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Saving Ukrainian Lives During the Russian War: Ukraine Must Waive IP Rights under Article 73 TRIPS to Provide Access to Essential Medicines

In light of the severity of the health crisis in Ukraine due to the Russian aggression, the Ukrainian government must urgently implement expeditious solutions to increase the supply of essential medicines and medical products. One such measure is to exploit all existing domestic manufacturing capacities that are still intact and seek any potential possibility to import essential medicines from abroad. For this, all the barriers would need to be eliminated, including those in the form of intellectual property (IP) rights that might protect many essential medicines that are currently needed in Ukraine. This article argues that the existing mechanism of compulsory licensing under TRIPS and Ukrainian IP law is not effective to resolve the problem of access to medicines during such a critical situation as the ongoing war. It therefore suggests that Ukraine must immediately waive all IP rights related to essential medicines and medical products to enable the domestic production and seek any potential import of generics and biosimilars of essential medicines. Such a waiver would be justified based on ‘security exceptions’ of Art. 73(b)(iii) TRIPS. This provision allows a WTO member to utilise measures to protect its essential security interests taken in time of war. It is hoped that this article will provide guidance to the Ukrainian government on the most effective way to deal with the current health crisis in Ukraine and, thus, would help to save lives of millions of people in Ukraine that suffer from Russia’s unjustified, horrific aggression.

I. Introduction

On 24 February 2022 the Russian Federation launched an unprovoked and unjustified war against its neighbour Ukraine.¹ At the time of writing there is a full-blown war on the territory of Ukraine. The Russian occupation forces have already killed thousands of civilians,² including

children.³ They have inflicted multiple damages on the Ukrainian civil infrastructure⁴ in violation of international laws,⁵ deliberately hitting various parts of Ukraine with missiles, vacuum bombs and artillery shells attacking residential areas, kindergartens, hospitals, maternity

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1 The Russian war against Ukraine began in February 2014, when Russia invaded and annexed Crimea and triggered a separatist rebellion in the east, followed by the Russian army’s overt invasion of the eastern Ukraine to support the rebels. See ‘The Russo-Ukrainian War’ (*Wikipedia*) (‘It began in February 2014 following the Ukrainian Revolution of Dignity, and initially focused on the status of Crimea and parts of the Donbas, internationally recognised as part of Ukraine. The first eight years of the conflict included the Russian annexation of Crimea (2014) and the war in Donbas (2014 - present) between Ukraine and Russian-backed separatists, as well as naval incidents, cyberwarfare, and political tensions. Following a Russian military build-up on the Russia–Ukraine border from late 2021, the conflict expanded significantly when Russia launched a full-scale invasion of Ukraine on 24 February 2022’) <https://en.wikipedia.org/wiki/Russo-Ukrainian_War> accessed 11 April 2022; see also UN General Assembly Resolution No 71/205 ‘Situation of Human Rights in the Autonomous Republic of Crimea and the city of Sevastopol (Ukraine)’, 19 December 2016, A/RES/71/205 (the Resolution condemned the ‘temporary occupation of part of the territory of Ukraine’, ie the Autonomous Republic of Crimea and the city of Sevastopol by the Russian Federation, and reaffirmed the non-recognition of its ‘annexation’).

2 Office of the High Commissioner for Human Rights, ‘Ukraine: civilian casualty update 7 April 2022’ (from 4 am on 24 February 2022, when the Russian Federation’s armed attack against Ukraine started, to

24:00 midnight on 6 April 2022 (local time), the Office of the UN High Commissioner for Human Rights (OHCHR) recorded 3,838 civilian casualties in the country: 1,611 killed and 2,227 injured). These numbers are preliminary and are likely to be much higher following the withdrawal of the Russian forces from the previously occupied territories and the unveiled atrocities they committed, eg in Bucha and Borodyanka. See eg UN, ‘Ukraine: UN’s Guterres joins call for Bucha war crimes probe’ (‘The Secretary-General’s comments came after shocking images from Bucha on the outskirts of Kyiv showed hundreds of dead people, some with bullet wounds and their hands tied behind their backs and others burned or in mass graves, in areas previously under the control of Russian troops.’) <<https://news.un.org/en/story/2022/04/1115522>> accessed 11 April 2022.

3 ‘Since the beginning of Russian invasion of Ukraine, 183 children have died and more than 342 have been injured, Office of Prosecutor General’ (*Sensor.Net*, 11 April 2022) <<https://censor.net/en/n3333090>> accessed 11 April 2022.

4 ‘Russia’s war in Ukraine has caused at least \$68bn in physical damage’ *The Economist* (London, 4 April 2022) (‘The true extent of the devastation will be a lot worse’) <<https://www.economist.com/graphic-detail/2022/04/05/russias-war-in-ukraine-has-caused-at-least-68bn-in-physical-damage>> accessed 11 April 2022.

5 John B Bellinger III, ‘How Russia’s Invasion of Ukraine Violates International Law’ (*Council on Foreign Relations*, 28 February 2022) (‘Russia’s invasion of Ukraine violates Article 2(4) of the UN Charter, a central tenet of the charter that requires UN member states to refrain from the “use of force against the territorial integrity or political independence of any state.”’) <<https://www.cfr.org/article/how-russias-invasion-ukraine-violates-international-law>> accessed 11 April 2022;

hospitals and other civil infrastructure.⁶ Many towns and villages in northern, eastern and southern Ukraine have been severely damaged or completely destroyed.⁷ These attacks have forced more than 10 million of Ukrainians to flee their homes.⁸

Considering the horrific atrocities unleashed on the Ukrainian population by the Russians since the beginning of this aggression,⁹ the humanitarian crisis that has been unfolding is unprecedented; it is the largest

humanitarian crisis since the World War II.¹⁰ The constant bombing, death and destruction, as well as the blockades and siege of numerous cities, towns and villages, have led to the catastrophic shortages of food and water,¹¹ and nearly one million people have been left without electricity.¹²

One of the most affected sectors in Ukraine is the healthcare system. It had already been stretched to the limits by the severity of the ongoing COVID-19 pandemic, the war has now elevated this problem to the disastrous level. Since the beginning of the war, demand of medical supplies has vastly increased by, on the one hand, the sharp and constant growth of casualties caused by the Russian attacks on densely populated areas and, on the other hand, by millions of patients with serious infectious and chronic conditions that require urgent access to medicines.¹³ Many of those who had to flee Ukraine struggle to access essential medicines as they may only have a few weeks' supply of medication such as HIV treatment with them.¹⁴ At the beginning of the war, some medicines and medical products, including bandages, haemostatic drugs, antibiotics and painkillers have disappeared from pharmacies.¹⁵ Access to some essential medicines, such

'Ukraine's ambassador to US says Russia used a vacuum bomb, international groups say banned cluster munitions used to strike shelter' (*ABC*, 28 February 2022) <<https://www.abc.net.au/news/2022-03-01/ukraine-ambassador-us-russia-used-vacuum-bomb-cluster-munitions/100870638>> accessed 11 April 2022; Patricia Zengerle, 'Ukraine, rights groups say Russia used cluster & vacuum bombs' (*Reuters*, 1 March 2022) ('Human rights groups and Ukraine's ambassador to the United States on Monday accused Russia of attacking Ukrainians with cluster bombs and vacuum bombs, weapons that have been condemned by a variety of international organizations'.) <<https://www.reuters.com/world/europe/ukraines-ambassador-us-says-russia-used-vacuum-bomb-monday-2022-02-28/>> accessed 11 April 2022; Lisa Schlein, 'UN: Russian Military Attacks on Ukrainian Civilians Likely Violate International Humanitarian Law' (25 March 2022) ('U.N. human rights monitors in Ukraine are condemning the use of explosive weapons and indiscriminate attacks by Russian military forces on civilians and civilian infrastructure as a probable violation of international humanitarian law.'). <<https://www.voanews.com/a/un-russian-military-attacks-on-ukrainian-civilians-violate-international-humanitarian-law/6501552.html>> accessed 11 April 2022.

6 UN News, 'Russian attacks on civilian targets in Ukraine could be a war crime: UN rights office' ('Civilians are being killed and maimed in what appear to be indiscriminate attacks, with Russian forces using explosive weapons with wide area effects in or near populated areas,' said Office of the United Nations High Commissioner for Human Rights (OHCHR) spokesperson Liz Throssell, speaking in Geneva. 'These include missiles, heavy artillery shells and rockets, as well as airstrikes'. 'Fifteen days into the war, schools, hospitals and nurseries have been hit by shelling', Ms. Throssell said, adding that cluster bombs had also been used in several populated areas.) <<https://news.un.org/en/story/2022/03/1113782>> accessed 11 April 2022; Keith Collins and others, 'Russia's Attacks on Civilian Targets Have Obliterated Everyday Life in Ukraine' *The New York Times* (New York, 23 March 2022) <<https://www.nytimes.com/interactive/2022/03/23/world/europe/ukraine-civilian-attacks.html>> accessed 11 April 2022; Lorenzo Tondo and Isobel Koshiw, 'Mariupol: Russia accused of bombing theatre and swimming pool sheltering civilians' *The Guardian* (London, 17 March 2022) <<https://www.theguardian.com/world/2022/mar/17/mariupol-ukraine-russia-seized-hospital>> accessed 11 April 2022.

