‘No-one is Safe Until Everyone is Safe’ – Patent Waiver, Compulsory Licensing and COVID-19

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Recent months have seen intensified global calls for an intellectual property waiver of COVID-19 related vaccines, treatments and related products. Where one side of the debate elevates Intellectual Property Rights as an obstacle to affordable and expeditious global access to vaccines and treatments, the other side of the debate points to the existing TRIPS flexibilities such as compulsory licensing, the necessity of Intellectual Property Rights for future innovation as well as other factors such as manufacturing capacity and know-how being of greater importance.

This dualistic approach risks ignoring the manifold law, economics, and policy nuances inherent in the intersection of intellectual property law and Right-to-Health, as well as innovation and health policy. A balanced approach guided by real world indicators regarding law and economics of pharmaceutical innovation, procedural feasibility of compulsory licensing and legal applicability of an IPR waiver is needed. Thus, the key to understanding the current debates lies in a holistic approach to ratio legis of intellectual property rights, innovation policy and health policy. The innovation inducing facets of monopoly rights, and interconnected monopoly profits, need to be balanced against public policy rationales such as Right-to-Health, but also against the ratio legis of IPRs, which focuses on maximizing societal welfare.

After the introduction framing the background regarding unequitable global access to COVID-19 vaccines and treatments paving the way to the current debates on patent waiver and compulsory licensing, the Article proceeds as follows. Section II briefly sketches the main contours of the debate on right-to-health and intellectual property rights from a law and policy perspective. Section III details the legal, historical and procedural background of international codification of patents and the compulsory licensing instrument within the TRIPS agreement, as well as some instances of compulsory licensing during COVID-19. Section IV recounts the patent waiver proposal at TRIPS Council and the arguments for and against the proposal. Section V concludes with some law and policy reflections on the balance between Right-to-Health, intellectual property rights and innovation policy.

I. Introduction

The pricing of patented medicines, starting with the enactment of the TRIPS agreement coinciding with the HIV/AIDS crisis in the 1990's, is once again front

and centre of the global debate following the COVID-19 pandemic. Global health budgets, already strained in recent decades due to rapid increase of health spending relative to overall GDP-growth,¹ must now also come to terms with a prolonged pan-

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1 World Health Organization, 'Global Spending on Health: A World in Transition' <https://www.who.int/health_financing/documents/health-expenditure-report-2019.pdf?ua=1> accessed 23 June 2021.

demic. Despite early calls for a coordinated global response to a global pandemic, affecting countries rich and poor alike, and despite historically unique cooperation between private and public entities to develop vaccines in record time, hitherto the global response is one of failure if approached via the Right-to-Health as a basic human right discourse. Recent reports indicate that although COVID-19 infection rates and related deaths are decreasing in many regions around the world, Africa displays a 44% increase in weekly infections and an alarming 20% increase in death rate.²

This failure can be contrasted to the innovation policy success story of the record-breaking development of COVID-19 vaccines. As of February 2021 at least seven different vaccines across four platforms (mRNA, recombinant DNA, viral vector and inactivated virus) had been rolled out in some countries, and as of June 2021 some 287 additional vaccine candidates were in development, of which more than 103 in clinical development and 184 in pre-clinical phase.³

Furthermore, the tension between Right-to-Health as a basic human right, and there among affordable access to essential, life-saving medicines on the one hand, and pharmaceutical innovation and patents on medicines on the other hand, becomes most urgent in the present situation of a global pandemic.

In the words of WHO Director General 'I need to be blunt: the world is on the brink of a catastrophic moral failure – and the price of this failure will be paid with lives and livelihoods in the world's poorest countries. Even as they speak the language of equitable access, some countries and companies continue to prioritize bilateral deals, going around COVAX, driving up prices and attempting to jump to the front of the queue. This is wrong.'⁴

The 'catastrophic moral failure' castigated by the WHO Director General refers to the vaccine hoarding and vaccine nationalism; the unmet needs of the COVAX-program set up to facilitate discovery and sharing of vaccines and treatments; and the deadlocked positions at WTO TRIPS Council on the matter of patent waiver and compulsory licensing of COVID-19 related vaccines, treatments, and other relevant products such as personal protective equipment. COVAX, co-led by the World Health Organization (WHO), Gavi, the Vaccine Alliance, and the Coalition for Epidemic Preparedness Innovations (CEPI), serves as the vaccines pillar of ACT-A (Access to COV-

ID-19 Tools), which is the main global system put in place to fight COVID-19 set up by WHO.⁵

Looking at mortality rates in the most affected countries, it becomes all but evident that the developing countries have paid the highest human toll, with Yemen, Peru, Afghanistan, Mexico, Bolivia, Sudan and Syria on top with mortality rate of above 3 percent (case fatality ratio).⁶ Looking at mortality rate as total death per 100 000 population, we find Peru, Brazil, Colombia and Argentina on the top of the list.⁷

The unequitable access to COVID-19 vaccines is another cause for alarm, where just four nations or regions with less than half the world's population have administered seventy percent of all COVID-19 vaccine doses, according to a report by Duke Global Health Institute.⁸

As detailed by the report 'while confirmed purchases of vaccines globally cover 8.6 billion doses, the world's high-income countries, with a population of 1.2 billion (16% of global population), account for 4.6 billion doses (53% of all purchased doses), while low-income countries hold just 770 million doses. Finally, even if COVAX, the global COVID-19 vaccine mechanism, were to be fully funded this year, it would still vaccinate only 20-25% of the population of the world's 92 poorest countries. At the current rate, these countries may not reach 60% coverage until 2023 or later.'⁹

- 2 CNBC, 'HEALTH AND SCIENCE Africa sees 44% spike in new Covid infections, 20% increase in deaths' <<https://www.cnbc.com/2021/06/16/africa-sees-44percent-spike-in-new-covid-infections-20percent-increase-in-deaths-.html>> accessed 27 June 2021.
- 3 World Health Organization, 'COVID-19 vaccine tracker and landscape' <<https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>> accessed 23 June 2021.
- 4 WHO, 'Director-General's opening remarks at 148th session of the Executive Board, 18 January 2021' <<https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-148th-session-of-the-executive-board>> accessed 20 June 2021.
- 5 WHO, ACT-A, <<https://www.who.int/initiatives/act-accelerator>> accessed 23 June 2021.
- 6 John Hopkins University Coronavirus Resource Center, Mortality Analysis, <<https://coronavirus.jhu.edu/data/mortality>> accessed 23 June 2021.
- 7 Ibid.
- 8 Mark McClellan et al., 'Reducing Global COVID Vaccine Shortages: New Research and Recommendations for US Leadership' (Duke Global Health Institute, April 15, 2021), <<https://healthpolicy.duke.edu/publications/reducing-global-covid-vaccine-shortages-new-research-and-recommendations-us-leadership>> accessed 20 June 2020.
- 9 Ibid.

Add to this a lesser-known fact regarding the pricing of vaccines, with some reports¹⁰ pointing to developing countries in fact paying a higher price per vaccine dose than developed countries, and the ‘moral catastrophe’ is all but self-evident, seen against the background of promises made regarding global solidarity and coordinated efforts to combat a truly global pandemic. The prices paid by European Union was accidentally revealed by a now-deleted tweet by a Belgian Minister, whereafter health officials in countries such as South Africa and Uganda could confirm that they are indeed paying more per vaccine dose than European counterparts.

The prices paid by the European Union detailed by the now-deleted tweet ranged from €1.78 for AstraZeneca shot to €12.00 for Pfizer / BioNTech and \$18.00 for Moderna shots, respectively. European Commission declined to comment on the matter pricing, citing confidentially clauses with the vaccine makers.¹¹ It should be noted that these prices are ‘pandemic prices’, with Pfizer already indicating the prices will be increased post pandemic.¹² Indeed, Pfizer had indicated a price target of \$150 ‘post pandemic’, and already hiked the price per dose charged to European Union by 60%.¹³ Seen in the context of a manifest rise in antitrust cases against excessive pricing in the pharmaceutical sector in the European Union,¹⁴ there is risk of much legal turmoil ahead.

The calls for waiving of IP rights, beyond addressing the immediate needs created by the pandemic, are grounded in the public funding of the vaccine’s development, partial protection of vaccine develop-

ers for legal risks (e.g., product liability) and the legal basis in TRIPS agreement regarding a balanced interaction between protection of intellectual property rights and protection of public health. Public funding for COVID-19 vaccines developments came mainly from national governments such as US, Germany and China, as well as the Coalition for Epidemic Preparedness Innovations (CEPI). Of the total investment in vaccine development (from publicly available data) amounting to \$ 6 billion, more than 98% of the funding came from public coffers.¹⁵ The private investments in R&D of COVID-19 vaccines are not fully disclosed, but captured where available in the above. Janssen, Moderna and BioNTech were the three top recipients of the funding noted in the data.

This can be contrasted to the profits private companies are to make from the vaccines developed by substantial public funding, where e.g. Pfizer and Moderna are set to make a combined \$45 billion of sales in 2021 alone.¹⁶ According to a report by Morgan Stanley, Pfizer is projected to earn \$9.3 billion more in combined Covid-19 vaccine revenue in 2022 and 2023. Moderna saw its shares skyrocket by 700% in one year, and BioNTech similarly saw a spike of 300% increase in share value.¹⁷ Moderna nevertheless had already in October 2020 declared that it would not enforce its patent rights on its vaccines during the pandemic, although with some caveats. AstraZeneca had also early on announced its intention to make its vaccine available at marginal cost during the entirety of the pandemic¹⁸ but internal documents showed preliminary intention to declare

10 Common Dreams, ‘Deeply Alarming’: AstraZeneca Charging South Africa More Than Double What Europeans Pay for Covid-19 Vaccine’, <https://www.common-dreams.org/news/2021/01/22/deeply-alarming-astrazeneca-charging-south-africa-more-double-what-europeans-pay>, accessed 2021-06-23.

11 Channel News Asia, ‘European Commission embarrassed by COVID-19 vaccine price leak’, <https://www.channelnewsasia.com/news/world/covid-19-vaccine-price-leak-european-commission-13802104>, accessed 2021-06-23.

