Health justice for the global South during a global health crisis: Intellectual property, human rights, and a global health treaty

De Kok A

orcid.org 0000-0002-5704-8158

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Supervisor: Prof KD Beiter

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ABSTRACT

Intellectual property rights (IPRs) refer to legal protections afforded to producers and creators for their intellectual creations and consists of a variety of exclusive rights such as trademarks, trade secrets, copyright, and patents. There are constant interactions between human rights and IPRs, and the fundamental principle at play is balancing these private, exclusivity rights with the public's interest in both the production and dissemination of information and technology.

It is argued that IPRs have the potential to diminish the rights to health and society's right to benefit from scientific advancements. It further restricts the free flow of knowledge and ideas, thus stifling further innovation. Counterarguments include that IPRs provide economic incentive for individuals (including juridic persons) to continuously contribute to the betterment of society through innovation.

A state's ability to ensure access to affordable medicines and to promote further medical research and innovation, as required by the rights to life, health, and science, can be negatively impacted by IPRs. The current COVID-19 pandemic serves as a good example of the free flow of knowledge and technology from the global North to the global South having been unacceptably slow and disproportionate, with vaccine and treatment shortages having driven many economies to the ground.

Intellectual property (IP) today is regulated by The Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994 (TRIPS). TRIPS is an international agreement between all the member nations of the World Trade Organization. It attempts to establish the minimum standards for IP regulation. But the reality of matter is that big private pharmaceutical companies dominate the market and are currently excluding poor and developing nations from accessing essential medical technologies and medicines by setting high monopoly prices for the use of their inventions. IP and public health care have been interlinked since the dawn of the IP era.

This study will revisit the age-old concern of whether TRIPS could facilitate public health emergencies and more specifically the public health of developing nations. TRIPS does have certain instruments at its disposal when IPRs interfere with effective action during a public health crisis, often referred to as the TRIPS flexibilities. TRIPS flexibilities are virtually unused by countries of the global South. It would seem that they are ineffective for these countries and better suited for countries of the global North during public health emergencies. The TRIPS flexibilities, at the time of their adoption, were helpful to promote access to medicines in a time where supply chains where fairly simple and where patent barriers were the only barriers in place. But since the emergence of free trade agreements, incorporating TRIPS-Plus provisions, have overridden the use of most TRIPS flexibilities and left developing nations vulnerable while protecting the interests of developed countries.

During the COVID-19 pandemic, South Africa and India introduced the proposal of a COVID-19 IP-related waiver. A COVID-19 IP-related waiver would suggest that all IP protections should be temporarily waived until the pandemic is under control. This proposal was received with mixed feelings. It was felt by rich countries that this would lead to diminished incentivisation to continuously improve the vaccine portfolio, and that, even if all countries did have the freedom to produce vaccines themselves, they would lack the know-how and facilities to produce quality vaccines. But various countries of the global South do possess basic infrastructure and resources that, with some assistance from overseas, can develop their potential to replicate and even develop own vaccines. The real issue that this study attempts to address is whether a few pharmaceutical corporations in the global North should retain complete control over whether and where production occurs, and thus control supply, price, and distribution globally. The waiver proposal was eventually watered down and currently does not address the dire need to close the vaccine gap between the global North and South, which will be critically analysed.

COVID-19 is not the first, nor is it the last global pandemic we will encounter. Consequently, a global solution to the COVID-19 pandemic and any other comparable future health crisis would have to establish a balance between patents

on vaccines and medicines and access to these. This study asserts that a global health treaty could be the starting point to address the disparities during a global health emergency and should attempt to achieve global health justice by closing the vast gaps in global health equity between the North and South through ensuring fairer distribution of health and scientific benefits. A new health treaty that attempts to provide global access to medical countermeasures must consider the current international law limitations and the vastly different economic realities of all parties to the treaty. A pandemic treaty should promote technology transfer, require knowledge and IP sharing, and create greater transparency. Apart from a liberal use of compulsory licences, parallel imports, and competition law measures, the waiver of IP monopolies on technologies and medicines relevant to the pandemic would be the heart of the treaty.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
Africa CDC	Africa Centres for Disease Control and Prevention
API	Active Pharmaceutical Ingredients
ARVs	Antiretrovirals
CESCR	Committee on Economic, Social and Cultural Rights
CL	Compulsory License
COVAX	COVID-19 Vaccines Global Access Initiative
C-TAP	Technology Access Pool
DPA	US Defence Production Act of 1950
ETOs	Extraterritorial Obligations
FTAs	Free Trade Agreements
GSP	Generalized System of Preferences
HIC	High Income Country
HICs	High Income Countries
HIV	Human Immunodeficiency Virus
HMICs	High- And Middle-Income Countries
HPV	Human Papillomavirus
ICCPR	International Covenant on Civil and Political Rights, 1966
ICESCR	International Covenant on Economic, Social and Cultural Rights, 1966

IHRL	International Human Rights Law
ITO	International Trade Organization
LDCs	Least Developed Countries
LICs	Low-Income Countries
LMIC	Low-Medium Income Countries
MA	Marketing Authorization
MFN	Most-Favoured Nation
Mpox	Monkeypox
mRNA	Messenger Ribonucleic Acid
MRSCA	Medicines and Related Substances Control Act 101 of 1965
MTN	Multilateral Trade Negotiations
NDAs	Non-Disclosure Agreements
NT	National Treatment
OHCHR	Office Of the United Nations High Commissioner for Human Rights
PCT	Patent Cooperation Treaty
PCV	Pneumococcal Conjugate Vaccine
PHEIC	Public Health Emergency of International Concern
PIP	Pandemic Influenza Preparedness
PIs	Parallel Importations
PMA	Pharmaceutical Manufacturers Association
R&D	Research and Development

REBSPA	Right to Enjoy the Benefits of Scientific Progress and Its Applications
S&DT	Special and Differential Treatment
TAC	Treatment Action Campaign
UDHR	Universal Declaration of Human Rights, 1948
UNCTAD	United Nations Conference on Trade and Development
UNDRIP	United Nations Declaration for The Right of Indigenous People, 2007
VL	Voluntary License
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1 Global health crisis and the law of the jungle?

The legal situation pertaining to global health crises within the realm of international law is currently similar to that of the law of the jungle, where larger animals prey upon the smaller ones: there are no international legal rules adequately protecting the health rights of those in poorer States during global health crises. This scenario is that which prevailed during the COVID-19 global pandemic, revealing the disjunct between world trade, the sharing of Intellectual Property (hereinafter referred to as IP), and the realization of human rights (notably the right to health). In the absence of adequate mutually agreed rules among nations regulating this type of scenario, larger countries tend to abuse IP rights to the detriment of poorer countries. The existing multilateral IP system, under the TRIPS Agreement, appears to lack the necessary balance to protect poorer States and does not properly cater for global health crises. Unfortunately, due to the expansionist interpretations of IP protection within TRIPS, and the reductionist interpretation of exceptions and limitations to IP rights that could protect public access in this type of scenario, major disparities in vaccine distribution between the global North and the global South occurred.