7 Ruby Mellen, 'Ukrainian cities see massive destruction' *The Washington Post* (Washington, 17 March 2022) ('Parts of the country are unrecognizable as people flee and buildings crumble') <<https://www.washingtonpost.com/world/interactive/2022/ukraine-before-after-destruction-photos/>> accessed 11 April 2022; 'Eastern Ukrainian town of Volnovakha destroyed after Russia invasion, local governor says' (*Reuters*, 12 March 2022) <<https://www.reuters.com/world/europe/eastern-ukrainian-town-volnovakha-destroyed-after-russia-invasion-local-governor-2022-03-12/>> accessed 11 April 2022; 'Over 600 buildings destroyed in Ukrainian city of Kharkiv, mayor says' (*Reuters*, 15 March 2022) <<https://www.reuters.com/world/europe/over-600-buildings-destroyed-ukrainian-city-kharkiv-mayor-says-2022-03-15/>> accessed 11 April 2022.

8 United Nations High Commissioner for Refugees (UNHCR), 'Ukraine Refugee Situation' (10 April 2022) ('In the first five weeks, more than four million refugees from Ukraine crossed borders into neighbouring countries, and many more have been forced to move inside the country.'). <<https://data2.unhcr.org/en/situations/ukraine>> accessed 11 April 2022; International Organization for Migration, 'Almost 6.5 Million People Internally Displaced in Ukraine: IOM' (21 March 2022) <<https://www.iom.int/news/almost-6-5-million-people-internally-displaced-ukraine-iom>> accessed 11 April 2022; Chris Reiter, 'Russia's War Drives 10 Million Ukrainians From Their Homes' (*Bloomberg*, 21 March 2022) <<https://www.bloomberg.com/news/articles/2022-03-21/russia-s-war-has-driven-10-million-ukrainians-from-their-homes>> accessed 11 April 2022.

9 See UN, 'Ukraine: UN's Guterres joins call for Bucha war crimes probe' (n 2); Jennifer Rankin and Daniel Boffey, 'Killing of civilians in Bucha and Kyiv condemned as 'terrible war crime'' *The Guardian* (London, 2 April 2022) <<https://www.theguardian.com/world/2022/apr/03/eu-leaders-condemn-killing-of-unarmed-civilians-in-bucha-and-kyiv>> accessed 11 April 2022; Andrew Buncombe, 'Ukraine's Zelensky warns situation in Borodyanka is 'significantly more dreadful' than in Bucha' *The*

Independent (London, 8 April 2022) <<https://www.independent.co.uk/news/world/europe/ukraine-zelensky-bucha-borodyanka-war-crimes-latest-b2053389.html>> accessed 11 April 2022; Thomas Bolton, 'Kyiv fears a civilian massacre at Borodyanka worse than Bucha' (*Euronews*, 5 April 2022) <<https://www.euronews.com/2022/04/04/fears-over-more-civilian-massacres-as-russian-troops-retreat-north>> accessed 11 April 2022.

10 UN, 'The war has caused the fastest and largest displacement of people in Europe since World War II' (24 March 2022) <<https://ukraine.un.org/en/175836-war-has-caused-fastest-and-largest-displacement-people-europe-world-war-ii>> accessed 11 April 2022.

11 'Ukraine's Mariupol says city's last reserves of food and water are running out' (*Reuters*, 13 March 2022) <<https://www.reuters.com/world/europe/ukraines-mariupol-says-citys-last-reserves-food-water-are-running-out-2022-03-13/>> accessed 11 April 2022; Sophie Morris, 'Ukraine war: UK to send dried food, tinned goods and water to areas surrounded by Russian troops' (*SkyNews*, 26 March 2022) <<https://news.sky.com/story/ukraine-war-uk-to-send-dried-food-tinned-goods-and-water-to-areas-surrounded-by-russian-troops-12574911>> accessed 11 April 2022; UN Security Council, 'Conflict, Humanitarian Crisis in Ukraine Threatening Future Global Food Security as Prices Rise, Production Capacity Shrinks, Speakers Warn Security Council' (29 March 2022, SC/14846).

12 Furfah Shah, 'Nearly 1 million people in Ukraine have no electricity, says state energy firm' *The Independent* (London, 11 March 2022) <<https://www.independent.co.uk/news/world/europe/ukraine-civilians-electricity-russia-invasion-b2033789.html>> accessed 11 April 2022.

13 David A Leon and others, 'The Russian invasion of Ukraine and its public health consequences' (2022) 15: 100358 *The Lancet Regional Health – Europe* 1; Rosalie Hayes, 'Ukrainians displaced by Russian invasion struggling to access HIV and drug dependency treatment' (*Nam Aidsmap*, 21 March 2022) <<https://www.aidsmap.com/news/mar-2022/ukrainians-displaced-russian-invasion-struggling-access-hiv-and-drug-dependency>> accessed 11 April 2022 ('destruction of healthcare facilities and disruption to medical supply chains within Ukraine has also increased the risk of illness and death from pre-existing health conditions, including cancer and diabetes. Inadequate sanitation and overcrowding in bomb shelters and refugee camps will likely contribute to the spread of infectious disease – prior to the invasion, Ukraine had the second highest incidence of multi-drug resistant TB in Eastern Europe and only half of the population were vaccinated against COVID-19.').

14 Hayes (n 13).

15 Serhiy Guz, 'Accessing food and medicine in a warzone: Ukraine's supply crisis' (*OpenDemocracy*, 28 February 2022) ('People bought medicine in a panic, while sending other materials to reserves in hospitals in case the city came under attack. The military also required additional medical supplies.'). <<https://www.opendemocracy.net/en/odr/ukraine-insulin-medicine-food-russia-warzone-supply-crisis/>> accessed 11 April 2022.

as insulin, have been extremely challenging too.¹⁶ While there is an acute need to increase the supply of essential medicines and medical products, Ukraine's ability to meet these needs has been severely affected by the shortages of essential medical supplies, as well as a deliberate destruction by the Russians of the Ukraine's medical infrastructure, while also blocking import of medicines.¹⁷

In certain less affected areas in Ukraine, the domestic pharmaceutical industry continues functioning despite a constant threat to its production sites and workers (albeit in a new, wartime regime due to regular airstrike warnings).¹⁸ There is also a significant support from the international community that has been sending humanitarian help to Ukraine, including medicines.¹⁹ However, the vast scale of the tragedy that affects the majority of Ukrainians suggests that the current level of local production, limited import and humanitarian support are undoubtedly not enough to resolve the problem of access to essential medicines in Ukraine. As millions of Ukrainians are directly and indirectly affected by the Russian aggression, there is an urgent need to find an expeditious solution that would allow to increase both in volume and speed the supply of medicines to Ukrainians. This solution would also need to take into account the drastic economic pressure and significant restraints on the state budget of Ukraine, as a large chunk of its financial resources are now directed towards supporting the heroic Ukrainian army and strengthening the defence of Ukraine. Therefore, such a solution must also be low-cost and affordable.

One such measure is to exploit all existing domestic manufacturing capacities (i.e. those factories that have not been damaged or destroyed by the Russian occupation forces), as well as to seek any potential possibility to import essential medicines from abroad. For this, all the barriers would need to be eliminated, including those in the form of intellectual property (IP) rights that might protect many essential medicines that are currently needed in Ukraine.²⁰ It must be noted that Ukraine has always ensured a just balance of protection between private and public interests by implementing high standards

¹⁶ *ibid* ('For those who require insulin, the situation is especially difficult. For many, it is quite literally a matter of life and death. However, getting hold of insulin is extremely challenging, even with a prescription. Where regular deliveries are impossible because of fierce fighting, volunteers or the military try to deliver insulin and other drugs to those who desperately need it. Those deliveries are not always possible.')

¹⁷ Leon and others (n 13) 1; Ministry of Health of Ukraine, 'What medicines are needed in Ukrainian hospitals?' (18 March 2022) <<https://en.moz.gov.ua/article/news/what-medicines-are-needed-in-ukrainian-hospitals>> accessed 11 April 2022.

¹⁸ Kateryna Shpival and Nata Shtuka, 'The Military pharma. How drug manufacturers work during the war' (*Forbes*, 2022) <<https://forbes.ua/inside/viyskova-farma-yak-pratsyuyut-virobnik-likiv-pid-chas-vyni-03032022-4096>> 11 April 2022.