12 Fierce Pharma, ‘Pfizer eyes higher prices for COVID-19 vaccine after the pandemic wanes’, <https://www.fiercepharma.com/pharma/pfizer-eyes-higher-covid-19-vaccine-prices-after-pandemic-exec-analyst>, accessed 2021-06-23.

13 Poppy Wood, ‘Pfizer hikes cost of Covid vaccine for EU by 60 per cent’, City AM, <https://www.cityam.com/pfizer-hikes-cost-of-covid-vaccine-for-eu-by-60-per-cent/> accessed 23 June 2021.

14 Behrang Kianzad and Timo Minssen, ‘How Much Is Too Much? Defining the Metes and Bounds of Excessive Pricing in the Phar-

maceutical Sector’ (2018) 2 European Pharmaceutical Law Review 3, 133–48.

15 Global Health Center, Knowledge Portal for COVID-19 vaccines, <https://www.knowledgeportal.org/covid19-r-d-funding> accessed 22 June 2021.

16 Reuters, ‘COVID-19 vaccine maker shares sink as governments mull patent waiver’, <https://www.reuters.com/business/healthcare-pharmaceuticals/pharma-shares-reel-after-biden-backs-covid-19-vaccine-ip-waiver-2021-05-06/> accessed 22 June 2021.

17 CNN Business, ‘Pfizer and Moderna could score \$32 billion in Covid-19 vaccine sales -- in 2021 alone’, <https://edition.cnn.com/2020/12/11/business/pfizer-vaccine-covid-moderna-revenue/index.html> accessed 23 June 2021.

18 The Hill, ‘AstraZeneca’s no-profit pledge for vaccine has expiration date: report’ <https://thehill.com/policy/healthcare/520202-astrazenecas-no-profit-pledge-for-vaccine-has-expiration-date-report> accessed 23 June 2021.

the pandemic ‘over’ by July 2021.¹⁹ To delve more deeply in the patent pledges made is outside of the scope of the paper, but a matter which deserves closer scrutiny.

The above background re-connects with the ‘moral’ element of whether and at what levels profitability should be considered ‘efficient’ and ‘incentive inducing’ for vaccine innovation propelled by immense public funding during a pandemic affecting all branches of society. The ratio legis of intellectual property rights, including patents on life-saving, essential drugs, is to secure necessary public goods through sustainable innovation. The pricing of vaccines is not only a matter for developing countries, but an acute future challenge also for rich countries, if the pricing would follow the same trend as other influenza vaccines. As noted by Ramachandran et alia. ‘Pricing trends for influenza vaccines in the US since the 2000-01 flu season portend a potentially perilous future for ensuring fair pricing of covid-19 vaccines.’²⁰

Israel and Russia also issued compulsory licensing during COVID-19, Israel issued a compulsory license on lopinavir/ritonavir (Kaletra) by Abbvie, with the company declaring that ‘(i) it would not enforce its patent exclusivity rights worldwide for the said drug (adult and pediatric), and (ii) with respect to the Medicines Patent Pool licenses, it waived the limitations imposed on generic manufacturers with respect to providing supplies of the same drug ‘[a]nywhere in the world for any purpose, effective immediately [...]’ AbbVie’s declaration had been noted to be an unusual industry response to the grant of a

compulsory license.’²¹ Also Russia issued a compulsory license on Remdesivir by Gilead. This resulted in criticism²² and a lawsuit²³ amid calls for intensifying compulsory licensing efforts.²⁴ The lawsuit against the Russian compulsory license demonstrates the procedural and temporal challenges surrounding compulsory licensing as an effective tool to combat an unfolding pandemic.

These challenges are also highlighted in a review of literature, evidencing that compulsory licensing as a tool to access life-saving medicines is fraught with many legal and political challenges, where the main element of a successful compulsory licensing is conditioned towards local manufacturing capacity, import possibilities, and political pressure and retaliation.²⁵ To this we might add the importance of parallel imports.²⁶

Previous experience with global pandemics such as HIV / AIDS crisis makes for a grim future prospect during this current pandemic, as noted ‘In 1996, a treatment for HIV/AIDS was developed and priced at £6500 per person. Despite the determination of HIV/AIDS campaigners, it took eight years—and many millions of unnecessary deaths—before the treatment was made available at prices that were affordable for people in countries such as South Africa and India.’²⁷

One example illustrating the complex role of IPRs in relation to access to COVID-19 related treatments is the case of Remdesivir in Bangladesh and US, respectively. As remdesivir was hailed as a possible treatment against COVID-19, US opted to hoard the entire global supply of remdesivir in June 2020,²⁸ un-

19 Financial Times, ‘AstraZeneca vaccine document shows limit of no-profit pledge’ <<https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686>> accessed 23 June 2021.

20 Reshma Ramachandran et al, ‘Future of Covid-19 Vaccine Pricing: Lessons from Influenza,’ (2021) BMJ, n1467.

21 Danielle Navarro and Marcela Vieira, ‘Research Synthesis Compulsory Licensing’ (Global Health Center - KNOWLEDGE PORTAL on innovation and access to medicines, February 2021) <<https://www.knowledgeportal.org/compulsory-licensing>> accessed 23 June 2021.

22 Ephraim Heiliczer, ‘The Worldwide Stakes of Israeli Compulsory Licenses for Anti-Coronavirus Drugs’ March 24 2020, PearlCohen, <<https://www.pearlcohen.com/the-worldwide-stakes-of-israeli-compulsory-licenses-for-anti-coronavirus-drugs/>> accessed 23 June 2021.

23 Ed Silverman, ‘Gilead sues Russia over a compulsory license issued to a company making remdesivir’, STAT News, May 4 2021, <<https://www.statnews.com/pharmalot/2021/05/04/gilead-sues-russia-over-a-compulsory-license-issued-to-a-company-making-remdesivir/>> accessed 23 June 2021.

24 Hillary Wong, ‘The case for compulsory licensing during COVID-19’ (2020) Journal of Global Health.

25 Shyama V Ramani and Eduardo Urias, ‘Access to Critical Medicines: When Are Compulsory Licenses Effective in Price Negotiations?’ (2016) Social Science & Medicine 135, 75–83; see also Eduardo Urias and Shyama V. Ramani, ‘Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence’ (2020) 3 Journal of International Business Policy 4, 367–84.

26 Lorelei Garagancea, ‘Access to Medicines: The Interplay between Parallel Imports, Compulsory Licensing, and Voluntary Licensing’ (2021) 5 European Pharmaceutical Law Review 1, 37–56.

27 Nabil Ahmed, ‘A call for a people’s vaccine’, BMJ Opinion, July 16, 2020 <<https://blogs.bmj.com/bmj/2020/07/16/a-call-for-a-peoples-vaccine/>> accessed 27 June 2021.

28 The Guardian, ‘US secures world stock of key Covid-19 drug remdesivir’ <<https://www.theguardian.com/us-news/2020/jun/30/us-buys-up-world-stock-of-key-covid-19-drug>> accessed 27 June 2021.

der patent by Gilead Sciences, drawing much global criticism.²⁹ Despite the unilateral, protectionist measure to hoard the entire global supply of a possibly life-saving drug in the midst of a global pandemic, at a price level which also drew some criticism,³⁰ US was still unable to secure its needed supply of the drug.

There were simply not enough doses to be sold, despite the 'willingness-to-pay', leading doctors to have to make tough choices and ration the drug among the patients in need.³¹ At the same time, Bangladesh, being a Least Developed Country (LDC) could avail itself of the TRIPS exception, and thus approve a generic version of Remdesivir. Bangladesh begun producing the drug in such quantities that it was able to even export surplus doses to the rest of the world, including India.³² This was in 2020, where a year later, US Customs have seized more than 100 shipments of counterfeit or generic versions of Remdesivir coming from India and Bangladesh on route to Mexico.³³

This saga illustrates both the possibilities and challenges of setting aside IPR rights related to medicines, as speedy and affordable access might develop to trade diversion, counterfeit goods with health security risks and manifest risk to sustainable innovation and investments. A further element necessary to consider in a law and economics perspective is the effectiveness of the treatment has yet to be fully substantiated in order to enable an in-depth cost-effectiveness analysis, as noted by ICER regarding pricing of Remdesivir.³⁴

As noted by one study, there was a wide discrepancy between the manufacturing cost of Remdesivir (calculated at \$0.93/day)³⁵ and the actual global price (\$390)³⁶ as well as the price charged to US (\$520). Although this does not capture the costs borne by Gilead regarding clinical trials and other regulatory measures related to Remdesivir as COVID-19 treatment, it indicates the need for transparency regarding costs and benefits.

The phrase coined by World Health Organization, No-one is safe until everyone is safe, is indeed matched by reports from institutions such as International Monetary Fund (IMF), noting the peril to global economic recovery if the developing and least developed countries are left behind.³⁷ This economic inter-connectedness, beyond the human rights approach underpinning the Right-to-Health discourse, has taken the form of calls for People's Vaccine and Vaccine Justice.³⁸

The next section depicts the delicate interaction between right-to-health as a basic human right, and intellectual property rights, such as patents on life-saving medicines.

II. Right-to-Health versus Intellectual Property Rights

Costly and risky pharmaceutical innovation entails a balance to be struck between financing and reimbursement of innovative, life-saving medicines on the one hand, and the need for equitable access and

29 Global News, 'Experts slam U.S. for hoarding world's supply of remdesivir — only licensed COVID-19 drug' <<https://globalnews.ca/news/7128987/us-criticized-hoarding-remdesivir/>> accessed 27 June 2021.

30 The Wired, 'The US Is Paying Way Too Much for Remdesivir' <<https://www.wired.com/story/the-us-is-paying-way-too-much-for-remdesivir/>> accessed 27 June 2021; Fierce Pharma, 'Marketing Gilead's long-awaited remdesivir price is \$3,120, in line with watchdog estimates' <<https://www.fiercepharma.com/marketing/gilead-prices-covid-19-drug-remdesivir-line-cost-analysis>> accessed 27 June 2021; Joshua T. Cohen Peter J. Neumann Daniel A. Ollendorf, 'Valuing And Pricing Remdesivir: Should Drug Makers Get Paid For Helping Us Get Back To Work?', Health Affairs May 20 2020 <<https://www.healthaffairs.org/doi/10.1377/hblog20200518.966027/full/>> accessed 27 June 2021.