As of June 2022, it has been reported that 72.09% of individuals residing in high-income countries (hereinafter HICs) have received at least one dose of the COVID-19 vaccine.[1] In contrast, a mere 17.94% of individuals residing in low-income countries (hereinafter LICs) have been vaccinated against the virus.[2] Achiume contended that the *status quo* amounted to "vaccine apartheid" between the global North and the global South.[3]

The current situation, whereby the production and distribution rights of the COVID-19 vaccine are still predominantly held by the wealthiest nations, has resulted in third-world countries experiencing severe economic, social, and health-related consequences.[4] Despite the efforts of the COVID-19 Vaccines Global Access Initiative (hereinafter COVAX) facilitated by the World Health Organization

[1] Achiume United Nations OHCHR *UN expert urges States to end 'vaccine apartheid'.*
[2] Achiume United Nations OHCHR *UN expert urges States to end 'vaccine apartheid'.*
[3] Achiume United Nations OHCHR *UN expert urges States to end 'vaccine apartheid'.*
[4] Oehler and Vega 2021 Open Forum Infectious Diseases 6.

(hereinafter WHO), the assistance provided has been insufficient.[5] The ramifications of this disparity – in the context of the COVID-19 but also similar future health crises – will have a profound impact on the collective fabric of these nations, exacerbating the existing geopolitical and financial inequalities between the affluent and the impoverished.[6]

The U.N. Special Rapporteur on contemporary forms of racism has reported that COVID-19 vaccines and treatments were stockpiled in HICs of the Global North, thereby depriving States in the global South of affordable access to life-saving treatments.[7] Due to the TRIPS agreement, at any rate its restrictive interpretation favouring innovation at the expense of dissemination, the safeguarding of IP has hindered the ability of nations in the global South to manufacture COVID-19 vaccines and treatments protected under existing patents, resulting in financial gains for Northern corporations at the expense of human lives in the South.[8]

It is for this reason that a treaty needs to be created where the rules are set by the capabilities, not the powers, of nations. In partnership with Achal Prabhala, the coordinator of the AccessIBSA project,[9] a comprehensive study revealed the existence of 120 manufacturers across the Global South with the capacity to produce mRNA vaccines in a safe manner.[10] However, these manufacturers are currently restricted by the IP laws of powerful nations in the global North from establishing local vaccine production.

This dissertation delves into the issue of global vaccine inequity during the COVID-19 pandemic, and in resolving the repercussions for similar crises in the future, the analysis scrutinises IP law as stipulated in the 1994 World Trade Organization's (hereinafter WTO) TRIPS Agreement, both prior and post its amendment. The role that IP has played in perpetuating the disparities in vaccine production, distribution,

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[5] Oehler and Vega 2021 Open Forum Infectious Diseases 7.
[6] Oehler and Vega 2021 Open Forum Infectious Diseases 3.
[7] Achiume United Nations OHCHR UN expert urges States to end 'vaccine apartheid'.
[8] Achiume United Nations OHCHR *UN expert urges States to end 'vaccine apartheid'.*
[9] The AccessIBSA initiative https://accessibsa.org/about/ is a project spanning three continents, made possible by a fellowship granted by the Shuttleworth Foundation. They aim to enhance the availability of essential medicines and vaccines to those who require them the most, ultimately saving lives.
[10] Prabhala and Alsalhani 2021 MSF Southern Africa 3.

and pricing in the context of COVID-19 will be examined. But more specifically, the role that IP and IP-related trade plays in realizing the internationally recognized human right to health will be the core of discussion in considering a global health treaty to prevent inequities in future pandemic scenarios. In light of the inadequacy of the international response mechanisms, such as the COVID-19 Vaccines Global Access initiative (hereinafter COVAX) and the COVID-19 Technology Access Pool (hereinafter C-TAP), in addressing vaccine inequity, this dissertation contends that the recently agreed TRIPS waiver should be regarded as a necessary and proportionate legal measure for removing IP barriers that cannot be resolved through existing TRIPS flexibilities in responding to the COVID-19 crisis.[11] Lastly, the study will reflect on the waiver debate in the broader context of TRIPS and the imperative to enhance global pandemic preparedness for the future through the possibility of a global health treaty, and to reach health justice for the global South.

1.2 Important definitions and concepts

Before delving into the discourse surrounding public health and pharmaceutical products, this section establishes key definitions and concepts pertinent to this chapter and the broader study.

1.2.1 Intellectual Property

Intellectual property (IP) refers to "creations of the mind, such as inventions, literary and artistic works, designs, symbols, names, and images, used in commerce."[12] It encompasses legal rights that allow individuals or entities to control the use and dissemination of their creations, thereby providing incentives for innovation and creativity. Common forms of IP include patents (for inventions), copyrights (for literary and artistic works), trademarks (for brand names and logos), and trade secrets (for confidential information). These rights enable creators and innovators to benefit financially from their creations and encourage the development of new

[11] Thambisetty *et al* 2022 Camb Law Journal 392.
[12] WIPO 2022 https://www.wipo.int/about-ip/en/.

ideas and products, ultimately contributing to economic growth and societal progress.[13]

2.2.2 Patents

Article 27 of the TRIPS Agreement defines a patent as the exclusive right granted for an invention in any field of technology, provided it is new, involves an inventive step, and is capable of industrial application. To qualify for patent protection, an invention must meet three criteria: novelty, inventive step, and industrial applicability. These requirements align with section 25 of South Africa's Patents Act 57 of 1978. Patent protection grants the holder exclusive rights to market, sell, import, use, and exploit the invention for a period of 20 years from the date of registration. Once this 20-year period expires and no extension is granted, generic versions of the product may be produced without the need for consent from the patent holder, as the protection has lapsed.

2.2.3 Pharmaceuticals (medicines including vaccines)

As per Annex (a) of Article 31bis, a "pharmaceutical product" encompasses any patented product or product created using a patented process within the pharmaceutical industry. Patents within this sector cover various aspects, including the chemical composition of new drugs and, notably, newly developed vaccines that meet the criteria for patentability outlined earlier.