¹⁹ Medicines For Europe, 'Call On EU Leaders To Safeguard Access To Medicines And Build Resilience In Response To Russia-Ukraine War' (23 March 2022) <<https://www.medicinesforeurope.com/news/call-on-eu-leaders-to-safeguard-access-to-medicines-and-build-resilience-in-response-to-russia-ukraine-war/>> accessed 11 April 2022.

²⁰ Ukraine has a strong generic industry with several large generic manufacturers. See World Health Organization, 'Evaluation of The Affordable Medicines Programme in Ukraine' (Report) WHO 2019, 2. The author of this article is aware of a number of domestic pharmaceutical companies that are willing to produce certain essential medicines, which would significantly improve access to such medicines in Ukraine, while would also be cheaper than the original products, and thus, would save substantial financial resources for the state budget. However, such medicines are protected by a range of IP rights, and the local manufacturers are concerned that should they start producing the much-needed medicines for Ukrainians they would be infringing on such rights.

of IP protection aligned with its obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)²¹ and bringing its standards closer to the European standards under the Association Agreement signed between Ukraine and the European Union.²² However, the extreme circumstances of the ongoing war require the employment of drastic measures.

This article, therefore, argues that in light of the humanitarian crisis and the severity of the health crisis in Ukraine due to the Russian aggression, the Ukrainian government must urgently implement expeditious solutions to increase the supply of essential medicines and medical products for Ukrainians. Some of the life-saving medicines may be protected by patents and other types of IP rights and thus the local production or import of their generics or biosimilars would not be possible.²³ Therefore, this article first analyses whether the currently available mechanism in the form of compulsory licensing is suitable for resolving the health crisis during this war. The article explains that this mechanism in general, and as it currently exists in Ukrainian IP law in particular, is not effective to deal with such an urgent situation as the ongoing war. It, therefore, considers whether an alternative mechanism may be better suited to expedite the supply of medicines in Ukraine. The article suggests that the urgent measures must include a waiver of the IP rights related to essential medicines and medical products to enable the employment of all existing domestic manufacturing capacities and attract any potential import of generics and biosimilars of essential medicines needed in Ukraine. Such a waiver would be justified based on the 'security exceptions' provision of Art. 73(b) (iii) TRIPS. This provision allows utilising measures by a WTO member with the aim of protecting its essential security interests taken in time of war. It is hoped that this article will provide guidance to the Ukrainian government on the most effective way to deal with the current health crisis in Ukraine and, thus, would help to save lives of millions of people in Ukraine.

II. Unsuitability of the currently available mechanism of compulsory licensing in TRIPS and Ukrainian IP law to improve access to medicines during the war in Ukraine

IP rights are exclusive rights given to the right holder over the use of their creations for a certain period of time;²⁴

²¹ Ukraine joined the TRIPS Agreement (1994) on 16 May 2008.

²² 'Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part' ([2014] OJ L161/3, ISSN 1977-0677), in which ch 9 'Intellectual Property' contains a comprehensive list of substantive provisions on various types of IP, as well as procedural provisions on IP enforcement.

²³ It must be noted that Ukraine has implemented the Law 'On the Protection of Interests of Persons in the Field of Intellectual Property During Martial Law Imposed in Connection with the Military Aggression of the Russian Federation against Ukraine' (dated 1 April 2022, No 2174-IX), which, *inter alia*, extended the duration of terms related to the protection of IP rights. In particular, it provides that IP rights, the validity of which expires on the day of imposition of martial law in Ukraine or during martial law, shall remain valid until the day following the day of termination or abolition of martial law. This means that those rights that would not have acted as a barrier to access to medicines during the war because they would have expired during the war, will still be valid and will pose a challenge in accessing essential medicines that they protect.

²⁴ WTO, 'What are intellectual property rights?' <https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm#:~:text=Intellectual%20property%20rights%20are%20the,a%20certain%20period%20of%20time> accessed 11 April 2022.

such exclusive rights empower the owners to stop others from using their creations without their consent. In the field of pharmaceuticals, pharmaceutical companies typically extensively protect the results of their research by means of IP rights, including applying for multiple patents.²⁵ Owning such exclusive rights enable them to control the distribution and prices of their products, which, in turn, may restrict or even block access.²⁶ At the same time, international laws contain certain mechanisms that are aimed at balancing such strong protection. One such mechanism is compulsory licensing.²⁷ The TRIPS Agreement contains provisions that allow to set certain limitations on the exercise of exclusive rights under a patent.²⁸ A compulsory licence is the authorisation granted by a state authority that permits a third party to use a patented invention without the patent holder's consent. The right of all WTO members to use this flexibility under the TRIPS Agreement was confirmed by the 2001 Doha Declaration on the TRIPS Agreement and Public Health.²⁹ This mechanism has been implemented in the majority of jurisdictions worldwide, including in Ukraine.³⁰

Article 31(b) of the TRIPS Agreement also contains a special type of compulsory licenses, i.e. 'government use' or a 'public non-commercial use'.³¹ This mechanism allows a government to grant the authorisation for its own use, including for production, importation and distribution of the patent protected products.³² Government use may be an effective tool when dealing with public health crises, because governments can authorise the use of a patented medicine upon its own volition, which could help

to improve access to more affordable drugs.³³ Moreover, government use licences present some advantages over a 'normal' type of compulsory licences. Thus, with respect to the latter, Art. 31(b) TRIPS contains a requirement of prior negotiations with the patent holder before granting a compulsory licence, which must be 'on reasonable commercial terms and conditions' and it will be only granted if 'such efforts have not been successful within a reasonable period of time'. However, this requirement may be waived in the case of 'government use'. Similarly, under the same provision, there is no need to conduct prior negotiations in the case of compulsory licences granted to third parties to address a national emergency or other circumstances of extreme urgency.³⁴

While compulsory licensing can be an effective tool in facilitating access to affordable medicines, as can be evidenced by its use in relation to life-saving drugs by developing countries in the past,³⁵ the scale and dimensions of the current assault on Ukraine by the Russian occupation forces pose certain challenges for the effective and expedite utilisation of this mechanism. One of the reasons is that a compulsory licence must be granted only on a product-by-product basis.³⁶ This means that it is currently not possible to issue a general compulsory licence that would relate to all or certain medicines and medical products that are urgently needed in Ukraine. The need to grant such licences for each product (which may include multiple patents covering various aspects of the product) would, therefore, significantly impede the process, which, considering the urgency during the war, is obviously unacceptable. Moreover, the compulsory licensing mechanism regulates only patents, however, medicines and medical products needed in Ukraine may be protected by other types of IP, including copyright, designs, trademarks, marketing authorisation, supplementary protection certificates, trade secrets, etc. In particular, it is arguable whether compulsory licensing may be applied to supplementary protection certificates, as they create a separate *sui generis* form of protection different from patents.³⁷ Also, this mechanism may not be effective in relation to complex biologic medicines (for example, the human blood plasma-derived drugs), because their manufacturing technology and other aspects of such medicines may be protected by trade secrets.³⁸ In addition, the issue of compensation for the use of IP rights that must be paid to IP rightsholders under compulsory

²⁵ Olga Gurgula, 'Drug Prices, Patents and Access to Life-saving Medicines: Changes Are Urgently Needed in the Covid-19 Era' (2021) 43 EIPR 381; Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies: Should Competition Law Intervene?' (2020) 51 IIC 1062.

²⁶ Olga Gurgula, 'Compulsory licensing vs. the IP waiver: what is the best way to end the COVID-19 pandemic?' (2021) 104 The South Centre Policy Brief 1.

²⁷ For an extensive literature review related to compulsory licensing see Danielle Navarro and Marcela Vieira, 'Research Synthesis: Compulsory Licensing' (2021) Graduate Institute <<https://www.knowledgeportalia.org/compulsory-licensing>> accessed 11 April 2022; Olga Gurgula and Wen Hwa Lee, 'COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?' (2021) 17(2) Journal of Generic Medicines 61 <<https://journals.sagepub.com/doi/pdf/10.1177/1741134321993182>> accessed 11 April 2022; Olga Gurgula, 'International approaches to enhancing access to medicines during the COVID-19 pandemic: German and French examples' (2021) Legal Gazette <<https://yur-gazeta.com/legal-business/articles-in-english/international-approaches-to-enhancing-access-to-medicines-during-the-covid19-pandemic.html>> accessed 11 April 2022; Carlos M Correa, 'Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents' (2020) the South Centre, Research Paper 107, 13; European Patent Academy, 'Compulsory licensing in Europe: a country-by-country overview' (2018) <<https://www.epo.org/learning/materials/compulsory-licensing-in-europe.html>> accessed 11 April 2022.

²⁸ art 31 of the TRIPS Agreement.

²⁹ Declaration on the TRIPS Agreement and Public Health (14 November 2001), Doc.WT/MIN(O1)/DEC/2 (20 November 2001). Subpara. 5 (b) 'Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: ... b. Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.'

³⁰ Correa (n 27) 13.

³¹ art 31 TRIPS.

³² Medicines Law & Policy, 'Research and resources on intellectual property and health' <<https://medicineslawandpolicy.org/tools/>> accessed 11 April 2022.