31 CNN, 'Covid-19 drug rationed in the US is plentiful in developing countries' <<https://edition.cnn.com/2020/09/09/health/covid-remdesivir-us-vs-other-countries/index.html>> accessed 27 June 2021.

32 The Hindu, 'Coronavirus - Bangladesh gifts India 10,000 Remdesivir vials' <<https://www.thehindu.com/news/national/coronavirus>

-bangladesh-gifts-india-10000-remdesivir-vials/article34499574.ece> accessed 27 June 2021.

33 Dhaka Tribune, 'US seizes unauthorized Covid-19 drugs shipped from Bangladesh, India' <<https://www.dhakatribune.com/world/2021/06/24/us-seizes-unauthorized-covid-19-drugs-shipped-from-bangladesh-india>> accessed 27 June 2021.

34 ICER, 'ICER Comments on Gilead's Pricing for Remdesivir' <<https://icer.org/news-insights/commentaries/icer-comments-on-gileads-pricing-for-remdesivir/>> accessed 27 June 2021.

35 Andrew Hill, Junzheng Wang, Jacob Levi, Katie Heath, Joseph Fortunak, 'Minimum costs to manufacture new treatments for COVID-19' (2020) 6 Journal of Virus Eradication 2, 61-69.

36 Gilead, 'An Open Letter from Daniel O'Day, Chairman & CEO, Gilead Sciences' <<https://stories.gilead.com/articles/an-open-letter-from-daniel-oday-june-29>> accessed 27 June 2021.

37 IMF Blog, 'Without help low income developing countries risk a lost decade' <<https://blogs.imf.org/2020/08/27/covid-19-without-help-low-income-developing-countries-risk-a-lost-decade/>> accessed 27 June 2021.

38 Sophie Harman et al, 'Global Vaccine Equity Demands Reparative Justice — Not Charity' (2020) 6 BMJ Global Health 6.

affordability, on the other hand, in the delicate intersection between protection of investments, and protection of health. This section begins with detailing the Right-to-Health framework, before moving on to the global codification of intellectual property rights.

1. Right-to-Health as a Legal Norm

Right-to-Health as a basic human right is re-affirmed in a range of international conventions, where access to affordable, life-saving medicines has been construed as an integral part of universal human rights.

Universal human rights have mainly been defined and codified through international agreements, which vary heavily in their scope and enforceability. This process of codification can be said to have begun with the Cyrus Cylinder in 539 BC, via the Magna Carta (1215), the Petition of Right (1628), the US Constitution (1787), the French Declaration of the Rights of Man and of the Citizen (1789), and the US Bill of Rights (1791), culminating in the Universal Declaration of Human Rights (henceforth UDHR)³⁹ in 1948 and the subsequent codification of different aspects of international human rights law in various treaties and conventions ever since.⁴⁰

Right to health as part of human rights is referred to in UDHR Article 25, stating: 'Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services'.⁴¹

The constitution of the WHO defined the concept of right to health further, noting: 'The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being'.⁴²

Right to Health as a basic human right has been further acknowledged in the International Covenant on Economic, Social and Cultural Rights (henceforth ICESCR)⁴³ Article 12.1, noting: 'The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.⁴⁴

A further clarification of the normative interpretation of Right to Health was offered by the Committee on Economic, Social and Cultural Rights in their General Comment No. 14⁴⁵ regarding the enjoyment of the highest attainable standard of physical and mental health as a basic human right. Stating 'Obligations to protect include, inter alia, the duties of

States to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties; to ensure that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services'.⁴⁶

Although many of the rights entailed in ICESCR are subject to progressive realization, the issue of securing access to essential medicines has been described as casting 'immediate obligations on States, including the provision of essential medicines to all persons in a non-discriminatory manner', by the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover.⁴⁷ Further noting the role of the pharmaceutical companies in providing access to health, he stresses in his report '...the need to shift the dominant market-oriented paradigm on access to medicines towards a right-to-health paradigm'.⁴⁸

In relation to the TRIPS-agreement⁴⁹ (the most important legislation on Intellectual Property Rights, addressed more in depth in next section), the Doha Ministerial Declaration⁵⁰ sought to implement Right-

39 Universal Declaration of Human Rights, G.A. res. 217A (III), U.N. Doc A/810 at 71 (1948)

40 A Brief History of Human Rights <<http://www.humanrights.com/what-are-human-rights/brief-history/cyrus-cylinder.html>> accessed 23 June 2021.

41 Universal Declaration of Human Rights, G.A. res. 217A (III), U.N. Doc A/810 at 71 (1948), art 25.

42 Constitution of the World Health Organization, entry into force 7th April 1948, 14 UNTS 185, Preamble.

43 International Covenant on Economic, Social and Cultural Rights, GA res. 2200A (XXI), 21 UN GAOR Supp. (No. 16) at 49, UN Doc. A/6316 (1966); 993 UNTS 3; 6 ILM 368 (1967).

44 *ibid*, Art 12.1.

45 CESCR, 'General Comment No.14: The Right to the Highest Attainable Standard of Health' (11 August 2000) 22nd Session E/C. 12/2000/4

46 *ibid*, para 35.

47 Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines, A/HRC/23/42, p. 3; referring regarding the legal obligations of the States to the General Comment No.14.

48 *ibid*, 5.

49 Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization <https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm> accessed 23 June 2021.

50 Doha Ministerial Declaration, WT/MIN(01)/DEC/1, 20 November 2001, <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm> accessed 23 June 2021.

to-Health considerations in regard to Intellectual Property protection regime entailed in the TRIPS. This laid the groundwork for what came to be known as Paragraph 6 system and later amendment of TRIPS Agreement by way of Article 31bis.⁵¹ The aim was to ensure affordable access to patented pharmaceutical products for the least developed country members. A ratio legis in regard to public health which is also represented throughout the TRIPS agreement and indeed a codification of collective preferences in regard to what weight protection of health and access to affordable medicines as core part of Right to Health entails.

Looking to European Union, as aforementioned there is a sound legal basis regarding the interaction of public health and competition law, which can also be read as a matter of codified collective preferences to be taken account of in a legal-economic assessment. As stipulated by the Article 168(1) TFEU "A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."⁵²

Similarly, Art 35 Charter of Fundamental Rights of the European Union establishes that "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall

be ensured in the definition and implementation of all Union policies and activities."⁵³

2. Intellectual Property Rights as a Legal Norm

Intellectual Property Rights can be described as 'non-physical property that is the product of the thought',⁵⁴ i.e., societies granting property rights to knowledge, knowhow, invention and creativity. Diverse and shifting in their scope as they might be, they share the common characteristics of attributing an exclusive right of property and ownership to the original thought and intellectual creation of their creator.⁵⁵

These legal rights, granted to the creators, enable the exclusive utilization of that specific intellectual creation for a limited period, and at the same time 'they give the creator the right to prevent others from making unauthorized use of their property for a limited period.'⁵⁶

The argument for granting property rights to these inventions of the mind is twofold, firstly they can easily be reproduced and copied, and secondly this protection covers a certain amount of time and space, in order for the creator and right holder to recoup his investment in the creation.⁵⁷

The public policy rationale for granting these exclusive rights to private actors, although limiting the dissemination and spread of knowledge and knowhow during the patent term, is the proposed public gains from these creator's risk-taking and investment in R&D, and the dissemination of knowledge by way of mandatory disclosure during the patent application process. These exclusive rights enable the right-holder to charge a price based on the ability to exclude competition, and recoup investments in R&D. The potential disadvantage invoked on consumers due to higher monopoly prices are thus balanced against the long-term benefits and value of costly inventions, which would not be forthcoming if sufficient protection at least during a limited term was guaranteed.

However, a balance needs to be struck, since if too much protection is granted, consumers may not benefit, even in the long run, for example if the length of the patent term is set too long, or the scope of protection is too broad.⁵⁸ What also must be taken into considerations are the transactions costs, i.e., the costs incurred on for instance developing countries

51 World Trade Organization, General Council, WT/L/641 8 December 2005, 'Amendment of the TRIPS Agreement Decision of 6 December 2005' <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> accessed 23 June 2021.

52 Consolidated version of the Treaty on the Functioning of the European Union OJ C 326, 26.10.2012, 47–390, Art 168(1).

53 Charter of Fundamental Rights of the European Union, Art 35.

54 Stanford Encyclopaedia of Philosophy, <<http://plato.stanford.edu/entries/intellectual-property/>> accessed 23 June 2021.

55 Chandra Nath Saha and Sanjib Bhattacharya, *Journal of Advanced Pharmaceutical Technology & Research* (2021) 88.

56 Final Report of the Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development (2002) 12.

57 Laurence. R. Helfer and Graeme W. Austin, 'Human Rights and Intellectual Property – Mapping the Global Interface' (2011) 20.

58 Hanns Ulrich, 'Intellectual Property: Exclusive Rights for a Purpose – the Case of Technology Protection by Patents and Copyright' (2012) Contribution to Klafkowska- Wasniowska et al (Eds.), *Problemy Polskiego i Europejskiego Prawa Prywatnego, Księga Pamiątkowa Profesora Mariana Kepińskiego* (Contributions in Honour of Marian Kepiński), Warsaw (Wolters Kluwer Polska, 2012) 425 – 459; Jens Schovsbo, 'Fire and Water Make Steam: Redefining the Role of Competition Law in TRIPS,' (2009) SSRN Electronic Journal.

lacking the legal and infrastructure to uphold the IP-laws.

In late 19th century the first international codifications regarding IP-law saw the light, beginning with the Paris Convention for the Protection of Industrial Property⁵⁹ in 1883, which codified international norms on patent and trademark rights.