2.2.4 Generic medicine

Generic medicines are those that do not have patent or trademark protection, or whose protection has expired.[14] They may contain the same chemical ingredients as brand-name products.[15] For instance, Amoxicillin is a generic version of Augmentin, both being broad-spectrum antibiotics.[16] However, generic pharmaceuticals need only replicate the chemical composition of another product. They typically have different names and lack the registered trademark of the

[13] Van der Merwe *et al Law of Intellectual Property in South Africa* 3.
[14] WTO date unknown https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm03_e.htm.
[15] WTO date unknown https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm03_e.htm.
[16] WTO date unknown https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm03_e.htm.

original. This creates a distinction between lawful generics and unlawful ones, known as counterfeit medications. The legality depends on whether the original product still holds patent protection. If it does, any generic version is considered counterfeit. Conversely, if the patent has expired or the patent holder has granted reproduction rights, the generic is lawful.[17]

2.2.5 Developing country/lower middle-income country (LMIC)

A developing or lower-middle-income country is typically characterized by its relatively low gross national income (GNI) per capita, as defined by the World Bank. These countries often face economic challenges, including limited access to healthcare, education, and infrastructure development. They may also experience higher levels of poverty and inequality compared to higher-income nations.[18]

2.2.6 Developed country/ High income country

A developed or higher-income country is typically characterized by its high gross national income (GNI) per capita, advanced infrastructure, access to quality healthcare and education, as well as high standards of living. These countries often have well-established industrial and service sectors and exhibit low levels of poverty and inequality compared to lower-income nations.[19]

2.2.7 Global health justice

Global health justice refers to the ethical principle and practice of ensuring equitable access to healthcare and addressing health disparities on a global scale. It emphasizes the right of every individual, regardless of their socioeconomic status, geographical location, or other factors, to receive adequate healthcare and enjoy the highest attainable standard of health.[20] This concept acknowledges that health outcomes are influenced by various social, economic, and political factors, and

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[17] WTO date unknown https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm03_e.htm.
[18] World Bank. 2021 https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups.
[19] World Bank. 2021 https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups.
[20] Venkatapuram 2011 *Health justice: An argument from the capabilities approach 13-16*.

therefore, efforts to improve global health must address underlying injustices and structural inequalities. It advocates for policies and interventions that promote fairness, solidarity, and cooperation among nations to tackle health challenges collectively.[21]

2.2.8 Global health crises

A global health crisis refers to a widespread, often sudden, and severe threat to public health that affects populations across multiple countries or regions, potentially causing significant illness, death, and societal disruption. These crises can arise from various sources, including infectious disease outbreaks, natural disasters, environmental pollution, and humanitarian emergencies. Global health crises require coordinated responses from international organizations, governments, healthcare systems, and communities to mitigate their impact and prevent further spread.[22] This will be discussed in the light of the current pandemic, and to prepare for future pandemics.

2.2.9 Trade secret

In South African IP law, a trade secret is defined as confidential information that provides a business with a competitive advantage and is kept confidential through reasonable measures.[23] Trade secrets can include formulas, designs, processes, techniques, or any other information that is not generally known or readily ascertainable by others and provides economic value to the business. Unlike patents, trademarks, and copyrights, trade secrets are protected under the common law and statutory law in South Africa.[24] The protection of trade secrets is primarily governed by the common law principles of confidentiality and contract law. Additionally, South Africa has enacted legislation such as the Protection of Personal Information Act (POPIA) and the Competition Act, which may offer additional protections for trade secrets in certain contexts. Under South African law, to

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[21] Venkatapuram 2011 *Health justice: An argument from the capabilities approach. 16*.

[22] WHO Health emergency and disaster risk management framework 2020 https://www.who.int/hac/techguidance/preparedness/health-emergency-and-disaster-risk-management-framework-2019/en/.

[23] Kleyn et all *Trade Secrets - South Africa* 2021 6.

[24] Kleyn et all *Trade Secrets - South Africa* 2021 6.

maintain trade secret protection, businesses must take reasonable steps to maintain the secrecy of the information.[25] This may include implementing confidentiality agreements, restricting access to the information on a need-to-know basis, and implementing security measures to prevent unauthorized access or disclosure. In cases of misappropriation or unauthorized use of trade secrets, businesses may seek remedies such as injunctions, damages, or other appropriate relief through civil litigation in South African courts.[26]

2.2.10 Free trade/ Free trade agreements

Free trade refers to the exchange of goods and services between countries without the imposition of tariffs, quotas, or other barriers to trade. It is based on the principle of comparative advantage, wherein each country specializes in producing goods and services in which it has a relative efficiency, leading to increased economic efficiency and overall welfare. Free trade promotes competition, fosters economic growth, and expands consumer choice by allowing countries to access a wider range of goods and services at lower prices.[27]

Free trade agreements (FTAs) are treaties between two or more countries that facilitate free trade by reducing or eliminating tariffs, quotas, and other trade barriers on specified goods and services. These agreements aim to liberalize trade and promote economic integration among participating countries. FTAs typically include provisions related to market access, rules of origin, trade facilitation, intellectual property rights, investment protection, and dispute resolution mechanisms.[28]

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[25] Kleyn et all *Trade Secrets - South Africa* 2021 6.
[26] Kleyn et all *Trade Secrets - South Africa* 2021 6.
[27] WTO 2022 Understanding the WTO: What is free trade? https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm.
[28] WTO 2022 Understanding the WTO: What is free trade? https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm.

2.2.11 Most Favoured Nation

Most Favoured Nation (MFN) treatment is a principle in international trade whereby countries agree to extend to each other the same trade concessions, privileges, and advantages granted to any other trading partner. In other words, if a country grants preferential treatment (such as lower tariffs or import quotas) to one trading partner for certain goods or services, it must also extend the same treatment to all other trading partners covered by the MFN principle. This principle aims to promote non-discrimination and equal treatment in trade relations among countries.[29] *2.2.12 Treaty*

A treaty is a formal agreement between two or more sovereign states or international organizations, establishing legally binding obligations and commitments for the parties involved. Treaties can cover a wide range of subjects, including matters of peace, trade, disarmament, human rights, and environmental protection. They are typically negotiated through diplomatic channels and may require ratification by the participating states' respective legislative bodies or other designated authorities before entering into force.[30]

1.2 Intellectual property rights at odds with human rights: COVID-19 and future global pandemics

Intellectual property rights (hereinafter IPRs) refer to legal protections afforded to producers and creators for their intellectual creations and consist of a variety of exclusive rights such as trademarks, trade secrets, copyright, and patents.[31] There are constant interactions between human rights and IP, as IPRs by their very nature impact access to certain otherwise public goods and services, and the fundamental principle at play is balancing these private, exclusivity rights with the public's interest in both the production and dissemination of information and technology.

[29] United States International Trade Commission 2016 *The Economic Effects of Significant U.S. Import Restraints: Eighth Update* https://www.usitc.gov/publications/332/pub4619.pdf. 2-3.
[30] United Nations Treaty Collection, https://treaties.un.org/Pages/Overview.aspx.
[31] Van der Merwe *et al Law of Intellectual Property in South Africa* 3.

Strong monopolies are created by the protections afforded by patents and trade secrets, especially over pharmaceuticals, which enable companies to price their products near the maximum market price, consequently making them unaffordable to many countries and their citizens.[32] While the demand for many consumer products is elastic, that for pharmaceuticals is inelastic. This means that if consumer products are charged at monopoly prices, this would be merely inconvenient in terms of affordability, but maximum market prices on pharmaceuticals could make unaffordability dire, as the products concerned are needed and not a substitutable convenience.[33] Internationally recognised human rights to life, health, and access to science and its applications are thereby compromised. It is argued that IPRs have the potential to diminish the rights to health[34] and society's right to benefit from scientific advancements.[35] It further restricts the free flow of knowledge and ideas, thus stifling further innovation.

