to conduct a re-assessment of their existing trade agreements. This initiative is geared at uncovering instances where the agreements run counter to the intended purpose, or where the Agreement appears to have clauses that damage effective competition and in particular, clauses that affect the timeframe within which generics can enter the market. Whilst it may not be feasible to effect changes to the Agreements, this measure may assist in finding solutions around the clauses and legislating tactically that may hinder certain clauses from being enforced beyond the ambit of the agreement itself. This exercise may also assist in crafting proactive language for future agreements but also finding ways to incorporate those solutions into local legislation, without touching the agreements already in place.

Tapping into Patent Pools to address emergency access.

The Covid-19 pandemic has shown that significant use of patent pools and the value that may be attributed to such when addressing access matters. As discussed previously, patent pools, if utilised correctly, can provide an enhanced system of procurement which addresses both cost and availability. No doubt, finding creative ways in dealing with any adverse effects that may arise will have to form part of the equation, however, overall, based on the recent need for patent pools, they create a legal and practical solution in addressing access matters. A look at the system for pooling in the telecommunication industry can lend support to this measure. Special agreements that facilitate equitable distribution of profits/rents and render products available and costly can contribute to life saving efforts, as is seen in the current pandemic. Nonetheless, this requires specialist technical expertise but with the appropriate framework can create plausible outcomes.

Increased use of Partnerships to facilitate access.

Effective use of partnerships provides another excellent opportunity for countries to address access matters. There is no prescribed format as to how these partnerships are to be formed but this may involve a variety of stakeholders. Collaboration between regulators, health authorities and payers seem an ideal starting point. The regulation and assessment of medicines can no longer be carried out in isolation. Strong collaboration can boost medicine development and facilitate an early and affordable access for patients to innovative treatments. Chantal Bélorgey, Ad Schuurman and Michael Berntgen discuss the challenges and benefits of fostering mutual understanding among decision-makers[562] however countries may consider identifying tools and initiatives specific to their respective requirements local situation and aim to facilitate patients' access to innovative medicines.

Effective use of public procurement initiatives by the OECS sub region; the partnerships by BENELUX group,[563] and new arrangements being considered by the BRIC countries[564] are indicative of initiatives which provide excellent opportunities at tackling access and are strongly recommended. This measure may beneficial cost-wise, in that it may reduce the cost of countries adopting certain measures on their own, which in the end would run contra to the intended aim of having cheaper drugs available. Joint arrangements not only reduce cost to individual countries but provides strength in numbers where countries can negotiate as a group, which would in turn impact the cost of drugs locally or regionally.

[562]EMA Annual Report (2017), Part 2, Pg. 50, http://Annual-report-european-medicines-agency_en.pdf Accessed online – 11th April 2020

[563] See Informa UK Ltd (2019) and <https://beneluxa.org/collaboration> accessed December 2019

[564] Peter K Yu, 'Access to Medicines, BRICS Alliances, and Collective Action', (200) 3 American Journal of Law and Medicine, 345-94, (2008), accessed August 2020

6.3. CONCLUSIONS

Based on the forgoing, and following a thematic structure, the overall conclusions of the research include:

Introductory matters - From the outset the aim of this research was to understand the extent to which PTEs have impacted access to medication in terms of time and cost. In so doing specific focus was placed on SPC's in EC legislation and its global reach. Although SPC's are a European construct, term extensions are generally utilised as a TRIPS-Plus mechanism by developed countries to assist the pharmaceutical industry to recoup costs associated with bringing drugs to the market. With the increased cost of medication, particularly in developing countries and with access to medication being considered a human right by international standards, it was imperative to add to the literature on access matters through the investigation of the rules associated with making drugs available which operate to bar access to cheaper medication and impact public health considerations. Thus, this section included details on jurisprudential and methodological aspects of the research.

Having outlined the introductory, jurisprudential and methodological aspects of the research, from an access viewpoint, through the lens of the generic pharmaceutical industry and adopting a thematic format, presentation of the findings was as follows:

Legal Theory/Legislation (Chapter 1) - The section demonstrated the confusion faced by international cross-border patenting issues regarding access to medication but further delineates that the imperfect system is not near to finding a solution.