The focus was on national treatment of patent rights, noting in Article 4A 'Any person who has duly filed an application for a patent, or for the registration of a utility model, or of an industrial design, or of a trademark, in one of the countries of the Union, or his successor in title, shall enjoy, for the purpose of filing in the other countries, a right of priority during the periods hereinafter fixed'.⁶⁰

The subsequent Berne Convention for the Protection of Literary and Artistic Works⁶¹ in 1886 codified works of art, but also thereby comparable work of the scientific domain, as they would be expressed in books, pamphlets, cinematographic works, drawings, architecture and so on.⁶²

Both conventions were more limited in their scope of enforceability and protection of the subject matter of patents, for example many countries offered limited patent protection for pharmaceutical products and/or had compulsory licensing schemes.

The international framework of IP-law was further enhanced and promoted through the creation of the United International Bureau for the Protection of Intellectual Property (commonly known as BIPRI) in 1893, resulting from the combination of the secretariat of Paris and Berne Conventions.⁶³

In 1970 the Convention establishing the World Intellectual Property Organization entered into force, replacing the BIPRI and creating an international body for IP-law.⁶⁴

The convention defined Intellectual Property as including the rights to 'literary, artistic and scientific works, performances of performing artists, phonograms, and broadcasts, inventions in all fields of human endeavour, scientific discoveries, industrial designs, trademarks, service marks, and commercial names and designations, protection against unfair competition, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields'.⁶⁵ The objective of the organization was defined as to 'promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization'.⁶⁶

WIPO became a specialized agency of the United Nations in 1974, and all members of the United Nations are entitled, but not obliged to, become members of the WIPO. Currently, WIPO has 188 members.⁶⁷ In 2007 WIPO adopted a Development Agenda entailing 45 recommendations, in order to, among other points, 'Promote measures that will help countries deal with intellectual property-related anti-competitive practices, by providing technical cooperation to developing countries, especially LDCs, at their request, in order to better understand the interface between IPRs and competition policies'.

Notwithstanding the functional mandate of WIPO, developed countries and multinational companies desired to tackle the issue of lack of enforceability of global intellectual property rights and counterfeit goods, leading these countries and multinational companies to push for a new world order in the subject matter of intellectual properties. Resulting from the standstill in the WIPO negotiations in early 1980's, where developing countries demanded preferential treatment in the field of IP-law, the issue was included in the Uruguay Round on General Agreement on Tariffs and Trade (GATT).⁶⁸

The result of the Uruguay Round was the establishment of the TRIPS-agreement and WTO in 1994, seen as a huge leap forward regarding protection and enforcement of intellectual property among the 164 members of the WTO as of 2021.⁶⁹

The TRIPS-agreement, referring to both Paris and Berne conventions and the rights entailed therein (in Article 1.3) requires the members of the WTO to pro-

59 Paris Convention for the Protection of Industrial Property, 1883, UST 1583, 828 UNTS 305

60 *ibid*

61 Berne Convention for the Protection of Literary and Artistic Works, 1886, 1161 U.N.T.S 31.

62 *ibid*, Art 2.1.

63 WIPO – A brief history <<http://www.wipo.int/about-wipo/en/history.html>> accessed 23 June 2021.

64 Convention Establishing the World Intellectual Property Organization (WIPO) <<https://www.wipo.int/treaties/en/convention/>> accessed 23 June 2021.

65 *ibid*, Art 2 (viii).

66 *ibid*, Art 3 (i).

67 World Intellectual Property Organization, <<http://www.wipo.int/members/en/>> accessed 23 June 2021.

68 World Trade Organization, <https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm> accessed 23 June 2021.

69 World Trade Organization, Members and Observers, <https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm> accessed 23 June 2021.

vide procedures and remedies under their domestic law to ensure that intellectual property rights can be effectively enforced, by foreign right-holders, as well as their own nationals.⁷⁰ This was a bright contrast to the former Paris and Berne conventions, where the developing countries could opt out from being party to the treaties, and thus not having any obligations regarding protection of IPRs. TRIPS brought about a global, harmonized and highly enforceable IPR regime, since membership in World Trade Organization also were combined with the TRIPS Agreement in the Annex.

One of the key features of this new world order of IP-law is the enforceability of TRIPS-provisions, where a Dispute Settlement Body (DSB) was set up at WTO to deal with claims from different right-holders under Article 67. The decision by the DSB is binding for member states and enforceable through withdrawal of trade concessions, effectively creating a strong global intellectual property regime. Also, the Council for Trade-Related Aspects of Intellectual Property Rights has the authority to review the compliance of the member states regarding the required conformity with the obligations in the TRIPS agreement.⁷¹

Least Developed Countries, many of whom did not protect intellectual property rights (Even developing countries such as India only in 2005 begun to protect patents on medicines)⁷² were granted a transition period to adopt legislation and erect suitable bodies for enforcement. The deadline was initially set to January 1st 2006, nevertheless the deadline has since subsequently been extended to 2016 and further to 2033 regarding Least Developed Countries (LDCs). In order to take advantage of the transition period, a 'mailbox' system was created, for patents filed from

January 1st 1995 to have priority once the new patent system would be in place. This was due to the need of the developing countries as well as the Least Developed Countries (LDCs), which risked being dramatically affected by the enactment of IP-laws that for instance would put an effective end to generic medicines and parallel import of patented pharmaceutical products.

Worth mentioning in this regard are the unilateral so-called TRIPS-plus treaties, negotiated by United States and European Union towards developing countries. These treaties are characterized by containing intellectual property protection standards going beyond the provisions in the TRIPS, obliging developing countries and LDCs to implement TRIPS provisions fully before the end of the transition periods, and/or requiring these countries to accede to or conform to the requirements of other multilateral intellectual property agreements.⁷³

III. TRIPS, Right-to-Health and Compulsory Licensing

The explicit term 'compulsory licensing' is found only once in the TRIPS agreement, namely in Article 21, stating 'Members may determine conditions on the licensing and assignment of trademarks, it being understood that the compulsory licensing of trademarks shall not be permitted and that the owner of a registered trademark shall have the right to assign the trademark with or without the transfer of the business to which the trademark belongs'.

The corresponding Article and legal content mimicking Article 5A(2) of the Paris Convention regarding common notion of compulsory licensing is instead found in Article 31 TRIPS, defining compulsory licensing as 'Other Use Without Authorization of the Right Holder' under specific provisions given in Article 31 (a-l).⁷⁴

Regarding possible limitations and exceptions from the rights entailed in the TRIPS, Article 30 is of interest, under the headline of 'Exceptions to Rights Conferred', it is noted that 'Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'.⁷⁵

70 TRIPS Agreement, Art 3.

71 TRIPS Agreement, Art 68.

72 The New York Times, 'India Alters Law on Drug Patents' <<https://www.nytimes.com/2005/03/24/world/asia/india-alters-law-on-drug-patents.html>> accessed 27 June 2021.

73 Jakkrit Kuanpoth, 'TRIPS-Plus Intellectual Property Rules: Impact on Thailand's Public Health' (2006) *The Journal of World Intellectual Property* 9, 573-591.

74 Some parts of this section have previously appeared in: Behrang Kianzad, 'Excessive Pharmaceutical Prices as an Anticompetitive Practice in TRIPS and European Competition Law' in Klaus Mathis and Avishalom Tor (eds.) *New Developments in Competition Law and Economics* (Springer International Publishing, 2019) 197-220.

75 TRIPS Agreement, Art 30.

The reference to possible limitations and exceptions from the rights is further found in Article 27 (2) bears also some weight on this regard, stating 'Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law'.⁷⁶

Most importantly for a teleological legal interpretation of the treaty and the rights and obligations therein, the main objectives of the TRIPS Agreement are defined in Article 7, stating 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.⁷⁷ It is thus a holistic approach seeking to maximize societal welfare, re-affirming the ratio legis of IPRs as being employed at the behest of the society, although being granted in form of monopolistic rights during a limited period to private entities.

Furthermore, and most relevant for the present discussion on Right-to-Health versus IPRs, Article 8 is of importance, noting :

'1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology'.⁷⁸

Regarding 'abuse of intellectual property rights' and 'practices which unreasonably restrain trade or adversely affect the international transfer of technology', Article 40 of the agreement is worth mentioning in its entirety:

'1. Members agree that some licensing practices or conditions pertaining to intellectual property rights

which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member'.⁷⁹

Thus, TRIPS provides for long-ranging flexibilities, exceptions and limitations to IPRs grounded on both public health rationale, as well as on anti-competitive practices rationale.⁸⁰ TRIPS, as also re-affirmed by the Doha Declaration,⁸¹ re-connects with the legal-economic and legal-historical roots of IPRs as being of importance for societal welfare. TRIPS further distinguishes, as does European Law on the matter, between existence and exercise of IPRs, where the latter can come into conflict with other bodies of law, such as Right-To-Health, Competition Law and so on.⁸²

1. Compulsory Licensing under TRIPS and Access to Medicines

As can be seen from the Articles of the TRIPS agreement cited above, taken together they provide a solid legal foundation within the TRIPS / WTO legislative body for state intervention against abuses of

76 TRIPS Agreement, Art 27 (2).

77 TRIPS Agreement, Art 7.

78 TRIPS Agreement, Art 8.

79 TRIPS Agreement, Art 40.

80 (n 74)

81 Doha Ministerial Declaration, WT/MIN (01)/DEC/2 14 November 2001.

82 Some parts of this section on Right-to-Health and Compulsory Licensing have previously appeared in Behrang Kianzad, (2015) JURM02 20151, Department of Law, Lund University, <<https://lup.lub.lu.se/student-papers/search/publication/5432497>> accessed 23 June 2021.

IPRs, in order to satisfy public interest issues, order public and to preserve and protect competition.

The tension between monopolistic nature of IPRs and other public policy rationales such as Right-to-Health, solidified through the international implementation and codification of these rights through the TRIPS agreement, came soon to be criticized for what many feared would be a substantial decrease of access to patented medicines by the developing countries.⁸³

Although Article 30 of the TRIPS agreement taken together with Articles 7 and 8 would justify granting of compulsory licensing in cases of national emergencies, and the epidemic situation of for example HIV/AIDS in many developing and least developed countries can arguably be described as a national emergency⁸⁴, the many provisions of the Article 31, mainly Article 31(f) posed a real obstacle.