Counterarguments include that IPRs provide economic incentive for individuals to continuously contribute to the betterment of society through innovation. Of all the industries, perhaps no other industry relies as heavily on IP protection as the pharmaceutical industry.[36] Innovation in the field of medical technologies and medicines, however, is different from innovation in other sectors, due to the ethical dimension of the research, the need for a demanding and precise regulatory framework, questions of liability, the expensive cost of medical research and development (R&D), and then undoubtedly the great risk of failure[37] – all of which result in high fixed and sunk costs for these companies.[38] The economic premise underlying the patent system is that the granting of patents is necessary to incentivise individuals to invent, disclose, and commercialise their inventions;[39] but it should also be recognised that this incentivisation comes at a cost, such as the potential abuse of the exclusive rights afforded to the patent holder, for example,

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[32] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[33] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[34] Van der Merwe *et al Law of Intellectual Property in South Africa* 11.
[35] This right is echoed in Art. 15(1)(b) the *ICESCR*.
[36] Cowart *et al* Laws 2023 1.
[37] WIPO *et al Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual Property and Trade* 8.
[38] Cowart *et al* Laws 2023 1.
[39] McManis CR and Contreras J American University, WCL Research Paper 118.

by charging excessive prices.[40] Patents paired with trade secrets, or should one say excessively strong patent and trade secret protection, limit and diminish healthy competition, create artificial scarcity, reduce the availability of products and finally increase the prices of these products, as will be discussed in the following chapters. Therefore, patents can potentially create barriers to accessing life-saving medicines, medical technologies and, as seen more recently, vaccines.

Conversely, international customary law and international treaties currently globally establish the rights to life, health, and science. The right to health is a fundamental right that imposes a responsibility on governments to guarantee the availability, accessibility, acceptability, and quality of health facilities, services, and goods, which includes vaccines.[41] In the context of COVID-19 vaccines, it is of the utmost importance that their production and availability are accompanied by comprehensive measures to ensure universal accessibility for all individuals. Various international legal instruments establish the right to health, including Article 25 of the Universal Declaration of Human Rights (UDHR) and Article 12(1) of the International Covenant on Economic, Social, and Cultural Rights (ICESCR). The U.N. Committee on Economic, Social and Cultural Rights, the independent expert committee supervising implementation of the ICESCR, has shed some light on the normative content of Article 12. Its General Comment No. 14 on the Right to the Highest Attainable Standard of Health considers health a fundamental and indispensable human right crucial for the fulfilment of any other human right.[42] Consequently, governments are prohibited from acting in a manner that threatens an individual's right to live or exist.[43] A government's failure to adequately address a disease outbreak can constitute the deprivation of the right to life.[44] This would cover failure to regulate the availability, accessibility, cost, and quality of pharmaceuticals, but also failure to regulate the activities of private actors in the health sector.[45] Most governments have entrenched the right to health in their domestic legislation, which places a

[40] McManis CR and Contreras J American University, WCL Research Paper 118.
[41] See CESCR 2000 General Comment No 14 para 12.
[42] CESCR 2000 General Comment No 14.
[43] Abbott 2003 Oxford University Press 280.
[44] Abbott 2003 Oxford University Press 280.
[45] Hallo De Wolf and Toebes 2016 Health Human Rights 89.

positive obligation upon them to progressively realise this fundamental right by taking necessary steps. Being able to access essential medical technologies and medicines is one of the required elements to fulfil every individual's right to the "enjoyment of the highest attainable standard of health."[46] Article 6(1) of the International Covenant on Civil and Political Rights (ICCPR) protects every human being's inherent right to life. Article 15(1)(b) of the ICESCR protects every person's right to "enjoy the benefits of scientific progress and its applications", that is, the right to science. The latter covers access to affordable and good quality vaccines and medicines as a human right, as may be inferred from the Committee's recent General Comment No. 25 on the Right to Science.[47] States have both domestic and extraterritorial obligations under human rights, including protecting and promoting the rights to life, health, and science. This requires them not only to protect these rights of their own citizens, but they also bear some responsibility to people beyond their borders, obliging them *inter alia* to create an international environment conducive for the universal fulfilment of economic, cultural and social rights.[48] – for example, through the endorsement of a global health regime that ensures access to essential medicines. A State's ability to ensure access to affordable medicines and to promote further medical research and innovation, as required by the rights to life, health, and science, can be negatively impacted by IPRs. The current COVID-19 pandemic serves as a good example of the free flow of knowledge and technology from the global North to the global South having been unacceptably slow and ineffective, with vaccine and treatment shortages having driven many economies to the ground, as nations across the world, especially in the low/middle-income countries (LMICs), experience a dual impact from pandemics, with short-term fiscal implications and long-term economic consequences.[49] In light of economies struggling with the fallout of the pandemic, patent holders still charge monopoly prices on medicines, leaving them unaffordable to more vulnerable

[46] WIPO *et al Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual Property and Trade* 8.
[47] CESCR 2000 General Comment No 25.
[48] ETO Consortium date unknown https://www.etoconsortium.org/en/what-are-etos/.
[49] Shang *et al* 2021 Frontiers in public health 2.

populations and barring further participation in medical research and development relating to improved or cheaper drugs by competitors.[50]

One may have a closer look at how the IP regime carefully packages and protects these medicines (including vaccines), diagnostics and treatments. A good example is a single rapid antigen test. This product can have copyrights, trade secrets, trademarks, and patents protecting it.[51] The most problematic IP protection lies in trade secrets and patents, as they can significantly impede equitable access.[52] The value of trade secrets are that they keep commercially valuable information confidential, protecting them against unfair appropriation by competitors.[53] If the inside know-how and knowledge regarding the production of the vaccine is not shared, other manufacturers will accordingly not be able to exploit them competitively and only encounter trail and errors in an attempt to replicate them.[54] Contrastingly, the granting of patents requires that both the invention and the best way of executing it must be disclosed, but due to the protection that a patent offers, the disclosed invention is barred to be used by any other parties for the 20 year lifespan of the patent.[55] The misuse of the patent monopoly arises when the conduct of the patent-holder undermines the economic and social objectives of the patent system.[56] This type of misconduct can take on different forms, including inadequate disclosure of the invention, failure to make use of or insufficient use of the patented invention, and engagement in exploitative practices in licensing agreements.[57] (As was the case during this pandemic, where the information disclosed in the patent is insufficient for a person skilled in the art to replicate it without any additional information; where supply for the patented vaccines and related COVID-19 products did not sufficiently meet demand due to vaccine hoarding in the Global North; and finally there were numerous accounts of exploitative practices in licensing agreements, such as the lack of price transparency and that countries in the Global

[50] WIPO *et al Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual Property and Trade* 12.
[51] Gleeson *et al* 2023 Medical Journal of Australia 46.
[52] Gleeson *et al* 2023 Medical Journal of Australia 46.
[53] Gleeson *et al* 2023 Medical Journal of Australia 46.
[54] Gleeson *et al* 2023 Medical Journal of Australia 46.
[55] Gleeson *et al* 2023 Medical Journal of Australia 46.
[56] Roffe 1974 World Development p15-26.
[57] Roffe 1974 World Development p15-26.