³³ Correa (n 27) 13.

³⁴ Gurgula, 'Compulsory licensing vs. the IP waiver' (n 26) 2.

³⁵ Examples of compulsory licensing, including public non-commercial use, can be found in the TRIPS Flexibilities Database that provides worldwide information on the instances when authorities have invoked, planned to invoke, or have been asked to invoke a TRIPS flexibility for public health reasons, in particular, to assure access to medicines. See Medicines Law & Policy, 'The TRIPS Flexibilities Database' <<http://trips-flexibilities.medicineslawandpolicy.org>> accessed 11 April 2022.

³⁶ art 31(a) TRIPS 'authorization of such use shall be considered on its individual merits'.

³⁷ *ibid*.

³⁸ See the discussion on the need to supplement compulsory licensing of patents with an additional mechanism of compulsory licensing of trade secrets in relation to complex biologic medicines, such as vaccines, that would allow an involuntary transfer of such technologies in Olga Gurgula and John Hull, 'Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer' (2021) 16 Journal of Intellectual Property Law & Practice 1242.

licences may further complicate the matter, especially considering the vast amount of essential medicines and medical products that are needed today in Ukraine and significant limitations on the state budget discussed above.

Finally, Ukraine may potentially rely on Art. 31^{bis} TRIPS.³⁹ This ‘Special Compulsory Licensing System’ essentially allows WTO members with domestic manufacturing capacity to issue compulsory licenses for export to those countries that do not have such capacities.⁴⁰ Thus, should Ukrainian manufacturing capacities not be enough to produce the required volume of essential medicines to satisfy the need of the Ukrainian population, or in case Ukraine incurs further significant damage to its pharmaceutical manufacturing capacities, it may request that other countries produce and import certain essential drugs to Ukraine. While in theory this may be a useful mechanism, due to its complexity and a cumbersome procedure,⁴¹ this system has been used only once to date. In 2007, Rwanda notified the WTO that it intended to import 260,000 packs of the combination AIDS therapy drug TriAvir,⁴² Canada also informed that it had granted a permission to Apotex to produce generics of this patent protected medicine for export.⁴³ With all the necessary compulsory licences being issued, and significant efforts by Médecins Sans Frontières (Doctors without Borders) and Apotex, the export of TriAvir began only in five years after it was initiated.⁴⁴ As a result Apotex announced that it would not take part in this mechanism again until it was reformed.⁴⁵ This is because, as Médecins Sans Frontières

explained, the Art. 31^{bis} system ‘through requirements that range from adding unnecessary steps (i.e. mandatory differential packaging and colouring of products under the compulsory license), to actively impeding the flexibility needed in an evolving public health crisis (i.e. requiring importing countries to specify the quantity needed for each product in each compulsory license used under the notification made to the WTO)’ impair the effective utilisation of this mechanism.⁴⁶ While Médecins Sans Frontières in their following statement referred to the COVID-19 pandemic, the same is true in relation to the ongoing war in Ukraine. Thus, paraphrasing their statement, the Art. 31^{bis} mechanism results in excessive procedural requirements that create unnecessary barriers, particularly during a war when all resources and every moment of time are precious.⁴⁷ These challenges, therefore, may present a significant barrier for Ukraine in utilising this mechanism effectively.

Moreover, the mechanism of compulsory licensing embedded in Ukrainian legislation is cumbersome and inefficient that makes it unsuitable for the currently unfolding health crisis, which requires prompt and urgent supply of medicines and medical products. In particular, Art. 30(3) of the Ukraine Patent Act provides that ‘to ensure public health, state defence, environmental security and other public interests, the Cabinet of Ministers of Ukraine may allow the use of a patented invention (utility model) to a person designated by the Cabinet without the consent of the patent owner.’ The requirements of granting such a compulsory licence in Art. 30(3) of the Patents Act, including the requirement that the patent holder should be paid an adequate remuneration and that such a use must be predominantly for the supply of the domestic market, generally reflect the requirements of Art. 31 TRIPS. The Decree of the Cabinet of Ministers of Ukraine No. 877 further clarifies the procedure on granting a compulsory licence for medicines and medical products (hereinafter ‘Procedure’).⁴⁸ According to this Procedure, the Cabinet of Ministers of Ukraine (CMU) may grant a permission to a designated person if this person can prove (by providing relevant documentary evidence) that the following two grounds are met: (a) the patent owner cannot satisfy the need for a relevant medicinal product with the abilities and capacities that are normally used for the production of such a medicinal product; and (b) the patent owner has groundlessly rejected the applicant’s request to issue a licence to use the invention (utility model).⁴⁹

This provision raises several challenges, which affect the efficient utilisation of this mechanism, especially during a war. First, the Procedure requires that a third party should request the grant of a compulsory licence. This potentially means that the government of Ukraine is not able to issue a government use licence upon its own initiative, as is permitted by the TRIPS Agreement discussed above. Second, it is not clear how the applicant

39 Decision of the General Council of 6 December 2005, ‘Amendment of the TRIPS Agreement’, WT/L/641 8 December 2005 <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> accessed 11 April 2022. WTO press release, ‘WTO IP rules amended to ease poor countries’ access to affordable medicines’ <https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm> accessed 11 April 2022.

40 Gurgula, ‘Compulsory licensing vs. the IP waiver’ (n 26) 4.

41 Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicine, ‘Promoting Innovation and Access to Health Technologies’ (2016) 9 <<http://www.unsgaccessmeds.org/final-report>> accessed 11 April 2022; Médecins Sans Frontières, ‘WTO COVID-19 TRIPS Waiver Doctors Without Borders. Canada Briefing Note’ (2021) <https://www.doctorswithoutborders.ca/sites/default/files/msf_canada_briefer_on_trips_waiver.pdf> accessed 11 April 2022 (While there is disagreement over how art 31^{bis} could be reformed to be more effective, or even whether such reform is possible, there is once again considerable agreement upon the fact that it does not work in its existing form).

42 WTO, ‘Canada is first to notify compulsory licence to export generic drug’ (2007) <https://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm> accessed 11 April 2022.

43 Priti Radhakrishnan and Tahir Amin, ‘Strengthening Patent Standards: An Alternative Route to Compulsory Licensing For Low And Middle Income Countries’ in Carlos M Correa (ed), *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* (the South Centre, 2013); Christopher Garrison, ‘Never say never – Why the High Income Countries that opted-out from the Art. 31bis WTO TRIPS system must urgently reconsider their decision in the face of the Covid-19 pandemic’ (*Medicines Law & Policy*, 8 April 2020) <<https://medicineslawandpolicy.org/2020/04/never-say-never-why-the-high-income-countries-that-opted-out-from-the-art-31bis-wto-trips-system-must-urgently-reconsider-their-decision-in-the-face-of-the-covid-19-pandemic/>> accessed 11 April 2022 (‘the core provision is hedged with potentially cumbersome procedures and it can only be regarded as a limited solution to the Art. 31(f) at best’).

44 Radhakrishnan and Amin (n 43) 319; Médecins Sans Frontières, ‘Neither Expeditious, nor a Solution: the WTO August 30th Decision is Unworkable’ (2006) <<https://msfaccess.org/never-expeditious-nor-solution-wto-august-30th-decision-unworkable>> accessed 11 April 2022.

45 Médecins Sans Frontières, ‘WTO COVID-19 TRIPS Waiver Doctors Without Borders. Canada Briefing Note’ (2021) <https://www.doctorswithoutborders.ca/sites/default/files/msf_canada_briefer_on_trips_waiver.pdf> accessed 11 April 2022.

46 *ibid.*

47 *ibid.*

48 Decree of the Cabinet of Ministers of Ukraine dated 4 December 2013, N 877, ‘The Procedure of granting by the Cabinet of Ministers of Ukraine of a permit for the use of a patented invention (utility model) related to a medicinal product’.

49 *ibid* para 2.

can meet the first condition and what evidence must be provided to prove that the patent owner cannot satisfy the need for a relevant medicinal product. More importantly, the second ground for issuing a compulsory licence requires that prior to requesting the government to grant a compulsory licence, the interested party must first request a licence from the patent holder, and only after the patent holder rejects the request to issue a licence, the interested party has the right to apply for a compulsory licence. At the same time, as discussed above, under Art. 31 TRIPS the requirement of prior negotiations may be waived in the case of ‘public non-commercial use’, as well as in the case of national emergency or other circumstances of extreme urgency.⁵⁰ Therefore, in the context of this war, Art. 31 TRIPS allows the Ukrainian government to grant compulsory licences/government use of patents related to medicines and medical products without negotiating with the patent holders. This is because the war clearly falls within the scope of Art. 31(b) TRIPS: e.g. the war may qualify as a ‘national emergency’ and such licences can be granted for public non-commercial use to protect public health. However, Ukrainian law does not contain relevant provisions permitted by TRIPS. As a result, the current requirement of prior negotiations in Ukrainian law significantly limits the possibility of an efficient and speedy grant of a licence.