Article 31 (f) states that ‘any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use’, referring to the ‘use without authorization of the Right Holder’ headlining the same Article.⁸⁵

Since many developing countries lack the know-how as well as manufacturing capacities required to produce generic versions of the patented medicines needed to combat the ‘national emergency’, the issuance of a compulsory licensing under Article 31 as an effective tool towards affordability comes with many caveats.⁸⁶

2. Doha Ministerial Declaration on Public Health

In order to respond to these concerns voiced by NGOs and developing countries alike, the Doha Ministerial Declaration in 2001 sought to clarify the TRIPS agreement in regard to public health issues.⁸⁷

The declaration stated that ‘We recognize that under WTO rules no country should be prevented from taking measures for the protection of human, animal or plant life or health’⁸⁸ and noted further ‘We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration’.⁸⁹

The adjoining Declaration on the TRIPS and Public Health concluded ‘We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all’.⁹⁰

The definition of what would constitute national emergency situations and threats to public health was left to the member’s own discretion to define the grounds in each case. There is not an established demand for national emergency as such, the existence of which can however nullify the provisions regarding seeking a voluntary license before issuing a compulsory license. The Declaration further acknowledged the fact that many developing countries which would best be served by compulsory licensing in order to gain access to patented essential medicines lacked the necessary manufacturing capacity to produce these medicines.⁹¹

3. August 30th Decision and its Implication

Accordingly, the Council of TRIPS was instructed to find an expeditious solution before the end of 2002,⁹² something that turned out to be a more lengthy

83 Keith E Maskus, ‘Private Rights and Public Problems’ (2012) 254.

84 Hans-Henrik Lidgard and Jeff Atik, ‘Facilitating Compulsory Licensing under TRIPS in Response to the AIDS, Crisis in Developing Countries, 2005, Loyola Law School, Legal Studies Paper No. 2005-18.

85 TRIPS Agreement, Art 31 (f).

86 Eduardo Urias and Shyama V. Ramani, ‘Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence’ (2020) 3 *Journal of International Business Policy* 4, 367–84.

87 Doha Ministerial Declaration, WT/MIN (01)/DEC/1 20 November 2001.

88 Doha Ministerial Declaration, WT/MIN (01)/DEC/1 20 November 2001, para 6.

89 *ibid*, para 17.

90 Doha Ministerial Declaration, WT/MIN (01)/DEC/2 14 November 2001, para 4.

91 Anthony Taubman et alia, *A Handbook on the WTO TRIPS Agreement*, 2012, p. 183ff.

92 Hans Lidgard and Jeffrey Atik, ‘Embracing price discrimination: TRIPS and the suppression of parallel trade in Pharmaceuticals’ (2005) *University of Pennsylvania Journal of International Economic Law* 11.

process than expected, and finally on August 30th 2003 the TRIPS Council reached a decision on how to move forward.⁹³

The aim was to amend the TRIPS agreement accordingly⁹⁴ with Article 31(bis) as detailed in the protocol amending the TRIPS agreement.⁹⁵ Regardless of the formal implementation, the waiver of the provisions set forth in Article 31(f) was legally binding and active. However, some 30 developed country members pledged not to use the system to their benefits as importing countries. However, to make use of the system, the member countries are required to amend their domestic legislations accordingly.⁹⁶ This was accordingly done in the context of COVID-19 pandemic.⁹⁷

Worth mentioning is the Chairman's Statement, read prior to and appended to the Decision. It recognized that the Paragraph 6 System should be interpreted in good faith to protect public health and not as an instrument to pursue industrial and/or commercial interests. The legal power of this statement is though interpretative at best.⁹⁸

The August 30th Decision waived some of the obligations under Article 31(f) TRIPS regarding the ban on export of compulsory licensing pharmaceutical products to other markets than domestic, and created a system for notification and procedure of the issuances of the compulsory licensing in this regard which has come to be known as the Paragraph 6 System, recognizing the flexibilities under the TRIPS agreement to address public health issues in the light of compulsory licensing under Article 31(f) TRIPS. The idea was to allow member states with a manufacturing capacity to aid less developed countries with no manufacturing capacity and in need of essential medicines, under what has come to be known as the Paragraph 6 System.

Unfortunately, this remedy, praised as it was as a comprehensive flexibility, has not produced the desirable results, this being mostly due to the 'maze of rules and procedure'⁹⁹ and the complexity and burdensome intricacies it entailed, for both the exporting country and the importing country alike.

These rules can be summarised as:

1. The importing country must first establish a national health emergency
2. The importing country must first seek a voluntary license from the patent holder, if failed, an application for compulsory licensing must be issued and granted
3. The importing country must establish the fact that domestic manufacturing capacity is lacking (LD-Cs are exempt from this demand).
4. The importing country must notify the TRIPS Council of its intent and decision to issue a compulsory licensing
5. The importing country must identify a potential exporter
6. The importing country must enact measures to prohibit trade diversion of the imported medicines and that the medicines will be used for addressing public health issues
7. The notification must include specific names and quantities of the medicines
8. The exporting country must first seek a voluntary license on commercially reasonable terms and for a commercially reasonable period
9. If this is refused, the exporting country must seek a compulsory licensing from its government
10. If such license is granted, develop the requested medicine while differentiate it regarding the patented products shape, colour, packaging etc. to avoid trade diversion
11. Seek to acquire data on safety and tests from the processor of the data, or else develop its own studies about toxicity and efficacy
12. Adequate remuneration must be paid to the patent holder, though only by the exporting country, even if this remuneration will be much less than in the case of a 'normal' patent (as according to Article 31(h) TRIPS).
13. The exporting country must also notify the TRIPS Council of its intention to produce a patented medicine under the compulsory licensing regime of Paragraph 6

93 Protocol Amending the TRIPS Agreement WT/L/641; Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (30 August 2003) WT/L/540

94 Amendment of the TRIPS Agreement WT/L/641 8 December 2005

95 Members Accepting Amendment of the TRIPS Agreement <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 23 June 2021.

96 Anthony Taubman et alia, 'A Handbook on the WTO TRIPS Agreement', (2012) 185.

97 Devex News, 'COVID-19: Countries race to strengthen compulsory licensing legislation' <<https://www.devex.com/news/covid-19-countries-race-to-strengthen-compulsory-licensing-legislation-97595>> accessed 23 June 2021.

98 (n 92) 13.

99 Raadhika Gupta, 'Compulsory Licensing under TRIPS, How far it addresses Public Health Concerns in Developing Countries' (2010) *Journal of Intellectual Property Rights* 15, 359.

14. Only the quantities specified by the importing country are allowed to be produced by the exporting country
15. The exporting country must notify the Council of TRIPS of the grant and the conditions entailed
16. All members must ensure enforceability against trade diversion and re-importation
17. The exporting country must post information about the quantities being supplied and the distinguishing features of the products so other member states custom divisions can have access to it and thereby hinder trade diversion and re-importation¹⁰⁰

This barrage of regulations renders it if not impossible, but indeed extremely difficult and time-consuming to achieve the desired flexibility intended by the Doha Declaration and subsequent August 30th Decision.

A testament to this fact is the meagre number of cases in the near two decades since the August 30th Decision. The most notable notification submitted under Paragraph 6 System / August 30th 2003 decision is the case of Rwanda¹⁰¹ as importing country, notifying the TRIPS Council in July 2007, and Canada as exporting country¹⁰², notifying the TRIPS Council in October 2007 of its willingness to supply a fixed-dose combination of the generic HIV/AIDS medicine ApoTriAvir. The shipments commenced in September 2008 and 2009 from the Canadian manufacturer Apotex, but the system was heavily criticized for not allowing production efficiency (being

on a case-by-case basis and specific quantities) and hence making it unprofitable for any potential exporter, also costing Canada a lot of money in the process.¹⁰³

On 5th May 2021, Bolivia issued a notification as importing member under Paragraph 6 system (now dubbed special compulsory licensing system post amendment of TRIPS by way of Article 31bis) to import 15 million doses of COVID-19 vaccines. As per the notification 'In particular, the

intention is to import the vaccine, Ad26.COV2.S, a replication-incompetent adenovirus type 26 (AD16) vectored vaccine encoding a stabilized variant of the S protein of SARS-Cov-2. The Plurinational State of Bolivia reserves the right to import other vaccines.'¹⁰⁴

The notification by Bolivia came after a deal with the Canadian pharmaceutical manufacturer Biolyse,¹⁰⁵ with the company declaring both willingness and capacity to produce and export the vaccines, if a voluntary or compulsory license could be obtained. Canada has at the time of writing not issued such compulsory licensing, nor had made any notifications to that effect.

It should also be pointed out that pharmaceutical manufacturers in Bangladesh, India, Denmark and Canada have reportedly failed to secure license to produce vaccines from the rights-holders.¹⁰⁶ This could be seen as a pushback against general notions making the claim that 'IP rights have not hindered access to COVID-19 vaccines and treatments', as such statement comes with many caveats.

The possibility of some developing countries 'pooling together' and realize economies of scale, requesting an exporting country to produce an essential medicine needed in all these importing countries is further limited, due to the complex rules regulating the overall process. As according to Paragraph 3 of the Protocol amending the TRIPS agreement, the country must be a member of a WTO recognized regional trade agreement (RTA), and that at least half of the countries parties to that RTA must be on the United Nations list of least developed countries. Furthermore, the country seeking to issue the compulsory licensing is the main responsible for administration, importation and re-exportation of the medicines to the other participating members of the RTA.¹⁰⁷

This 'regional mechanism' was elevated in the WHO/WIPO/WTO report on promoting access to

100 Jenny Wakely, 'Compulsory licensing under TRIPS: an effective tool to increase access to medicines in developing and least developed countries' (2011) *European Intellectual Property Review*, 304.

101 IP/N/9/RWA/1 19 July 2007

102 IP/N/10/CAN/1 8 October 2007

103 (n 100) 304.

104 Notification under the amended TRIPS Agreement by Bolivia, IP/N/9/BOL/1, 11 May 2021 <<https://e-trips.wto.org/En/MedicinesImportSpecificNotifications/View/1000862>> accessed 1 July 2021.