Importantly, this brings to the fore condition of IP systems where patent rules and access concerns are at cross roads and it stressed the recognition of the significance of the levels of protection in TRIPS which explicitly states that Members shall not be "obliged to, implement in their law more extensive protection than is required, provided that such protection does not contravene other TRIPS provisions. The Chapter also covered the World Health Policy on access which explicitly endorses measures aimed at rapid market availability of generic medicines thus the world health policy, as evidenced in recent authoritative statements from the leadership of international institutions responsible for health, suggests that the protection of public health entails, among other measures, provision of early working exceptions for patents. Thus, the

chapter gave a thorough account of patent theory and practical application and operation of the patenting systems, internationally, in Europe and Canada and outlined the many controversies encountered in addressing public health needs.

Term Extensions and Regulatory Data (Chapter 2) - Following from the patent and legal theory, this section focused on the SPC system whilst making links to the enabling regulatory system. A focus on the intricate working of the system demonstrated how the system, in practice, inherently contributes to the access discourse.

The information provided a greater appreciation for the SPC system as it delved into its inception as an attempt to bolster research and development but more particularly to give innovators extra time on patents as a means of recouping any time lost during the regulatory process. The chapter demonstrated an understanding that the 20-year rule which is enshrined in the international instruments that govern the general principles and standards for patents administration appears insufficient to innovator companies and so the use of term extensions became a tool to assist in that regard.

Additionally, the information also brought to light the legislative arrangements which governs term extensions that appears to not only give extra time to the innovators but delays time for generics to access the market. This means that it takes more time for the drugs to become cheaper and readily available as in most instances, the protection offered by the basic patent is extended to up to five years, and in some, an additional 6 months, in the event a paediatric extension applies.

The correlation between extension and access and the extent or impact that this correlation has had on actual access was discussed. This adds the divergent angle to the operation of SPC's, its interaction with the regulatory environment. Based on the hybrid nature of SPC's and in order to understand the environment within which medical patents are made to thrive, it was necessary to consider all aspects of pharmaceutical regulation. In this regard this section of the chapter emphasised that bridge between the patent system and the regulatory environment. Further, the Chapter delved into the legal and regulatory aspects the Canadian pharma system and added to the discourse details of different legislative and regulatory systems which

provides a more rounded understanding of the various issues at play and which, no doubt, impacts both the SPC system and access matters.

Presentation of published data

Having covered the background, legal and historical contexts and matters concerning the legalities and practicalities of accessing data, the next section provided details of secondary analysis of the published data, which are covered in 3 chapters.

Understanding cost, time and access from the European context (Chapter 3)

The section dissected the data from studies previously concluded and showed the effects of patents and SPCs, in a practical manner, on access in terms of time and cost. Data from recently concluded studies were analysed which incorporated information from: Results of Copenhagen study; PMRB data; Meijer Study; EFPIA; Drug cost, OECD and the Kyle Report.

The results of the studies illustrated that: the rate of filing of SPCs in Europe has arisen and continues to rise; that SPCS's delay an average price drop of approximately 50%; the average length of SPCs is 3.5 years; the total spending on medicinal products in the EU is USD 247bn. Hence a 10% change of total spending on medicinal products from originator products to generic products would entail a possible saving of USD 12.4bn; Potential savings attainable in case generic entry had taken place immediately upon loss of exclusivity of the originator medicine, could have led to additional savings of about €3 billion.[565] This meant that the generic savings could have been 20% higher.

The chapter provided wholistic coverage of both regulatory and industry aspects of SPCs. Based on the discussion of the data, areas for improvement of access were highlighted which includes avenues for addressing difficulties posed by the broken SPC system and utilisation of steps already taken towards harmonisation through the use of the Unitary patent and the SPC Waiver.

[565] Meijer, 2017

Understanding cost, time and access from the Canadian context (Chapter 4)

The chapter revealed that at over US$700 per person per year, Canada spends more per capita on pharmaceuticals than any other country in the world except the US. When measured against comparator countries in the OECD, Canada's growth in drug spending per capita between 2009 and 2011 was 43% per year compared to the OECD average of 35%.[566] In this chapter the focus shifted to understanding the issues of cost, time and access by analysing the generic industry in and Canadian contexts and exploring some data and insight into CETA as well as the projected implications on access through the new "restoration" system.

This allowed for delving into the reasons why the cost of medication in Canada was higher despite not having utilised term extensions prior to CETA, deducing the factors contributing to that rise in the absence of such extensions. It was ascertained that despite not utilising PTEs Canada's drug cost remained higher than most European countries which may appear to support a conclusion that SPCs do not automatically result in extensions and or higher prices and consequently hinder access as is made out in the literature. The data also indicated that there are other IP matters affecting the cost and availability of medicines in Canada as well as non-IP/patent developments which contribute to the cost of pharmaceuticals.