Other elements of the procedure for granting a compulsory licence pose further constraints on the effectiveness of this process. According to paragraph 4 of the Procedure, for a compulsory licence to be granted, an interested party must contact the Ministry of Health requesting a compulsory licence to be granted by the CMU. The application, among other things,⁵¹ must contain the following:⁵²

- the justification of the necessity to use the patented invention (utility model) indicating specific circumstances and a required duration of the permission to use the patent;
- the technical and economic justification of the ability, conditions and procedure for using the patented invention (utility model);
- the documentary confirmation of the patent owner’s unreasonable refusal of the applicant’s request to grant a licence to use the patented invention (utility model);
- the calculation of the amount of compensation, which will be offered to the patent owner by the applicant.

If the applicant’s request is accepted for consideration, the Ministry of Health of Ukraine sends it to (a) the IP office, asking it to provide information about the patented invention (utility model), and (b) to the authority that has the competence to provide information concerning the appropriateness of the amount of compensation suggested

by the applicant.⁵³ These two bodies are required to provide the requested information within ten days from the date they received the Ministry of Health’s request. Once the Ministry of Health receives the responses it then has ten days to prepare the draft decision of the CMU on the grant of a compulsory licence. It further sends the draft of the decision to the CMU.⁵⁴ The Procedure does not establish any terms by which the CMU must adopt the decision.⁵⁵ The decision of the CMU can be appealed to the court.⁵⁶

As could be seen, these further requirements, including the need to provide various justifications by the applicant mentioned above, can place a significant burden on the applicant. Moreover, the law does not provide any limitations on the waiting period of the applicant before it may be considered that the patent holder has rejected the applicant’s request to grant a licence. The patent holder may simply keep silence and ignore the request, and therefore, the applicant will not be able to provide any evidence that its request was rejected.⁵⁷ It is also difficult to calculate how much time this procedure may take, as it includes the time that needs to be spent on waiting for the reply from the state authorities, the time spent on preparing the draft decision by the Ministry of Health, as well as no specific time limits are set for issuing the decision by the CMU. There is also a possibility that the CMU’s decision may be suspended by the court as part of interim injunctions while the patent holder’s lawsuit challenging this decision is being considered by the court. The resolution of this dispute and its review by the higher judicial instances may take several years. All this may result in wasting a lot of time, which in the context of the war is clearly unacceptable. Finally, the ‘cherry on top’ of this procedure, is that the authority, which is supposed to assess the applicant’s suggestion on the compensation that should be payable to the patent holder, to the best knowledge of the author, has not been created yet. Therefore, these and other problematic elements of the compulsory licensing procedure in Ukraine, as well as more general challenges regarding compulsory licensing discussed above (including a product-by-product requirement and that compulsory licensing relates only to patents and cannot be applied to other types of IP rights), make this mechanism unsuitable for resolving the constantly aggravating health crisis in Ukraine.

III. Alternative mechanisms of facilitating access to medicines in Ukraine during the war: an IP waiver justified by Art. 73 TRIPS

1. A waiver of IP rights related to essential medicines and medical products

Considering the unsuitability of compulsory licensing to facilitate access to medicines during the war in Ukraine,

⁵⁰ Gurgula, ‘Compulsory licensing vs. the IP waiver’ (n 26) 2.

⁵¹ According to para 4 of the Procedure, this includes the information about the following: the international non-proprietary name of the medicinal product; the title of the invention (utility model); the number of the patent, information about its owner (owners), his (their) address or location; the name of the applicant, his location, the signature of the authorised person.

⁵² *ibid* para 4.

⁵³ *ibid* para 6.

⁵⁴ *ibid* para 8.

⁵⁵ *ibid* para 9.

⁵⁶ *ibid* para 16.

⁵⁷ It would be advisable for Ukraine to set a specific time limit, and define a period, which under art 31(b) TRIPS would be considered to be ‘within a reasonable period of time’. For example, art 11 of the Patent Act of Kazakhstan provides for a 90-day period.

other alternatives must be considered. This article argues that the most effective alternative is to waive the IP rights protecting medicines for the duration of the war (and potentially for a certain period after the war to overcome its grave consequences). Such a waiver would allow to effectively utilise all existing domestic manufacturing capacities to locally produce and seek possibilities to import generics and biosimilars of the essential medicines and medical products that are urgently needed in Ukraine.

Such a waiver has the potential to overcome the challenges of the compulsory licensing system in Ukraine discussed above.⁵⁸ These include the product-by-product requirement of compulsory licensing that restricts the effective and speedy application of this mechanism, as well as the need to spend time on identifying all patents that cover the products in question prior to issuing a compulsory licence.⁵⁹ With the adoption of the IP waiver, these obstacles would be removed. In addition, as will be discussed below, the issue of remuneration would not arise.⁶⁰ The waiver would also apply to supplementary protection certificates, as well as would relate to all other types of IP rights, including copyright, designs, trademarks, etc. Moreover, as was discussed, the existing procedure of compulsory licensing in Ukraine does not allow for an effective and speedy reaction to the urgency of the crisis, as it is cumbersome and time-consuming, putting significant pressure on the applicant. In addition, some of the requirements raise doubts about the possibility of using this procedure at all.

The adoption of the waiver would mean that certain IP rights would not be enforceable against third parties on the territory of Ukraine.⁶¹ Specifically, the adoption of the IP waiver would presuppose suspending the enforceability of IP rights, including Ukraine's obligations under free trade agreements, and declaring that the manufacture and import of IP-protected medical products and other activities that fall within the exclusive rights of the IP owner by third parties without their permission would not be considered an infringement.⁶² The suspension of enforceability would also mean that injunctions could not be granted against such third parties. In addition, such a suspension of IP rights would be temporary, e.g. for the duration of the war and potentially for a certain period of time after the war to deal with the consequences of the war.

a) Grounds for an IP waiver

The grounds for implementing an IP waiver in Ukraine in the circumstances of the ongoing war can be found in the TRIPS Agreement. Under the Agreement, a WTO member

may invoke 'Security Exceptions' under Art. 73.⁶³ In particular, Art. 73 TRIPS states that:

Nothing in this Agreement shall be construed:

...

(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;

...

(iii) taken in time of war or other emergency in international relations ...

Paragraph (b) of Art. 73 includes an introductory part that qualifies an action that a WTO member may not be prevented from taking 'which it considers necessary for the protection of its essential security interests'. This action may be taken notwithstanding that member's obligations under TRIPS. In other words, this provision ensures that WTO members have the right to invoke the protection of their essential security interests in order to justify a measure that is otherwise inconsistent with the TRIPS Agreement. Therefore, Art. 73 TRIPS essentially acts as an exception or defence for such measures.

As was explained by the panel in *Russia – Traffic in Transit*, which discussed an equivalent provision in Art. XXI(b)(iii) GATT:⁶⁴

the GATT 1994 and the WTO Agreements provide that, in specific circumstances, Members may depart from their GATT and WTO obligations in order to protect other non-trade interests. For example, the general exceptions under Art. XX of the GATT 1994 accord to Members a degree of autonomy to adopt measures that are otherwise incompatible with their WTO obligations, in order to achieve particular non-trade legitimate objectives, provided such measures are not used merely as an excuse to circumvent their GATT and WTO obligations. These concessions, like other exceptions and escape clauses built into the GATT 1994 and the WTO Agreements, permit Members a degree of flexibility. ...⁶⁵

The panel also found that 'a significant majority of occasions on which Art. XXI(b)(iii) was invoked concerned situations of armed conflict and acute international crisis, where heightened tensions could lead to armed conflict, rather than protectionism under the guise of a security issue'.⁶⁶ Importantly, the panel highlighted that the specific nature of this exception required no prior determination that the measures would be WTO-inconsistent if they had been taken in normal times, as well as there was no need to assess whether there was an alternative measure to achieve the protection of the legitimate interests

⁵⁸ Gurgula, 'Compulsory licensing vs. the IP waiver' (n 26) 5.

⁵⁹ *ibid.*

⁶⁰ *ibid.*

⁶¹ *ibid.*

⁶² See, eg, Carlos M Correa, Nirmalya Syam and Daniel Uribe, 'Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements' (2021) The South Centre Research Paper 135 <https://www.southcentre.int/wp-content/uploads/2021/09/RP135_Implementation-of-a-TRIPS-Waiver-for-Health-Technologies-and-Products-for-COVID-19_EN.pdf> accessed 11 April 2022.

⁶³ Frederick Abbott, 'The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic' (2021) The South Centre Research Paper 116 (in this paper Abbott discusses whether the COVID-19 pandemic may be considered an 'emergency in international relations' and how WTO Member States may invoke art 73 ('Security Exceptions') of the TRIPS Agreement as the legal basis for overriding IP rights otherwise required to be made available or enforced).