105 Newswire, 'Bolivia and Biolyse sign landmark agreement for export of COVID-19 vaccines' <<https://www.newswire.ca/news-releases/bolivia-and-biolyse-sign-landmark-agreement-for-export-of-covid-19-vaccines-832670191.html>> accessed 2 July 2021.

106 Aljazeera, 'Explainer: What are patent waivers for COVID vaccines?' <<https://www.aljazeera.com/cdn.ampproject.org/c/s/www.aljazeera.com/amp/news/2021/6/29/explainer-what-are-covid-vaccine-patent-waivers>> accessed 2 July 2021.

107 (n 100) 307.

medical technologies and innovation, noting ‘Under a regional mechanism established by the System, the condition that the products produced under the compulsory licence must be used predominantly to supply the domestic market is also waived. The purpose is to allow WTO members that are party to a regional trade agreement (RTA) to better harness economies of scale in their regional economic community and also enhance their purchasing power by combining demand to facilitate bulk imports or local production of pharmaceutical products for distribution within the relevant region...the products can be traded among the parties to the RTA without any further notification or adherence to any additional requirements other than those that apply at the time of the production in an RTA member or importation into the regional trade area under the System.’¹⁰⁸

These demands make it very difficult for developing and least developed countries already struggling with corruption, lack of infrastructure and maintenance of borders. As noted in a recent review of the literature and database analysis of instances of Compulsory Licensing ‘the future of compulsory licensing as an instrument of increasing access to medicines will be shaped by the evolution of two factors. First, under crisis situations, TRIPS has made the window of opportunity for generic producers to supply the rest of the world with drugs under patent, not only much smaller, but much more difficult to even open, given the cumbersomeness of the Paragraph 6 system. In the future, if there are other health crises, and activists force further refinements, this may change. Second, new drugs may be biologics in which emerging countries have an enormous technological (and often regulatory) retard. In such cases, if no alternative sources to a patent drug are available, a compulsory license will serve no purpose.’¹⁰⁹

As noted earlier, European Union with its member states opted out of the Article 31bis system as importing countries, thus the EU may only act as an exporter under the 31bis system, but also make use of parallel import rights within the Union.

IV. Patent Waiver Proposal at WTO TRIPS Council

The story of the COVID-19 IPR waiver started with a scenario that seemed to repeat the pattern of the pre-

vious decades when it comes to the discourse on IPRs related to healthcare products: The developing and least developed countries in favor of weakening IPRs, and the industrialized countries – including the EU – in favor of strong IPR protection, and a restrictive interpretation of the TRIPS flexibilities including the article 31bis system. This section depicts the background leading up to the waiver, including the (pending) content of the waiver and the various arguments for and against it.

1. Symbols and Waiver

The strong patent systems in e.g. Europe took shape when science and industry melted together in the 19th century’s evolving chemical industry. In 1884, the Paris convention provided the basic principles for the intersection of national patent systems, i.e., the principle of national treatment and the rights of priority. In 1994 the TRIPS agreement under the WTO took a next big step to establish a minimum protection of IP in all fields of technology. The non-discrimination of technology in TRIPS entailed that countries that had opted not to provide product patents for pharmaceutical, such as India, were now obliged to provide such protection in line with their TRIPS obligations.

This entailed the introduction of the Paragraph 6 system which post amendment became Article 31bis in the TRIPS agreement, explicating the basic rules for compulsory licensing in the case of an importing / exporting country. However, the HIV-epidemic that hit South Africa in the end of the old millennium, demonstrated that there was significant disagreement about the interpretation and application of the flexibilities in TRIPS.

It took the Mandela government significant effort and a lot of precious time to ensure access to medicine to treat HIV, with a very un-willing pharmaceutical industry at the other end of the table despite the

108 World Trade Organization, World Health Organization and World Intellectual Property Organization, Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade (2020) Annex III, <https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf> accessed 2 July 2021.

109 Urias and Ramani, ‘Access to Medicines after TRIPS’ (2020) J Int Bus Policy 2.

obvious threat to public health¹¹⁰. This led to the Doha declaration in 2001 re-affirming the flexibilities already entailed in the TRIPS agreement. The declaration was intended to explicate the rights of states to circumvent parts of the patent system to ensure access to essential medicines, e.g., a right to employ compulsory licensing to address national health emergencies.

The history of the pharma industry's strong opposition to the HIV-compulsory licenses in South Africa has contributed significantly to the imaginary of patents being contrary to access to medicine and shaped the symbolic meaning of the patent institution. Stories about dramatic price-increases on essential medicines enabled by patent monopoly have only enhanced this symbolic meaning of the patent and made the patent institution a prime suspect of why access to medicine is so unequally distributed between the peoples and nations of the world.

2. Request for a Waiver of IPR

On 2 October 2020 India and South Africa introduced a proposal for an IPR waiver at the TRIPS Council¹¹¹. In the opinion of India and South Africa, developing and least developed countries were disproportionately impacted by the measures needed to fight the pandemic such as social distancing. An effective response requires rapid access to a pallet of medicinal products from surgical masks and testing kits to vaccines and ventilators.

Furthermore, it was argued, that developing and least developed countries were at high risk of socio-economic fallouts which would prolong the global

economic and health crisis. India and South Africa argued that it was pressing that diagnostics, therapeutics and vaccines for COVID-19 be made available promptly, in sufficient quantities and at affordable prices to mitigate the risks for humans as well as societies that the pandemic poses in particular to the developing and least developed countries.

Reports had surfaced of manufacturers stepping into 'a minefield of patents'¹¹² when shifting their production to e.g. ventilators and surgical masks, and developed countries such as Germany and Canada rushing amendments to their patent legislation through to expedite compulsory licensing.

In the opinion of India and South Africa, this shows that IPRs may create barriers to the timely access to affordable medicinal products and the scaling up of research, development, manufacturing and supply of medicinal products essential to combat COVID-19. The existing flexibility provided in TRIPS art 31bis is cumbersome and a lengthy process for countries with insufficient or no manufacturing capacity.

India and South Africa therefore suggested that under these exceptional circumstances a waiver from the implementation, application and enforcement of section 1,4,5 and 7 of part II of the TRIPS agreement in relation to prevention, containment or treatment of COVID-19 be adopted by the TRIPS Council. The waiver should continue, 'until widespread vaccination is in place globally and the majority of the world's population has developed immunity'¹¹³.

This initial call for a waiver split the WTO members in the usual frontlines when it comes to the limitations to the protection conferred by patent rights: Developing and least developing countries where in favor of the proposal backed by several NGO's, while the developed countries e.g. EU, US, Australia, Canada and Japan opposed the proposal.

Although debates and arguments were exchanged, this deadlock did not seem to shift. The position of the developed countries including EU was that there were already sufficient flexibilities in the TRIPS agreement and hence there was no reason to put further measures into action.

However, this all changed on May 6th 2021 when US President Joe Biden and his administration decided to support the COVID-19 IPR Waiver, citing 'extraordinary times calls for extraordinary measures'¹¹⁴. Despite the US U-turn, the EU Parliament

110 Emily Saslow, 'Compulsory licensing and the AIDS epidemic in South Africa' (2019) *AIDS patient care and STDs* 13.10, 577-584.

111 WTO communication from India and South Africa, Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19, IP/C/W/7669, 2. October 2020.

112 Susan Decker and Christopher Yasiejko, World War II-Style Mobilization Order May Carry Risks, Bloomberg, <<https://www.bloomberg.com/news/articles/2020-03-20/world-war-ii-style-production-may-carry-legal-risks-for-patriots>> accessed 2 July 2021.

113 WTO communication from India and South Africa, IP/C/W/669, 2. October 2020, sec. 13

114 See, White House Fact Sheet <<https://www.whitehouse.gov/briefing-room/statements-releases/2021/05/17/fact-sheet-biden-harris-administration-is-providing-at-least-80-million-covid-19-vaccines-for-global-use-commits-to-leading-a-multilateral-effort-toward-ending-the-pandemic/>> accessed 2 July 2021.

was still split on the issue of the waiver, with some arguing in favor of the waiver and others arguing that the waiver was a ‘false good idea’, the real problem being vaccine hoarding by UK and US, not IPR.¹¹⁵

However, on June 4th 2021, European Commission decided to support the waiver¹¹⁶, and on June 10th 2021, the European Parliament issued a statement formally backing the waiver while simultaneously calling for voluntary licensing and transfer of know-how, abolishment of US and UK export restrictions on vaccines and raw material and an increased support for the COVAX program¹¹⁷.

3. Draft Declaration

While it is still debated whether and IPR waiver is a solution to any of the challenges currently being faced regarding vaccine production, addition of EU and US to the official WTO list of sponsors of the waiver is still awaiting agreement on the text of the waiver.

The most recent version of the waiver from 25 May 2021 implements a few amendments to the initial text from 2 October 2020. In the recitals it is added, that unimpeded, timely and secure access is for *quality, safe, efficacious* and affordable health products.

Furthermore, a section recognizing the importance of preserving incentives for research and innovation is added. In the decision text, the first paragraph specifies that the waiver only applies to ‘*health-care products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture*’. In the second paragraph of the decision text, it is stated that the waiver shall be in force for at least 3 years from the date of the decision.

These amendments address some of the initial criticism of the idea of an IPR waiver. Firstly, public health issue could be aggravated rather than resolved if the waiver meant that drugs were produced without sufficient regulatory control with the quality, efficacy, and safety of the products. It is therefore important that not only IPR but also the regulatory system including regulatory exclusivities be taken into consideration. This issue could present a significant obstacle because the regulatory system in develop-

ing and least developed countries may not have the capacities to ensure that novel production sights for e.g., vaccines are fit for purpose or able to produce of a high enough quality.