South had to pay higher rates for the same vaccines and products, as will be discussed in the following chapters.) Patent disclosure refers to the public's claim to information regarding an invention. A disclosure of substandard quality may pose a risk of giving the impression of concealment. Currently, the problem is that many patents do not disclose information in a way that would enable the invention to be worked by a person skilled in the art.[58] Also, these days test data is increasingly protected for a certain number of years after the expiry of a patent, affording additional protection to the original right holder to prevent reliance on clinical test data to produce a generic. These data would thus have to be produced anew, increasing costs. This would mean that even the granting of a CL would potentially render no benefits.

For example, the European Union (EU), when considered in its entirety, holds the distinction of being the foremost global manufacturer of vaccines.[59] European legislation provides patent-independent regulatory exclusivity for both small molecule drugs and biologics, such as vaccines.[60] A drug is granted automatic data protection (trade secret protection) upon approval, for a period of eight years, as long as it is within Europe the first marketing authorization (MA) for that specific active ingredient.[61] No third party during this timeframe, including competitors attempting to file an abridged generic application, can access the data contained in the regulatory dossier of the reference medicinal product.[62] An approved medication also obtains a decade (10 years) of market exclusivity commencing from the approval date, safeguarding the reference product from competitors for the duration of this period.[63]

[58] Ouellette 2012 Harvard Journal of Law & Technology 590.
[59] Mukherjee *et al* 2023 PLOS Glob Public Health 11.
[60] Sinha *et al* 2023 Cambridge University Press 2.
[61] Mukherjee *et al* 2023 PLOS Glob Public Health 10.
[61] Sinha *et al* 2023 Cambridge University Press 2.
[62] Mukherjee *et al* 2023 PLOS Glob Public Health 11.
[62] Sinha *et al* 2023 Cambridge University Press 2.
[63] Mukherjee *et al* 2023 PLOS Glob Public Health 11.
[63] Sinha *et al* 2023 Cambridge University Press 2.

Public health, IP and IP-related trade have been in tension with each other for a very long time.[64] For developed countries, IP promotes innovation, including new medicines (and vaccines). The promise of IP for the developing world was to bring in foreign direct investment and then again turn it into development, but unfortunately it also raised cost of products such as vaccines and medicines and limited access to these in most parts of the globe.[65] A growing dichotomy in the pandemic is becoming evident, as wealthier nations (Global North) gain access to vaccines while poorer nations (Global South) are left behind.[66] The inequitable distribution of vaccines and dissemination of knowledge and technology regarding the production of vaccines and related life-saving products, not only exposes countless individuals to the virus but also facilitates the emergence of lethal variants that can rebound globally. As these variants persist and spread, even countries with well-established vaccination initiatives are compelled to reintroduce more stringent public health measures, including travel and trade restrictions.[67] Consequently, the ongoing pandemic exacerbates the divergence in economic prosperity, resulting in adverse outcomes for all parties involved. Consequently, a global solution to the COVID-19 pandemic and any other comparable future health crisis would have to establish a balance between IP protections for medicines (including vaccines) and access to these, as one important pillar.

Essential pillars for a comprehensive global health treaty encompass an "all-of-government and all-of-society approach",[68] the enhancement of the capacities and resilience of nations, regions, and the global community to effectively combat future pandemics.[69] The treaty should prioritize equity, transparency, and fairness in order to guarantee just and efficient collaboration in addressing global health crises.[70] With the lessons learned during the COVID-19 pandemic, the treaty should aim at presenting a crucial opportunity to enhance regional institutions in Africa through

[64] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[65] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[66] WTO World Trade Organization joint statement.
[67] WTO World Trade Organization joint statement.
[68] WHO Covid-19 shows why united action is needed for more robust international health architecture, world health organization.
[69] WHO Covid-19 shows why united action is needed for more robust international health architecture, world health organization.
[70] Evaborhene *et al* 2023 BMJ Global Health 1.

capacity building, free flow of knowledge and urgent technological transfers, particularly within a multipolar global landscape characterized by significant disparities in power and resources.[71] Then finally, the current fiscal space in several nations is more constrained than ever before.[72] The treaty should propose the implementation of comprehensive structural alterations, encompassing debt restructuring and other measures, to expand the capacities of these countries.[73]

The aforementioned pillars are extremely general and passive, and the outcomes might still result in disparities if there is not drastic intervention to ensure that the global South and North are brought onto the same footing. In order to address the disparities in global health equity, it is necessary to change the *status quo* and to establish a new public health order in the global South. During the United Nations General Assembly held in New York in September 2022, African leaders collectively expressed their urgent appeal for the establishment of a New Public Health Order. This transformative order, which deviates from the outdated colonial paradigms of development, encompasses a comprehensive strategy aimed at achieving sustainable health outcomes and ensuring health security across the African continent. This visionary plan is based on five fundamental pillars, namely "strong African Public Health Institutions; Investment in Public Health Workforce and Leadership Programs; Increased Domestic Investment in Health; Respectful, Action-Oriented Partnership and Expanded Manufacturing of Vaccines and Diagnostics."[74] This action taken by African leaders serves to emphasize once again the previous initiative put forth by the Africa Centers for Disease Control and Prevention (Africa CDC), which called for a greater emphasis on country leadership and ownership, as well as regional approaches, in tackling health security and disparities following the West Africa Ebola Outbreak.[75] This very same initiative was also apparent in response to the COVID-19 pandemic and has now become even more imperative

[71] Evaborhene *et al* 2023 BMJ Global Health 1.
[72] Evaborhene *et al* 2023 BMJ Global Health 1.
[73] Evaborhene *et al* 2023 BMJ Global Health 2.
[74] African Union Africa's new public health order.
[75] Nkengasong *et al* 2017 Lancet Glob Health.

due to the significant disparities in access to diagnostics, treatments, and vaccines that have afflicted the continent during the COVID-19 crisis.[76]

Until such time as a global health treaty has been realised, the current rules of international IP law would have to be read in the light of international human rights law to address serious global health challenges as best as possible under the existing rules. This may be stated to be a demand of the integration rule contained in Article 31(3)(c) of the Vienna Convention on the Law of Treaties.[77] It requires any treaty, thus also TRIPS, to be read in the light of any other relevant international agreements applicable between the parties. Relevant international agreements include the human rights agreements referred to above. Hence, a balance between the incentive and monopoly effect of a patent and access to vaccines and medicines to protect lives, public health, and access to science's benefits needs to be ensured.