⁶⁴ *Russia – Measures Concerning Traffic in Transit*, Report of the Panel, WT/DS512/R, 5 April 2019 (hereinafter '*Russia – Traffic in Transit*'). The panel in this case provided an in-depth analysis of the grounds for invoking 'security exceptions' under art XXI(b)(iii) (art 73(b)(iii) TRIPS mirrors this provision) that will be discussed below.

⁶⁵ *Russia – Traffic in Transit* (n 64) para 7.79.

⁶⁶ *ibid* para 7.81.

covered by the exception which was not violative or less violative. In particular, the panel noted that:

This provision acknowledges that a war or other emergency in international relations involves a fundamental change of circumstances which radically alters the factual matrix in which the WTO-consistency of the measures at issue is to be evaluated. The Panel considers that an evaluation of whether measures are covered by Art. XXI(b)(iii), as measures ‘taken in time of war or other emergency in international relations’ (unlike measures covered by the exceptions under Art. XX) does not necessitate a prior determination that they would be WTO-inconsistent if they had been taken in normal times, i.e. if they were not taken in time of war or other emergency in international relations. This is because [...] there is no need to determine the extent of the deviation of the challenged measure from the prescribed norm in order to evaluate the necessity of the measure, i.e. that there is no reasonably available alternative measure to achieve the protection of the legitimate interests covered by the exception which is not violative, or is less violative, of the prescribed norm.⁶⁷

This means that notwithstanding the existence of an alternative lawful measure, for example, compulsory licensing (even if we assume that compulsory licensing in Ukrainian law is an effective mechanism), Ukraine would not need to employ it, if it considers necessary to utilise an IP waiver for the protection of its essential security interests.⁶⁸

b) Legal framework of Art. 73 TRIPS

The application of the security exceptions by a WTO member was first interpreted by the panel in *Russia – Traffic in Transit*, in which it provided an extensive analysis of the measures taken under Art. XXI GATT. This case involved a complaint by Ukraine against the Russian Federation regarding the transit restrictions and the transit bans applied by the Russian authorities to traffic in transit by road or rail from Ukraine, which was destined for Kazakhstan, the Kyrgyz Republic, Mongolia, Tajikistan, Turkmenistan and Uzbekistan.⁶⁹ In that case, Ukraine claimed that such actions were inconsistent with Arts. V and X of the GATT 1994 and with commitments in Russia’s Accession Protocol. In response, Russia invoked the provisions of Art. XXI(b)(iii) of the GATT 1994 and asserted that the measures were among those that Russia considered necessary for the protection of its essential security interests, which it took, ‘[i]n response to the emergency in international relations that occurred in 2014 that presented threats to the Russian Federation’s essential security interests’.⁷⁰

In the *Saudi Arabia-IPRs* dispute regarding the application of Art. 73 TRIPS, the panel acknowledged that the wording of Art. 73(b)(iii) of the TRIPS Agreement was identical to that of Art. XXI(b)(iii) of the GATT

1994,⁷¹ and thus, the *Russia – Traffic in Transit* panel’s interpretation of Art. XXI(b)(iii) gave rise to an analytical framework that could guide the assessment of whether a respondent properly invoked Art. XXI(b)(iii) of the GATT 1994 or, for the purposes of that dispute, Art. 73(b)(iii) of the TRIPS Agreement.⁷² The *Saudi Arabia-IPRs* panel also provided a succinct summary of the approach that the panel in *Russia – Traffic in Transit* followed when assessing the lawfulness of invoking ‘security exceptions’ by a WTO member. The *Saudi Arabia-IPRs* panel explained:

‘Article XXI(b)(iii) of the GATT 1994, which is identical to Art. 73(b)(iii) of the TRIPS Agreement, was recently addressed by the panel in *Russia – Traffic in Transit*. It held that a panel must determine for itself whether the invoking member’s actions were “taken in time of war or other emergency in international relations” in subparagraph (iii) of Art. XXI(b) of the GATT 1994. It further found that a panel’s review of whether the invoking member’s actions are ones “which it considers necessary for the protection of its essential security interests” under the chapeau of Art. XXI(b) of the GATT 1994 requires an assessment of whether the invoking member has articulated the “essential security interests” that it considers the measures at issue are necessary to protect, along with a further assessment of whether the measures are so remote from, or unrelated to, the “emergency in international relations” as to make it implausible that the invoking member implemented the measures for the protection of its “essential security interests” arising out of the emergency. According to the panel in *Russia – Traffic in Transit*, the obligation of a member to interpret and apply Art. XXI(b)(iii) of the GATT 1994 in “good faith” requires “that the measures at issue meet a minimum requirement of plausibility in relation to the proffered essential security interests, i.e. that they are not implausible as measures protective of these interests”.’⁷³

Based on the analytical framework developed by the panel in *Russia – Traffic in Transit*, the *Saudi Arabia-IPRs* panel then put forward the conditions that must be assessed when considering whether a WTO member properly invoked the Art. 73 TRIPS security exception. The panel must consider the following:⁷⁴

- a) whether the existence of a ‘war or other emergency in international relations’ has been established in the sense of subparagraph (iii) to Art. 73(b);
- b) whether the relevant actions were ‘taken in time of’ that war or other emergency in international relations;
- c) whether the invoking member has articulated its relevant ‘essential security interests’ sufficiently to enable an assessment of whether there is any link between

⁷¹ Saudi Arabia – ‘Measures Concerning the Protection of Intellectual Property Rights’, Report of The Panel, WT/DS567/R, 16 June 2020 (hereinafter ‘*Saudi Arabia-IPRs*’), para 7.241.

⁷² *ibid.*

⁷³ *ibid* para 7.230.

⁷⁴ *ibid* para 7.242.

⁶⁷ *ibid* para 7.108

⁶⁸ Abbott (n 63) 17.

⁶⁹ *Russia – Traffic in Transit* (n 64).

⁷⁰ *ibid* para 7.4.

those actions and the protection of its essential security interests; and

- d) whether the relevant actions are so remote from, or unrelated to, the ‘emergency in international relations’ as to make it implausible that the invoking member considers those actions to be necessary for the protection of its essential security interests arising out of the emergency.

This article argues that due to the ongoing unprovoked and unjustified war launched by Russia against Ukraine and the horrifying atrocities inflicted on its population, there is an urgent need to take actions to protect essential security interests, and specifically, to protect lives and health of people in Ukraine by accelerating the supply of essential medicines. This would be possible to accomplish by exploiting all existing domestic manufacturing capacities and utilise all possibilities to import essential medicines and medical products from abroad. For this, any barrier in the form of IP protection must be waived. While Ukraine has undertaken an obligation under TRIPS to protect IP rights, in certain special circumstances such an obligation can be waived in light of the need to protect other non-trade, essential security interests. Art. 73 TRIPS permits Ukraine to derogate from its obligations under TRIPS by waiving IP rights on medicines and medical products so that it could protect its essential security interests, i.e. to save millions of lives of those who are directly and indirectly affected by the Russian aggression. It is submitted that by implementing the IP waiver, Ukraine would meet all the conditions for invoking the ‘Security Exceptions’ under Art. 73 TRIPS as will be demonstrated below.

(i) Whether the existence of a ‘war or other emergency in international relations’ has been established in the sense of subpara. (iii) to Art. 73(b)

The first step in the analysis under *Russia – Traffic in Transit* is to examine whether the existence of a ‘war or other emergency in international relations’ has been established in the sense of subpara. (iii) of Art. XXI(b) (or for the purpose of this article in the sense of subpara. (iii) of Art. 73(b) TRIPS).⁷⁵ The panel explained that the existence of an emergency in international relations is an objective state of affairs, and, therefore, the determination of whether the action was ‘taken in time of war or other emergency in international relations’ under subpara. (iii) of Art. XXI(b) is that of an objective fact and should be determined objectively.⁷⁶ The *Russia – Traffic in Transit* panel further explained that the term ‘emergency in international relations’ refers in general ‘to a situation of armed conflict, or of latent armed conflict, or of heightened tension or crisis, or of general instability engulfing or surrounding a state’.⁷⁷ These situations ‘give rise to particular types of interests for the Member in question, i.e. defence or military interests, or maintenance of law and public order interests’.⁷⁸

⁷⁵ *ibid* para 7.244.

⁷⁶ *Russia – Traffic in Transit* (n 64) para 7.77.

⁷⁷ *Russia – Traffic in Transit* (n 64) paras 7.75-7.76; *Saudi Arabia-IPRs* (n 71) para 7.245.

⁷⁸ *Russia – Traffic in Transit* (n 64) paras 7.75-7.76; *Saudi Arabia-IPRs* (n 71) para 7.245.