Secondly, recognizing the importance of incentives for R&D, addresses the criticism that a waiver dis-incentivize future investment in R&D. The amendments to the decision text clarify the intended scope of the waiver introducing a minimum timeline which is not dependent on assessment that could be controversial e.g. when ‘widespread vaccination is in place’.¹¹⁸

4. Vaccine Technology and Patent Landscape¹¹⁹

The waiver is intended to cover a broad range of IPR to enable access to both protective equipment, medicinal products and other things useful in fighting the pandemic. However, focus in the debate has been how a waiver of IPR would affect the production and access to COVID 19 vaccines. In this domain four different technologies are being used based on Adenovirus(s) vectors, inactivated corona virus, mRNA and Recombinant nanoparticle vaccine.

Adenovirus vectors are used in e.g. the AstraZeneca, Johnson & Johnson and Sputnik V vaccines. Inactivated coronavirus is used in the vaccine COVAXIN (r) sponsored by the Indian council of medical research and the Chinese Sinovac. mRNA technology is used in the Moderna, Pfizer-Biontech and CureVac AG vaccines.

Further, the recombinant nanoparticle technology is used in the Covovax vaccine from Novovax. The patent landscape for each of the four vaccine technologies varies significantly. Not surprisingly, the

115 See, <<https://www.europarl.europa.eu/news/da/press-room/20210517IPR04116/meps-split-over-waiver-for-covid-19-vaccine-patents>> accessed 2 July 2021.

116 WTO document IP/C/W/680

117 News European Parliament, MEPs split over waiver for COVID-19 vaccine patents <<https://www.europarl.europa.eu/news/en/press-room/20210604IPR05514/parliament-calls-for-temporary-covid-19-vaccine-patent-waiver>> accessed 2 July 2021.

118 Recital 13 of the initial proposal., (n 113)

119 The patent landscape analysis in the following section is based on information retrieved from the VaxPal – covid 19 vaccine patent landscape <<https://medicinespatentpool.org/what-we-do/disease-areas/vaxpal/>> accessed 6 July 2021.

well-established vaccine technologies based on AdenoVirus vectors, inactivated virus and recombinant nano particles compiles 47 patents in total, where a large portion (28) are held by J&J.

However, approximately half of these are expired or will expire within the next year. Similarly, the 5 patents on recombinant nano-particle vaccine (Novavax) will expire with the next 3-5 years. In contrast the mRNA vaccine technology shoulders 59 patents – 14 for Curevac, 28 for Moderna and 16 for Pfizer BioNTech. Most of these patents have 10+ years of patent life ahead. Furthermore, patent applications are generally not published until 18 months after the application have been submitted.

It is therefore likely that the intensified research efforts in the last 18 months spurred by the pandemic will manifest itself in the next year adding substantially to the patent landscape. It is therefore a very realistic scenario that thickets will emerge in vaccine technology with the risk of royalty stacking, increased transaction cost to ensure licensing of IP for manufacturers and increased litigation.

Regarding the complexity of the vaccines, and the complexity they in turn might present for compulsory licensing efforts, as explained by The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) 'Vaccine supply chains are international. The BioNTech/Pfizer vaccine contains 280 ingredients sourced from 19 countries. Moderna's, AstraZeneca's, and Johnson & Johnson's are similarly complex. Export controls threaten these supply

chains. This is a recurring concern we have heard from those present at the briefing.'¹²⁰

5. Know-how and Trade Secrets

Patents set a side, another important factor when considering access to vaccine technology is know-how. While adenovirus vector-, recombinant nanoparticle and inactivated virus technologies have been around for years and the techniques are well known, the use of mRNA technology in vaccines is a more recent endeavor. A patent must disclose the invention patented in a manner that enable a person skilled in the art to practice the invention.¹²¹

Nevertheless, when it comes to the new mRNA technology, there is not that many people skilled in the art to do the job. Furthermore, parts of the technology that goes into mRNA vaccine production is not patented but kept as a trade secret by the manufacturers. Though the waiver is also intended to encompass know-how, sharing tacit knowledge is obviously more cumbersome than reading a patent document and knowledge transfer are irreversible opposed to the use of patents.

However, some initiatives to disperse the tacit knowledge associated with the mRNA vaccine technology have recently been reported in South Africa¹²², raising hopes that the situation will not end in an unproductive deadlock of politics and negotiations.

6. Criticism of the Waiver

Pfizer CEO has stated that he does not lie sleepless at night over the suggested waiver fearing for Pfizer's patent portfolio¹²³. Instead, he raised concern, that a waiver would lead to a world-wide race for raw materials that could endanger safe and effective production of vaccines¹²⁴.

Other lines of criticism of the waiver has come from many sides presenting variations of three themes: 1) IPR is not problem, 2) waiving IPR will be detrimental to the innovation system and 3) a waiver is not the best solution. The Max Planck institute list 10 arguments that the waiver will not leave us better off neither during nor after the pandemic, which sum up most of the arguments against the waiver that has been presented¹²⁵.

120 IFPMA, 'Challenges and solutions to scaling-up COVID-19 vaccine manufacturing capacity' <<https://www.ifpma.org/global-health-matters/challenges-and-solutions-to-scaling-up-covid-19-vaccine-manufacturing-capacity/>> accessed 6 June 2021.

121 See e.g. TRIPS agreement art 29 and European Patent Convention art 83.

122 Kerry Cullinan, South Africa to Become Africa's First mRNA Vaccine Manufacturing Hub – WHO Asks Big Pharma to Support Scaleup, Health policy watch, <<https://healthpolicy-watch.news/africas-first-mrna-hub-to-be-set-up/>> accessed 2 July 2021.

123 Noah Higgins-Dunn, Moderna CEO says he's not losing any sleep over Biden's support for COVID-19 vaccine waiver <<https://www.fiercepharma.com/pharma/moderna-ceo-says-he-s-not-losing-any-sleep-over-biden-s-endorsement-for-covid-19-ip-waiver>> accessed 2 July 2021.

124 Kevin Breuninger, Pfizer CEO opposes U.S. call to waive Covid vaccine patents, cites manufacturing and safety issues <<https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html>> accessed 2 July 2021.

125 Max Planck Institute for Innovation and Competition, 10 Arguments Against a Waiver of Intellectual Property Rights <https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/Shortversion_10_Arguments.pdf> accessed 2 July 2021.

A group of arguments addresses, that the waiver will not have the effect intended. It will not increase production, distribution or remove regulatory requirements. And it will probably not lower prices or have any effect on trade secrets. A second set of arguments counters the reasons presented in favor of a waiver: the TRIPS flexibilities provides sufficient leverage to address the negative effects of patents and profit maximization by IP holders and public expenditure are not viable reasons for passing a waiver.

Finally, the lacking clarity of the waiver is held against it and global governance is presented as a better alternative to a waiver to support developing countries. Likewise, the international federation of pharmaceutical manufacturers and associations (IFPMA) has expressed their criticism of the waiver proposal both before the US decision to back the proposal¹²⁶ and after. They have taken the stand that the waiver does not address the real problems, 'namely elimination of trade barriers, addressing bottlenecks in supply chains and scarcity of raw materials and ingredients in the supply chain, and a willingness by rich countries to start sharing doses with poor countries.'¹²⁷

While industry and IPR-scholars have argued against, the political elite and NGO's have pushed for a decision to back an IPR waiver. In April 2021 more than 170 former heads of state and Nobel laureates called for the support of a COVID-19 IPR waiver¹²⁸. This was organized by an alliance of international NGO's including Medicines Sans Frontiers (MSF) and Oxfam. It seems that on the issue of the COVID-19 IPR waiver, the traditional frontline between developing and least developed countries and the developed countries does not describe the situation any more. Industry and a fair share of IPR scholars argue against, while a strong cohort of the political elite from both sides of the old demarcation line has joined on the NGO's in favor of a waiver.

Industry as well as academics have put forward substantial criticism of the waiver arguing not only that it will have no effect, but also that it could make things worse. However, first the US and now EU has announced their support of a COVID19-waiver of IPR. This raises the question whether the IPR waiver has anything to do with IPR, or is just another brick in the grand political puzzle, where the US support of a waiver is used to push the pharma industry to share and remove focus from US export restrictions on vaccines and raw materials for vaccines.

V. Conclusions

As noted by Holger Hestermeyer, the claim for inclusion of access to affordable essential medicines as a basic human right is divided into three aspects. Firstly, alleging the existence of a legal right to access to medicines, although that right is not explicitly mentioned in any legally binding agreement, but is commonly derived from the aforementioned right to health concept. Secondly, the assertion is made that the adoption of patent legislation (as according to TRIPS) causes the patent holders to charge higher prices due to the existence and enforceability of patents on pharmaceutical products, in effect rendering these products unaffordable for a majority of the developing countries. And thirdly, it is argued that these high and excessive prices pose an infringement in the right to access to medicines. An infringement not 'justified by other considerations, such as the necessity of patents to enable research and development.'¹²⁹

The statements should thus be complemented with the assertion that the TRIPS agreement does indeed provide a range of flexibilities to all signatories (such as compulsory licensing) as well as exceptions from the obligations per the TRIPS agreement to Least Developed Countries. Furthermore, there is little doubt in regard to the considerable costs related to such innovation, clinical testing and subsequent marketing, amounting to billions of dollars, making the case for a patent protection in order to be able to recoup costly and risky investments.

1. Pricing of Vaccines During and Post Pandemic

Dramatic price hikes of COVID-19 vaccines after the most urgent phases of the pandemic, risk nullifying

126 Thomas Cueni, The risk of suspending vaccine rules <<https://www.nytimes.com/2020/12/10/opinion/coronavirus-vaccine-patents.html>> accessed 2021-07-02.

127 IFPMA Statement on WTO TRIPS Intellectual Property Waiver <<https://www.ifpma.org/resource-centre/ifpma-statement-on-wto-trips-intellectual-property-waiver/>> accessed 2 July 2021.

128 UNAIDS, COVID -19 and HIV, <https://www.unaids.org/en/resources/presscentre/featurestories/2021/april/20210414_letter-waive-intellectual-property-rules-COVID-vaccines> accessed 2 July 2021.