1.3 TRIPS flexibilities and a COVID-19 waiver: Enough to address future health crises?

The COVID-19 pandemic reignited the concern of the 1990s and 2000s that TRIPS may not be able to adequately facilitate or address public health emergencies and more specifically the public health of developing nations. TRIPS does have certain instruments at its disposal when IPRs interfere with effective action during a public health crisis, often referred to as the TRIPS flexibilities. These flexibilities include parallel importations (PIs)[78] and compulsory licences (CLs).[79] Another potential instrument is competition law.[80]

Article 6 of TRIPS does allow (but not oblige) TRIPS Members to opt for international exhaustion schemes for IP rights, which would allow PIs. PI of cheaper patented products potentially available on the markets of other countries can take place where a country's patent system, as permitted by TRIPS, allows this. PIs, also referred to as "grey-market" imports, involve the legitimate production of goods

[76] Nkengasong and Tessema 2020 Cell.
[77] Vienna Convention on the Law of Treaties of 1980.
[78] See TRIPS Art 6.
[79] See TRIPS Art 31.
[80] See TRIPS Arts 8, 40.

under the safeguard of a trademark, patent, or copyright.[81] These goods are then introduced into a specific market and subsequently imported into another market without the explicit authorization of the local IPRs owner.[82] Generally, this owner is a local licensed dealer.[83] To illustrate, a trading firm has the legal right to procure quantities of prescription drugs in Germany and import them into Spain or Sweden without obtaining approval from the local distributor who holds the licensed patent rights. Compulsory licensing means that a national court or authority can grant licences to allow the production of a certain vaccine or medicine without the consent of the patent-holder, as long as adequate remuneration is provided for, in notably a situation of a public health emergency. Article 31 of TRIPS provides for CLs.[84] Competition law can allow for measures to be taken, for instance, where a company with a dominant position (e.g., by virtue of a patent) charges excessive prices. Articles 8(2) and 40 of TRIPS allow States to grant measures where companies engage in anti-competitive conduct. Effective measures include *inter alia* CLs under Article 31 of TRIPS. All these measures have historically been underutilised by States, as they have been proven to be problematic in securing equitable access to affordable medicines in developing countries, as will be discussed in depth in proceeding chapters.

Unfortunately, even with these measures in place, it has not been possible to keep prices affordable and medicines available to developing countries during the HIV/AIDS outbreak. The WTO therefore adopted the Doha Declaration on TRIPS and Public Health at the WTO Ministerial Conference in 2001 to reaffirm the TRIPS flexibilities and emphasise that Member States should use them if needed, as these could provide better access to essential medicines by circumventing patent rights.[85] Doha places emphasis on the protection of public health and the promotion of access to medicines for all,[86] implying the inclusion of the poorest segments of our

[81] Maskus Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries 2.
[82] Maskus Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries 2.
[83] Maskus Parallel Imports In Pharmaceuticals: Implications for Competition and Prices in Developing Countries 2.
[84] Article 31 of the TRIPS Agreement, 1995.
[85] WTO "Doha Declaration on the TRIPS and Public Health, WTO Ministerial Conference".
[86] See Paragraphs 4 to 6 of the Doha Declaration.

society. The Declaration also confirms the authority to all WTO Members to determine what constitutes a public health emergency and to act in a public health emergency.[87] Situations that usually constitute a public health emergency are situations where the health consequences are so severe that they have the potential to overwhelm or overburden a state's capabilities to address the emergency.[88] With COVID-19 pushing the whole world into a global lockdown, paired with high mortality rates, economic devastation, and with overburdened healthcare sectors, it is sufficient to say that it constituted a public health emergency. Since its emergence in 2019, numerous variants still plague the globe in the time of writing this dissertation. The Omicron derivative exhibits over 35 mutations in crucial segments of the virus in contrast to XBB.1.5, the prevailing variant during the majority of 2023.[89] This figure is approximately equivalent to the number of mutations observed in the Omicron variant, which led to unprecedented infection rates compared to its precursor. Furthermore, a significantly mutated COVID-19 variant known as BA.2.86 has recently been identified in Switzerland and South Africa, in addition to its presence in Israel, Denmark, the US, and the United Kingdom.[90] Regarding potential new pandemic threats, following a notable decline to an unprecedented minimum of five occurrences of wild poliovirus in the year 2021, the statistics have experienced an upsurge in 2023. Pakistan has reported a total of 20 cases, Afghanistan has documented two cases, and Mozambique has recorded eight cases.[91] In May 2022, a sudden and rapid outbreak of Monkeypox (Mpox) emerged, swiftly disseminating throughout Europe, the Americas, and subsequently encompassing all six regions under the jurisdiction of the WHO.[92] A total of 110 countries reported approximately 87 thousand cases and 112 fatalities.[93] The important point to take from this is that these are not the only global health crises that have emerged, and they certainly are not the last.

[87] Para 4(c) of the Doha Declaration.
[88] Nelson *et al* 2007 Am J Public Health 4.
[89] Rigby and Steenhuysen 2023 Reuters.
[90] Rigby and Steenhuysen 2023 Reuters.
[91] Ghebreyesus Seventy-sixth World Health Assembly.
[92] Mpox (monkeypox) 2023 https://www.who.int/news-room/fact-sheets/detail/monkeypox.
[93] Mpox (monkeypox) 2023 https://www.who.int/news-room/fact-sheets/detail/monkeypox.

It should also be explored why the TRIPS flexibilities are virtually unused by countries of the global South. It would seem that the flexibilities are ineffective for these countries and better suited for countries of the global North during public health emergencies, as will be discussed below. Developing nations have found themselves in a vulnerable position due to the prevalence of free trade agreements (FTAs) that include TRIPS-Plus provisions, which entail stronger IP protections compared to what is outlined in TRIPS. As a result, these nations have been compelled to prioritize the interests of developed countries while compromising on the utilization of TRIPS flexibilities.[94] Under FTAs, a CL might thus be seen as an act of forbidden expropriation of property as an investment. Also, the regulation of IP PIs (Intellectual Property Parallel Importations) within the pharmaceutical industry has emerged as a crucial concern within the global trading system.[95] Proponents of robust international patent rights for novel medications advocate for a worldwide prohibition of PI, contending that widespread acceptance of such trade would diminish profits within the research-driven pharmaceutical sector and impede the progress of innovative drug development.[96] TRIPS-Plus has expanded IP protection while further limiting or completely restricting the use of the provided flexibilities.[97] Other factors that discourage developing countries from using any flexibilities during the COVID-19 pandemic (or any other public health emergency) include pharmaceutical firms creating broader IP "thickets" of various patents, trade secrets, copyrights and industrial designs, effectively making it harder to obtain CLs to produce one product since each type of these protections surrounding COVID-19 vaccines and technologies requires a licence.[98] The current TRIPS flexibilities also do not encompass all the crucial elements of IP needed to produce COVID-19

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94 Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf 16.