On 24 February 2022, the Russian Federation launched a full-blown war against Ukraine. This aggression has received a widespread international condemnation. On 2 March 2022, at the United Nations General Assembly, 141 of the 193 countries voted in favour of the resolution,⁷⁹ which reaffirmed Ukrainian sovereignty, independence and territorial integrity and condemned the Russian aggression in Ukraine, including demanding the withdrawal of Russian forces from the Ukrainian territory.⁸⁰ Again, on 24 March 2022, the United Nations General Assembly, for the second time, adopted the resolution entitled ‘Humanitarian consequences of the aggression against Ukraine’, in which it overwhelmingly condemned the Russian invasion in Ukraine – 140 countries voted in favour and five voted against (i.e. Russia, Syria, North Korea, Eritrea and Belarus), while 38 countries, including China, abstained.⁸¹ The second resolution demanded the protection of civilians, medical personnel, aid workers, journalists, hospitals and other civilian infrastructure. It also demanded an end to the siege of cities, in particular Mariupol. The resolution echoes the 2 March General Assembly text by demanding that Russia stop fighting and withdraw its troops from Ukraine. Considering this, the existence of the war in Ukraine is objectively established, and thus, Ukraine would meet the condition under (a) when invoking the Art. 73 TRIPS security exception.

(ii) Whether the relevant actions were ‘taken in time of’ that war or other emergency in international relations

Under the second step of the *Russia – Traffic in Transit* analytical framework, the panel analysed the meaning of the phrase ‘taken in time of’ in subpara. (iii).⁸² The panel explained that this phrase described the connection between the ‘action’ indicated in the chapeau of paragraph (b) and the event of ‘war or other emergency in international relations’ in subpara. (iii).⁸³ The panel further explained that it understood this phrase to require that the action be taken *during* the war or other emergency in international relations and that the connection between these two elements constituted a ‘chronological concurrence [that] is also an objective fact, amenable to objective determination’.⁸⁴ The war in Ukraine is currently ongoing and, therefore, measures that would be taken to protect the lives and health of the Ukraine’s population would be taken during the war. Therefore, Ukraine would meet the condition (b) when invoking Art. 73 TRIPS.

⁷⁹ 35 abstentions and five voting against, including Russia, Belarus, Syria, Eritrea and North Korea.

⁸⁰ United Nations General Assembly Resolution ES-11/1, a resolution of the eleventh emergency special session of the United Nations General Assembly, adopted on 2 March 2022 (The text of the resolution included ‘demands that the Russian Federation immediately, completely, and unconditionally withdraw all of its military forces from the territory of Ukraine within its internationally recognized borders (para 6)’).

⁸¹ UN, ‘Ukraine: General Assembly passes resolution demanding aid access, by large majority’ (24 March 2022) <<https://news.un.org/en/story/2022/03/1114632>> accessed 11 April 2022.

⁸² *Russia – Traffic in Transit* (n 64) paras 7.70 and 7.77; *Saudi Arabia-IPRs* (n 71) para 7.247.

⁸³ *Russia – Traffic in Transit* (n 64) para 7.70; *Saudi Arabia-IPRs* (n 71) para 7.247.

⁸⁴ *Russia – Traffic in Transit* (n 64) para 7.70; *Saudi Arabia-IPRs* (n 71) para 7.247.

(iii) Whether the invoking member has articulated its relevant ‘essential security interests’ sufficiently to enable an assessment of whether there is any link between those actions and the protection of its essential security interests

The third step in this analytical framework requires to assess whether a WTO member has sufficiently articulated its ‘essential security interests’ in the sense of the chapeau of para. (b).⁸⁵ When considering the term ‘essential security interests’, the panel noted that this concept refers to those interests that relate to the ‘quintessential functions of the state, namely, *the protection of its territory and its population from external threats*, and the maintenance of law and public order internally’ (emphasis added).⁸⁶ Importantly, it stated that ‘[t]he specific interests that are considered directly relevant to the protection of a state from such external or internal threats will depend on the particular situation and perceptions of the state in question, and can be expected to vary with changing circumstances’.⁸⁷ Therefore, according to the panel, it should be left, in general, to every member to determine what it considers to be its essential security interests.⁸⁸ However, the panel noted that this did not mean that a member was free to elevate any concern to that of an ‘essential security interest’.⁸⁹ While a member has the discretion to classify a particular concern as ‘essential security interests’, this is limited by its obligation to interpret and apply Art. XXI(b)(iii) of the GATT 1994 in good faith.⁹⁰ Such an obligation of good faith requires that members not use the security exception as a means to circumvent their WTO obligations.⁹¹ The panel concluded that a member must ‘articulate the essential security interests said to arise from the emergency in international relations sufficiently enough to demonstrate their veracity’.⁹²

Therefore, under this condition, it is important to sufficiently articulate the ‘essential security interests’ that a WTO member considers the measures at issue are necessary to protect. The panel in *Russia – Traffic in Transit* explained that ‘what qualifies as a sufficient level of articulation will depend on the emergency in international relations at issue’.⁹³ For Ukraine, the emergency in international relations is the ‘hard core’ war.⁹⁴ In this regard, it is the protection of lives and health of people in Ukraine, which is the essential security interest that clearly ‘relat[es] to the quintessential functions of the state, namely, the protection of ... its population from external threats, and the maintenance of law and public order internally’.⁹⁵ Therefore, given the character of the ‘emergency’, i.e. the war, which has been recognised and condemned by the UN General Assembly, and which poses a threat to lives and health of millions of Ukrainians, the essential security

interests of Ukraine that need protection would be clearly articulated. Moreover, in this case there would be nothing in Ukraine’s expression of those interests to suggest that Ukraine would invoke Art. 73(b)(iii) merely as a means to circumvent its obligations under TRIPS.

(iv) Whether the relevant actions are so remote from, or unrelated to, the ‘emergency in international relations’ as to make it implausible that the invoking member considers those actions to be necessary for the protection of its essential security interests arising out of the emergency

The formulation of the specific essential security interests within the *Russia – Traffic in Transit* analytical framework ‘serves primarily to provide a benchmark against which to examine the “action” under the chapeau of Art. 73(b)’.⁹⁶ This means that ‘this analytical step enables an assessment by the Panel of whether either of the challenged measures found to be inconsistent with the TRIPS Agreement is plausibly connected to the protection of those essential security interests’.⁹⁷ The last step, therefore, aims at assessing the connection between the measures taken by the WTO member and the essential security interests. The *Russia – Traffic in Transit* panel considered that the ‘obligation of good faith’ must apply not only to the member’s articulation of ‘its essential security interests’ said to arise from the particular emergency in international relations, but also to the connection between the measures at issue and those interests.⁹⁸ This obligation, according to the panel is ‘crystallized in demanding that the measures at issue meet a minimum requirement of plausibility in relation to the proffered essential security interests, i.e. that they are not implausible as measures protective of these interests’.⁹⁹ In particular, a panel must assess ‘whether the measures are so remote from, or unrelated to, the [...] emergency that it is implausible that [the member] implemented the measures for the protection of its essential security interests arising out of the emergency’.¹⁰⁰ An important element of this condition is the ‘necessity’ of actions. In this regard, the *Russia – Traffic in Transit* panel noted that members have substantial discretion to decide what measures they ‘consider necessary’ to protect their essential security interests.¹⁰¹ Nevertheless, despite members having a wide discretion to decide on measures necessary to protect their essential security interests, such discretion must be ‘plausibly related’ to the emergency that the member aims to tackle.¹⁰²

In the circumstances of the ongoing war that has been launched by the Russian Federation against Ukraine, Ukraine would seek to protect the lives and health of people in Ukraine from the Russian aggression. One of the means through which Ukraine may seek to protect these essential security interests is by exploiting all domestic manufacturing capacity to produce locally and explore

⁸⁵ *Russia – Traffic in Transit* (n 64) para 7.131.

⁸⁶ *ibid* para 7.130.

⁸⁷ *ibid* para 7.131.

⁸⁸ *ibid*.

⁸⁹ *ibid* para 7.132.

⁹⁰ *ibid*.

⁹¹ *ibid* para 7.133.

⁹² *ibid* para 7.134.

⁹³ *ibid* para 7.135.

⁹⁴ *ibid* para 7.136.

⁹⁵ *ibid* para 7.130.

⁹⁶ *Saudi Arabia-IPRs* (n 71) para 7.281.

⁹⁷ *ibid*.

⁹⁸ *ibid* para 7.252.

⁹⁹ *Russia – Traffic in Transit* (n 64) para 7.138.

¹⁰⁰ *Russia – Traffic in Transit* (n 64) para 7.139

¹⁰¹ *ibid* paras 7.146-7.147.