129 Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press, 2007).

the great goodwill pharmaceutical industry is now enjoying – approval of industry increased by 50% in US as opposed to pre-pandemic indications.¹³⁰ If vaccine makers opt to price COVID-19 vaccines like influenza vaccines (ranging from \$150 to \$300), this would impact already strained health budgets considerably, as the vaccination would need to occur annually to protect against new variants and strains.¹³¹

This would mimic the pricing development for influenza vaccines, as noted by Ramachandran et al., noting, 'From 2000 to 2021, average prices for the influenza vaccine rose by 149% for the public sector and 163% for the private sector... Pricing trends for the influenza vaccine also do not seem to be affected by the number of manufacturers and products on the market... This suggests that the influenza vaccine market in the US has little price competition but steadily rising prices, despite growing government purchasing commitments and broadening populations of recommended users.'¹³²

Dramatic price hikes might run the risk of being caught by competition authorities by way of excessive pricing regulations, at least in EU, although US on Federal level lack a similar clear-cut prohibition. Nevertheless, the price gouging statutes introduced on the Federal level seen against the considerable federal funding of vaccines might trigger Congressional investigations and calls on Department of Justice to bring antitrust claims regarding price gouging. The risk for compulsory licensing also increases exponentially if vaccine prices are hiked.

2. State Responsibility - Public Health versus IPR Protection

Is there an inherent tension in the state responsibilities between their obligation to secure public health / right to health and access to medicines, versus their obligations to secure intellectual property rights pro-

tection in according with e.g. TRIPS? And if so, how can this be resolved?

Some of the portal paragraphs of TRIPS can be illuminating to how the agreement should be read and understood and interpreted in the context of the contradictory nature of state obligations in public health versus state obligations regarding patent protection resultant from TRIPS.

TRIPS also prescribes that the agreement and patent protection therein is not without limitation, and provides for a broad range of flexibilities for states – chief among those might be the powers of states to issue compulsory licensing against a patent holder, one of the grounds upon which CL might be issued is anti-competitive practice, which forms the bulk of this analysis of state responsibilities in regards to public health on the one hand and patent protection on the other hand within the framework of TRIPS.

Early on in the 90's following the AIDS crisis and due to fear of developing countries that their access to generic medicines would be limited when and if TRIPS were to be fully implemented, the Doha Ministerial Declaration on TRIPS and Public Health strived to strike a balance, as well as clearly defining the limits of IPR protection in TRIPS as regards to public health.

The Paragraph 5 in the Doha Declaration clearly leaves states some substantial leeway to define and implement so called TRIPS flexibilities in regards to interpretation of their obligation, specially when discussing the issuance of compulsory licenses and defining the grounds upon which such compulsory licenses are to be issued.

Turning back to the TRIPS agreement and the obligations of the states in public health on the one hand and securing of patent rights on the other hand, we can look beyond the traditional approach of issuing compulsory licensing on the grounds of protection of public health or national emergencies and the likes. Article 31 (k) of the TRIPS clearly mandates limitation of and enforcement against patent rights if anti-competitive practices are found.

Such anti-competitive practices can take the form of refusal to license, or excessive or 'unfair prices', in the wording at Treaty of the Functioning of the European Union Article 102a.

Article 40 of the TRIPS creates a clear legal mandate to act against anti-competitive practices and abuses of IPRs creating adverse effects on competi-

130 John LaMattina, former president of Pfizer Global Research and Development, in Forbes, 'Pfizer Should Be Wary About Covid-19 Vaccine Price Hikes' <<https://www.forbes.com/sites/johnlamattina/2021/02/25/pfizer-should-be-wary-about-covid-19-vaccine-price-hikes/>> accessed 23 June 2021.

131 Jennie S. Lavine, Ottar N. Bjornstad, Rustom Antia, 'Immunological characteristics govern the transition of COVID-19 to endemicity' (2021) 371 Science 741-745.

132 Reshma Ramachandran et al., 'Future of Covid-19 Vaccine Pricing: Lessons from Influenza' (2021) BMJ 373.

tion, a rather broad definition and thus enabling member states to define and enforce competition law rules entailed in their national legislation. Such enforcement must nevertheless adhere to standards regarding procedural aspects (right to appeal e.g.) as well as legal-economic standards relevant for competition law assessment.¹³³

Some practices such as royalty stacking¹³⁴ and patent thickets¹³⁵ might also present themselves further down the road in regard to COVID-19 vaccines, but also refusal to license and excessive pricing as mentioned before merit closer scrutiny.

3. Legal – Economic Arguments for Limitations of IPRs

Turning to the legal-economic perspective, the arguments for limiting IPR rights including patents can be found in the costs they induce on societies, healthcare systems and consumers. One legal rationale, behind patent rights lie in the total welfare gain of society as a whole. A patent proprietor can charge a premium price during the term of patent protection. This induce costs on consumers, but it is assumed either that without the patent enabled premium price we would not have the treatment, or that the price is worth the healthcare-gain.

However, possible societal and consumer gains are nullified to a great extent if anti-competitive practices such as pricing way over marginal costs occur on a long term, un-disputed markets, or monopolist markets, and since patents do bar competitors from entry, these are surely to be considered as one such market. Hence, detrimental effects to consumers are created due to high or excessive prices, leading to creation of deadweight losses.¹³⁶

The above entail potential impact on choice and design of innovation law and policy, thereamong pharmaceutical patents and lifesaving medicines, highly depending on the matter of what priorities are set and what values are pursued.

One study taking stock of much of the empirical and economic research on the matter concluded that "The question of whether innovation is too high or too low is a first-order—perhaps the first-order—policy question in the economics of the pharmaceutical industry. Yet, economists have not produced a definitive answer. At best, we have suggestive analyses that point to the low rate of surplus cap-

ture by innovators, and modelled estimates suggesting that the social return to innovation is positive on the margin. While helpful, these findings each require a speculative leap in order to draw an inference about the social efficiency of innovation. Much rides on the answer to this question. If innovation is indeed excessive, then public and private payers are wasting money paying excessively high rewards to firms producing innovations. In contrast, if innovation is too low, lives are being lost prematurely due to a lack of medical progress."¹³⁷

4. Concluding Remarks

To summarise, there is a strong legal basis in the TRIPS agreement for granting of exceptions to the protection of IPRs in order to fulfil other public policy rationales such as combatting a pandemic or other national health emergencies. There is further a strong legal basis in the TRIPS agreement regarding exceptions and limitations of IPRs if they are found to constitute abuses of the IPR system or entail anti-competitive practices, with refusal to license and excessive pricing being two such examples.

Some references to already existing TRIPS flexibilities seem to underplay the highly complex and time-consuming legal processes required to secure a multitude of patents regarding COVID-19 vaccines, where the trade secrets and know-how are not directly covered by the compulsory patent licenses. The temporal element is of added importance in the case of an evolving health crisis such as a global pandemic.

Although in place for two decades and being amended by Article 31bis, the state of compulsory licensing under TRIPS remains one of procedural, legal-economic and political uncertainty, with many arguments in the literature for and against the

¹³³ (n 74) 220.

¹³⁴ E. Elhauge, 'Do Patent Holdup and Royalty Stacking lead to Systematically Excessive Royalties?' (2008) 4 *Journal of Competition Law and Economics* 3, 535–70.

¹³⁵ Carl Shapiro, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting,' (2001) 1 *Innovation Policy and the Economy* 34.

¹³⁶ Marcel Canoy and Jan Tichem, 'Lower Drug Prices Can Improve Innovation' (2018) 14 *European Competition Journal* 2, 278–304.

¹³⁷ Darius N. Lakdawalla, 'Economics of the Pharmaceutical Industry' (2018) 56 *Journal of Economic Literature* 2.

regime.¹³⁸ Much uncertainty and research gaps remain on the matter of the actual impact of compulsory licensing on originator companies' innovation rate, and on the overall impact on health budgets, to be filled by future work on the matter.

Amidst the bells and alarms and deadlocked positions, policy makers need to employ a holistic approach to the intersection of Right-to-Health and Intellectual Property Rights, where the ratio legis of both areas of law should be weighed against each other, informed by real world indicators rather than theoretical or political posturing.

Indeed, neither compulsory licensing, nor an IPR-waiver, represent optimal solutions to a global problem caused by inequality, inequity and many broken promises in regard to a global effort towards sustainable economic development and reaching different goals regarding health.

If the main ratio legis of granting patents on medicines is to bring about necessary, life-saving drugs, then distribution and equal access to such life-saving medicines becomes of paramount importance amidst a global pandemic, where the validity and legitimacy of both intellectual property system, and the pharmaceutical innovation sector overall, becomes dependent on the resolution of this global task.

Arguments making the claim that if waiver is granted, then pharmaceutical companies might not be as willing to race to human relief in the next pan-

demic seem to ignore the 'compulsory' element in compulsory licensing, and the vast resources available at the hands of the Sovereign, with emergency laws being firmly on the table, as the US use of Defence Production Act¹³⁹ showed.

The manifest unequal access, the 'moral failure' as labelled by the Director of WHO and instances of nationalism and hoarding of vaccines and medicines make the calls for a blanket waiver of IPRs extremely loud, while the misguided positioning of compulsory licensing as an ideal alternative makes the procedural steps towards a waiver no one wants even closer.

The pandemic and the fact that a waiver of IPR rights is on the table, signifies a possible break with the policy of a market driven innovation system with state subsidies for basic research to drive pharmaceutical innovation. If the waiver becomes a reality and does not end crippled after political negotiations, it signifies an important break with the narrative of strong IPR protection as the cornerstone of pharmaceutical development and the resulting market/profit orientation. Nevertheless, as it has famously been put, although all want to share the cake, someone must make the cake in the first place, thus protection of incentives and investments will be of fundamental importance no matter what incentive model is chosen.

One could hope that it will be a first step towards a system of healthcare innovation with a more global outlook, based on private-public cooperation throughout the life cycle of healthcare innovations. Such development would benefit global economic recovery as well as sustained and sustainable pharmaceutical innovation.

138 Muhammad Zaheer Abbas, 'Pros and Cons of Compulsory Licensing: An Analysis of Arguments,' (2013) *International Journal of Social Science and Humanity*, 254–58.

139 FEMA, The Defence Production Act <<https://www.fema.gov/disasters/defense-production-act>> accessed 27 June 2021.