95 Maskus Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries 2.

96 Maskus Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries 2.

97 Bing 2021 Global Economic Governance Initiative 2.

98 Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf 18.

vaccines and medical technologies, such as trade secrets.[99] And then finally, developing nations who attempt to use these flexibilities are faced with geopolitical and legal attacks by powerful nations.[100] IP on vaccines and COVID-19-related products have become yet another global geopolitical weapon, where any attempt to use TRIPS flexibilities are barred by FTAs that incorporate TRIPS-Plus provisions that extend IP protection beyond what TRIPS allows, or Big Pharmaceutical companies who initiate intense legal actions against countries who set out to use these flexibilities, in an attempt to protect and enforce their monopoly power in the market. Disputes related to the use of TRIPS flexibilities and challenges to intellectual property (IP) on vaccines and COVID-19-related products often occur before national courts rather than through the WTO Dispute Settlement Body (DSB), as private actors typically initiate these legal actions.[101] For example, the mRNA vaccines possess a recipe that if replicated by any external entity other than Pfizer, could result in a high probability of facing a massive legal action.[102] It is clear that the current instruments are not working. It is necessary to focus on what can be done in the future to prevent unequal distribution of vaccines and related patented medical products in situations of a health crisis, to prepare rollout plans that are pro-poor from the beginning and to ensure that innovation is not stifled. There are constant interactions between trade, IPRs, competition law and human rights. These intersections must be harmonised to increase access to medical technologies and medicines.[103]

During the COVID-19 pandemic, South Africa and India introduced the proposal of a COVID-19 IP-related waiver to the TRIPS Council at the WTO in October 2020.[104] A COVID-19 IP-related waiver would suggest that all IP protections should be temporarily waived until the pandemic is under control. This proposal was received by WO Members with mixed feelings. It was felt by rich countries that this would

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[99] Gurgula and Hull 2023 Journal of Intellectual Property Law & Practice 16.
[100] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[101] *Brazil vs. Merck & Co.* 2007, *India vs. Pfizer* 2020, *South Africa vs. Pharmaceutical Manufacturers Association* 1997.
[102] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[103] WIPO *et al Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual Property and Trade* 8.
[104] Third World Network *India-South Africa Proposal for A Waiver from Certain Obligations Under the TRIPS Agreement* 1.

lead to diminished incentivisation to continuously improve the vaccine portfolio, and that, even if all countries did have the freedom to produce vaccines themselves, they would lack the know-how and facilities to produce quality vaccines.[105] But if one continues to use this as an excuse, the global South will always remain heavily reliant on the IP produced by the global North. Something that is often overlooked is that TRIPS stipulates the transfer of technology and building of manufacturing capacity benefiting least developed countries (hereinafter LDCs) as an obligation of developed States under article 66(2) of the TRIPS Agreement,[106] which cannot be realized if their vaccine production freedom is capped. This transfer of technology is simply not happening. The real issue is whether a few pharmaceutical corporations in the global North should retain complete control over whether and where production occurs, and thus control supply, price, and distribution globally.[107] It should also be appreciated that various countries of the global South do possess basic infrastructure and resources that, with some assistance from overseas, can develop their potential to replicate and even develop their own medicines (including vaccines). Examples of such countries include but are not limited to: India; Brazil; China; South Africa and Cuba.[108]

In a communiqué addressed to the Twelfth Ministerial Conference of the WTO, Achiume, the UN's Special Rapporteur, who was previously mentioned above, called for the adoption of a comprehensive COVID-19 waiver of TRIPS.[109] He stated that the COVID-19 pandemic has resulted in well-documented instances of vaccine discrimination, with marginalized groups experiencing disproportionate economic, social, and health-related adversities.[110] Unfortunately, the waiver proposal was ultimately accepted in a watered-down form in 2022, after a 20-month deadlock, and regrettably accomplishes little of what is really needed. It currently only

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[105] Third World Network 2020 https://twn.my/title2/resurgence/2020/345-346/cover01.htm 1.
[106] Correa 2002 University of Buenos Aires 36.
[107] Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf 18.
[108] Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf 18.
[109] Achiume United Nations OHCHR *UN expert urges States to end 'vaccine apartheid'.*
[110] Achiume United Nations OHCHR *UN expert urges States to end 'vaccine apartheid'.*

encompasses vaccines and does not extend to any other medical products associated with COVID-19. Its loose language fails to create obligations that Members must abide by and comes across as a tool that they can selectively utilize. Instead of the originally proposed comprehensive exemption of 35 TRIPS provisions, the current decision solely encompasses the exemption of a solitary provision, specifically Article 31 (f), which authorizes the exportation of vaccines under a CL.[111] Additionally, it is imperative to acknowledge that the duration of this decision has been limited to a span of five years.[112] The proposed TRIPS Waiver and the accepted watered-down version will be discussed in greater depth in the proceeding chapters, as the waiver will form the basis of what to expect in the final global health treaty.

1.4 Research question

Is there a need for a new global health strategy, notably safeguarding public health in the global South, entailing *inter alia* the adoption of a global health treaty, that would facilitate effectively responding to future health crises similar to the COVID-19 pandemic? If so, how should such strategy and treaty be designed in a way that achieves an adequate balance between the protection of intellectual property and human rights? Moreover, how would a treaty fit into the existing international intellectual property, human rights, and public health treaty architecture?

1.5 Research aim and objectives

1.5.1 ***Aims:***

1. To investigate the intersections of intellectual property rights (IPRs), human rights, and global health justice, particularly focusing on the implications for the global South during times of global health crises.

2. To examine the role of international intellectual property regimes, such as TRIPS-Plus agreements, in shaping access to essential medicines, healthcare technologies, and knowledge transfer between the global North and South.

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[111] Achiume United Nations OHCHR *UN expert urges States to end 'vaccine apartheid'.*
[112] Achiume United Nations OHCHR *UN expert urges States to end 'vaccine apartheid'.*

3. To assess the extraterritorial obligations of states in upholding the rights to health, life, and science, and their implications for addressing health disparities and promoting equity in global health governance.

4. To explore the potential of a comprehensive global health treaty in reconciling tensions between intellectual property rights and public health imperatives, with a specific emphasis on ensuring equitable access to healthcare resources for populations in the global South.

1.5.2 Objectives:

1. To critically analyse the impact of expansionist interpretations of Intellectual Property Rights (IPRs) and reductionist interpretations of competition law within TRIPS-Plus Agreements on access to essential medicines and technology transfer, particularly focusing on the disparity between industrialized and least industrialized countries.

2. To investigate the factors contributing to the underutilization of TRIPS flexibilities in developing countries, including geopolitical tensions and legal actions by pharmaceutical companies, and their implications for global health equity.

3. To assess the extent to which TRIPS-Plus agreements override TRIPS flexibilities, exacerbating vulnerabilities in developing nations and reinforcing monopolistic practices that hinder access to affordable treatments.

4. To explore strategies aimed at overcoming limitations imposed by TRIPS-Plus agreements and enhancing access to essential medicines and technology transfer in developing countries, with particular emphasis on the role of Intellectual Property (IP) waivers.

5. To examine the extraterritorial human rights obligations related to the rights to health, life, and science, and their implications for the international IP system during global health crises, emphasizing the responsibility of countries to protect the health rights of populations beyond their borders.

6. To analyse the potential impact of human rights obligations, including the principles of respect, protect, and fulfill, on international IP law, and their significance in promoting equitable access to healthcare technologies.

7. To evaluate existing proposals for IP waivers and other mechanisms aimed at addressing inequities in the global IP system and promoting access to essential medicines, considering their effectiveness and feasibility in the context of global health justice.

8. To provide suggestions as to how a new framework for a comprehensive and equitable global health treaty, informed by the analysis of the shortcomings of the current system and the identification of potential solutions to promote health justice for the global South during global health crises.