¹⁰² *ibid* para 7.138.

any potential of importing essential medicines and medical products to boost their supply. An action that Ukraine would need to undertake to achieve this purpose is to waive all IP rights related to such medicines and medical products. The relevant question is, therefore, whether the IP waiver meets ‘a minimum requirement of plausibility in relation to the proffered essential security interests, i.e. that they are not implausible as measures protective of these interests’.¹⁰³ It must therefore be reviewed whether the IP waiver measure ‘is so remote from, or unrelated to, the [‘war’] as to make it implausible that [Ukraine] implemented this measure for the protection of its essential security interests [i.e. protection of lives and health of people in Ukraine] arising out of the emergency’.¹⁰⁴

This article argues that waiving IP rights on essential medicines and medical products is relevant to the war that the Russian Federation has launched against Ukraine, and it is plausible that Ukraine considers the IP waiver to be necessary for the protection of its essential security interests arising from this war. As was mentioned, at the time of writing, there is an ongoing war launched by Russia against Ukraine. The lives and health of millions of people are in grave danger; they are in a dire need of accessing essential medicines, the supply of which is severely restricted or blocked by the Russian occupation forces. Russians are destroying the local manufacturing infrastructure and block the supply of medical shipments by sea and land, including carrying out the blockade in the Black Sea. They also steal or destroy humanitarian supplies, including medicines. Furthermore, since the beginning of the war, the country has been transferred to the ‘war rails’, and thus, a large chunk of the financial resources of the state budget is directed towards supporting the Ukrainian army and defence of the country, and thus, Ukraine’s ability to procure a necessary amount of (IP-protected and expensive) essential medicines and medical products is extremely restricted. This results in thousands of people (both Ukrainian soldiers and civilians, including children) that have been injured by the Russian occupation forces, and millions of people with serious infectious and chronic conditions that need access to life-saving medicines, having limited or no access to essential medicines.

Therefore, it is critical to undertake urgent measures that would allow to boost the supply of medicines and medical products at a maximum possible scale, while spending a minimum of financial resources. Thus, the employment of domestic manufacturing capacities that are still intact and have not been destroyed by the enemy for local production of essential medicines, as well as seeking any opportunity to import such products from abroad is necessary. For this, it is important to remove all the barriers in the form of IP rights that protect essential medicines and medical products that may allow the IP owners to prevent the local manufacturers and importers to produce/import life-saving medicines and medical products without their consent.

Therefore, to answer the question posed earlier, the IP waiver would allow to facilitate the supply of essential

medicines in order to save millions of people in Ukraine. The circumstances are such that there is an emergency in Ukraine that affects its essential security interests, which is recognised by the United Nations General Assembly as involving a war. Under these circumstances, the IP waiver measure cannot be regarded as being so remote from, or unrelated to, the war, that it is implausible that Ukraine would implement this measure for the protection of its essential security interests arising out of that emergency. It should also be taken into account that it is for Ukraine to determine the ‘necessity’ of the measures for the protection of its essential security interests.¹⁰⁵ Therefore, the fourth element would be met in the context of invoking Art. 73 TRIPS to address the protection of public health in Ukraine during the war.

IV. A suggested wording of the IP waiver in Ukraine that is aimed at facilitating the supply of medicines during the war launched by Russia against Ukraine

To ensure that the IP waiver is in line with the requirements of TRIPS and WTO case law, it is crucial that the wording of the legal act that would enact the IP waiver is aligned with the wording of Art. 73 TRIPS, as well as with the conditions for invoking this provision as they have been interpreted by the WTO panels in *Russia-Transit* and *Saudi Arabia-IPRs*. Moreover, it must be designed in a way that would help to avoid abuses by third parties. The latter condition is important because, while this is a drastic measure aimed at protecting public interests during a war, it is also crucial to avoid unnecessary restrictions imposed by such a waiver on private interests of the IP owners.

Taking the above into account, the legal act on the IP waiver should clearly state that Ukraine is in a state of war and that these measures are implemented during the war. It further must clearly articulate that the aim of this law is to protect essential security interests in Ukraine during the war, in particular to protect lives and health of people in Ukraine (both soldiers and civilians). It must also refer to the grounds that justify the implementation of such a waiver, i.e. Art. 73 TRIPS, as well as national laws, including the Law of Ukraine ‘On the legal regime of martial law’¹⁰⁶ and the Decree of the President of Ukraine ‘On the imposition of martial law in Ukraine’.¹⁰⁷

The following matters should be clearly addressed:

- The act must explain that its aim is to waive IP rights in Ukraine, including patents, supplementary protection certificates, copyrights, industrial designs, trademarks, trade secrets, marketing authorisations and other IP rights relating to essential medicines and medical products, which can be used to protect the lives and health of people affected directly by the military actions of the Russian aggressor and indirectly because of the inability of the state to ensure the supply of a sufficient amount of essential medicines in Ukraine.

¹⁰³ *ibid.*

¹⁰⁴ *ibid* para 7.139.

¹⁰⁵ *ibid* para 7.146.

¹⁰⁶ Gazette of the Parliament of Ukraine (VVR), 2015, No 28, p 250).

¹⁰⁷ No 2102-IX, dated 24 February 2022.

- The act would also need to indicate that the IP waiver must remain in force until the end of the war on the territory of Ukraine, as well as after the end of the war for certain period determined by the parliament of Ukraine in order to overcome the consequences of the war.
- To centralise information on the required essential medicines and medical products and to ensure that the process is supervised by the state, the Ministry of Health would be required to prepare the list of essential medicines and medical products that would be covered by the IP waiver and agree on their supply with potential producers/suppliers.
- As the result of the IP waiver, medicines and medical products that have been indicated by the Ministry of Health as essential for the purpose declared in this law, may be produced in and imported to Ukraine without the permission of the owner of IP rights that protect such products.
- Such a production and import of essential medicines and medical products during the period of the IP waiver will not be considered an infringement of IP rights.
- Finally, since Art. 73 TRIPS does not require any compensation to the IP right holders¹⁰⁸ (as opposed to Art. 31 TRIPS) and considering the emergency aspect of the situation, it is suggested that the use of the IP rights during the IP waiver and in accordance with the terms of this law would not be compensated either by the producers/importers, or by the state.

V. Conclusions

When discussing the negotiating history of Art. XXI of the GATT 1947, the *Russia – Traffic in Transit* panel recalled that the GATT 1947 arose out of a proposal by the United States to establish an International Trade Organisation.¹⁰⁹ The United States proposed an exception, which was later included in the GATT 1947. The US delegation's interpretation of its proposal for the security exception was reflected in the discussions of the provision during the Geneva negotiating session on 24 July 1947.¹¹⁰ When the delegation was asked about the meaning of the term 'essential security interests' and 'emergency in international relations', the delegate for the United States replied:

[W]e thought it well to draft provisions which would take care of real essential security interests [...]. With regard to subparagraph (e) [now it is subparagraph (b)(iii)], the limitation, I think, is primarily in the time. First, "in time of war". I think no one would question the need of a Member, or

the right of a Member, to take action relating to its security interests in time of war and to determine for itself – which I think we cannot deny – what its security interests are.'

Russia invaded Ukraine on 24 February 2022 and has inflicted horrifying atrocities on Ukraine's population. This action has been overwhelmingly condemned by the international community as an act of aggression, including by the United Nations, the European Union, G7 and other countries. Due to the terrifying crimes that Russians have been committing in Ukraine, millions of Ukrainian lives are currently in grave danger and require an urgent access to essential medicines and medical products. Therefore, Ukraine must urgently implement measures that would allow it to protect its essential security interests by facilitating medical supply for Ukrainians. This is, however, not an easy task. The Russian occupation forces deliberately destroy the infrastructure, block the supply by sea and land, as well as steal or destroy the humanitarian support, including medicines. In addition, the state budget is under significant pressure as most of its financial resources are directed towards supporting the Ukrainian army and the defence of the country.

Under these circumstances, it is important to exploit all existing domestic manufacturing capacities for local production and utilise all possibilities to import essential medicines and medical products from abroad. As some of the essential medicines and medical products may be protected by various IP rights, this barrier must be removed. As the analysis in this article demonstrates, the mechanism of compulsory licensing is not suitable to deal with the urgency and scale of the problem with the medical supply. Therefore, more drastic measures must be implemented. This article argues that Ukraine must urgently waive all the IP rights that would allow the domestic manufacture and import of any generic versions or biosimilars of the essential medicines and medical products. While Ukraine has undertaken an obligation under TRIPS to protect IP rights, in certain special circumstances such an obligation can be waived in light of the need to protect other non-trade interests. Specifically, Art. 73 TRIPS permits Ukraine to derogate from its obligations under TRIPS by waiving IP rights on essential medicines and medical products so that it could protect its essential security interests. The analysis in this article shows that by implementing the IP waiver, Ukraine would meet all the conditions for invoking Art. 73 TRIPS 'Security Exceptions'. It is hoped that guidance in this article will assist the Ukrainian government in implementing the IP waiver, which will enable Ukraine to facilitate medical supply and, thus, will save millions of people in Ukraine that suffer from Russia's unjustified, horrific aggression.

¹⁰⁸ Abbott (n 63) 21 ('Compensation is not a legal requirement under Article 73 TRIPS').

¹⁰⁹ *Russia – Traffic in Transit* (n 64) para 7.84.

¹¹⁰ *ibid* para 7.92.