The chapter discusses that licence cost and devaluation of the Canadian dollar were key however it appeared that the biggest threat lies in the patent legislation and Canada's relationship with trading agreements with other countries, in particular the EU. Moreover, special pricing schemes in the EU seem to favour a lower cost situation than what obtains in Canada, thus despite cost savings due to the efficient workings of the generics system, prices continue to sour. It is anticipated that there will be added cost to Canada's pharmaceutical system once the CSP system goes live with certain active ingredients in patents. Based on the figures, it is projected that the Restoration is likely to see prices continue on a steady incline which will no doubt have practical impacts on the whole pharmaceutical industry. For now, it appears that Canada is awaiting the expiry of the first set of patents caught by the Restoration to adequately

[566] OECD 2019 and PMRB at Chapter 5.

assess the impact but it seems that its dealings with other countries appear to be the major determinant in the cost at which the country can afford pharmaceuticals.

Attempts at fostering access (Chapter 5) - Having perused the problem as it pertains to access and term extensions and after having identified the key arears of distortion, this chapter showed an assessment of some practical useful measures that countries/payers of pharmaceuticals have adopted in an attempt to foster greater access to pharmaceutical products.

Analysing those efforts demonstrated that countries seemed at loss where choosing appropriate measures for access were concerned. Addressing public health matters, simultaneously adhering to international obligations present many challenges, some of which can be conquered but others may become hurdles, consequently requiring a total reorganisation of systems to accommodate all sectors. Such efforts were analysed in this chapter and offered presumptions on which efforts yielded positive results and those which can be considered work in progress opportunities that if explored fully may prove beneficial in addressing access, while other avenues proved unsatisfactory. Overall, the efforts which incorporates early working exceptions to PTE's, appropriate use of licences and collaborative measures by block countries illustrated more practical gains.

Nonetheless, the situation as presented suggested that ploughing a way forward, no doubt, requires a major paradigm shift which takes into account that the generic medicines industry depends on policymakers who respond to a dynamic environment. It was shown that increased access will incorporate polices that protect competition so that affordable medicines can continue to benefit society but encourages some degree of flexibility in that policies must be swift and effective. Specific points were raised for addressing legal and industry manoeuvring for Developing countries, particularly those with little or no manufacturing capabilities. Based on the literature and the findings of the schemes already utilised, the focus for governments must involve finding creative solutions to resist increasing intellectual property standards in international trade agreements. Strategically, addressing the content of existing trade agreements is stressed. Adopting a proactive offensive position in dealing with unbalanced provisions in such agreements represents a positive step in light of the trend where developing countries are increasingly becoming parties to these trade

agreements which appear to push the protection for pharmaceutical originators as they are home to the pharmaceutical giants.[567]

Optimising legal frameworks for increased access (Chapter 6)

This concluding chapter is based on an acknowledgement that the main concern for stakeholders where access is concerned relates to price and availability with an added dimension of the fear of drug shortages.

The issues raised when affordable generic medicines are unable to compete with expensive brand names as a result of strategic tactics by innovators to block generic entry continues to be a live one and to combat these initiatives advanced ought to consider long term strategies for both private and public sector dealings.

In light of the Covid-19 pandemic, addressing public health matters will no doubt involve a massive shift from business-as-usual to more dynamic approaches, as the world experienced the necessity to conduct Covid-19 ready solutions, to address more short-term needs. Accordingly, legal systems and industry must contain flexibility that allows such plug and play solutions but encompasses long-term arrangements in addressing access matters, particularly in low-income countries as the effect of the global IP climate on developing nations with little or no manufacturing paints a bleak picture. While most countries are still determining real impact on healthcare in a post Covid-19 environment, discussions on access have to take centre stage.

Looking forward, what is advocated is fostering in-country activity that enables growth and development with direct positive impact on access. Localised, proactive, legislative arrangements, with a view of enabling the co-existence of adequate flexibilities for generic companies to thrive simultaneously fostering innovation into new pharmaceutical technologies, will place countries in an offensive position and no doubt contribute to ensuring resilience whenever priorities require a shift.

[567] Riad al Khouri, 'EU and U.S. Free Trade Agreements in the Middle East and North Africa', (2008) Carnegie Endowment for International Peace, available at <http://www.jstor.com/stable/resrep12819> accessed December 2020

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