1.6 Research methodology

A literature review will critically analyse primary and secondary sources about IP and human rights law. Examples of primary sources are legislation, policies, treaties, and case law. Examples of secondary sources are books, chapters in books, and journal articles. A comparative method will be used to understand the disparities in access to medicines and vaccines in HICs and LMICs by looking at the Ip related transfer gap between the global Nort and the global South.

1.7 Scope of study and its limitations

The main focus of this study will be on the relationship between human rights, more specifically the right to health, and IPRs of the pharmaceutical sector. The study will focus on how IP is currently creating barriers to realize the right to health. This is fundamental to understand the need for a comprehensive global health treaty, that could balance these rights in order to achieve health justice for global South, who are most impacted by pandemics. The study will place emphasis on the need for the global exchange of technology and know-how in order to build capacity for the global South to participate in the production and distribution of vaccines, and to achieve global vaccine equity.

The main subject of this study is the effect of IP-protected pharmaceuticals under the TRIPS Agreement and its amendments. The study examines how this has influenced the balance between two important objectives: (i) the need to provide incentives for future development of pharmaceutical products by granting a monopoly through patent protection, and (ii) the need to ensure access to existing patented pharmaceuticals for countries whose citizens urgently require them.[113] It is important to acknowledge that although the study primarily examines the relationship between human rights and IPRs, there are other relevant factors such as IP-related trade and competition that are pertinent to the issue of accessing pharmaceuticals.

Though IP protection refers to an array of fields, such as trademarks; copyrights; designs etc, this study will place special emphasis on patents and trade secrets in the pharmaceutical sector and its impact during a global health crisis.

Although the manner which IP protection was formally integrated into international legislation and its deep-rooted history within the trade regime will be discussed, the study does not take into account other agreements and declarations formed under the General Agreement on Tariffs and Trade, 1994 (referred to as the GATT), as it focuses solely on the TRIPS Agreement and its subsequent amendments.

1.8 Framework of study

This study consists of seven chapters, each of which is elaborated upon below:

Chapter one presents a brief introduction to the dissertation and an overview is provided which includes the problem statement, research question, and the study's aims and objectives. Furthermore, the scope and limitations of the study are outlined.

Chapter two will give a concise summary of the origins and development of the current IP system. The interplay of trade, IP, and public health is remarkable, but it remains largely neglected. Throughout history, trade policy has exerted a significant

[113] WTO on TRIPS and Pharmaceutical Products 2006 https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm para 1.

influence on public health. IP protections are becoming more apparent in trade agreements, and this ultimately has an impact on the realization of human rights. To grasp this nexus, it is essential to gain a deeper understanding of IP's evolution within the trade regime.

Chapter three attempts to address the question if human rights and IPRs coexist or if they conflict. It will be explored if IP protected goods that are created for a pandemic situation should be regarded as a public good, instead of an exclusive property right. Consequently, this chapter asserts that it is crucial to strike a balance between IP regulations and universal human rights in order to guarantee that new knowledge can benefit everyone, rather than solely benefiting authors, creators, and inventors. Finally, it will revisit the consideration if TRIPS can adequately deal with a global health crisis, and if it is effective in facilitating the needs of the vulnerable global South during such a crisis.

Chapter four explores the vaccine gap between the global North and the global South and how geopolitics surrounding IP protectionism further exacerbates the negative impact of the pandemic on human lives and the economies of less affluent nations.

Chapter five will discuss the IP waiver proposal brought forth by South Africa and India, and what it sought to achieve during this time of urgent need to accelerate production and distribution of vaccines and related medical technologies. Further, it discusses the acceptance of the final waiver, and scrutinize its shortcomings.

Chapter six will explore the current negotiations for global health treaty and provide recommendations on how medical countermeasures should be formulated to achieve health justice in the global South and international equitable access to life-saving medicines (including vaccines) and technologies.

Chapter seven will give conclusionary remarks on the *status quo* and what is expected from a pandemic treaty to bridge the vaccine gap between the global North and South, and its importance in achieving health justice in the global South.

2 A brief overview of the history: intellectual property and its incorporation in international law

2.1 Introduction

This chapter offers a historical perspective on the interconnection between trade, human rights and IP. Additionally, it delves into the intricate subject of access to pharmaceuticals, while introducing significant concepts related to the access of medicines, including IP, trade, and human rights.[114] The chapter establishes the nexus between human rights, IP, and access to medicines within the framework of developing nations generally and the global South specifically.

The utilization of IP can be perceived as both an offensive tool, likened to a 'spear', and a defensive mechanism, akin to a 'shield', within a fiercely competitive business landscape.[115] The significance of IP continues to escalate progressively, with each passing day, month, and year, as an abundance of novel technologies are being created, potentially numbering in the thousands or even tens of thousands. These technologies are employed to enhance or introduce fresh attributes to existing products, or to generate entirely new products altogether.[116] Within this Chapter, the objective is to ascertain the rationale behind the significance of IP matters for trade, and ultimately how it impacts the realization of the fundamental human right to health. Further, this chapter will address the question of what potential impact the right to health could have on the reform of trade-related IPRs and the enhancement of accountability among corporate and state actors in ensuring worldwide availability of medications.[117] Considering the current global drug gap that is worsened by trade-related IP regulations,[118] these rules limit the ability of governments to obtain more affordable medications.

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[114] Akonumbo 2022 Pretoria University Law Press.

[115] World Intellectual Property Organization IP and International Trade https://www.wipo.int/export/sites/www/sme/en/documents/pdf/ip_panorama_9_learning_points.pdf.

[116] World Intellectual Property Organization IP and International Trade https://www.wipo.int/export/sites/www/sme/en/documents/pdf/ip_panorama_9_learning_points.pdf.

[117] Forman 2008 Health and Human Rights 37.

[118] Forman 2008 Health and Human Rights 37.

The phenomenon of global interdependence is a direct consequence of the process of globalization.[119] The notion of trade and its consequential importance for societies has surpassed the mere transportation of goods across national borders.[120] In the past, States were considered entirely separate and sovereign entities, but they have now become interdependent.[121] In modern international trade, a significant proportion of the exchanged value is derived from innovation, creativity, and branding.[122] This interdependence has led to the intertwining of the economic, social, and political survival of States with the success of their trading partners.[123] The evidence of this interdependency is particularly apparent in the market of patented pharmaceutical products, which are often desperately needed by individuals residing in both developed and developing States.[124]

Governments bestow upon creators the privilege of impeding others from utilizing their inventions, designs, or other artistic works, and to exercise this privilege in order to engage in negotiations for compensation in exchange for the utilization of said creations. These privileges are commonly referred to as "intellectual property rights."[125] The TRIPS Agreement is the most significant role-player in enabling the exchange of knowledge and creativity, resolving trade-related disputes pertaining to IP, and guaranteeing that WTO Members possess the autonomy to pursue their domestic responsibilities and objectives.[126] This Agreement serves as a legal acknowledgement of the profound nexus between IP and trade,[127] and consequently the realization of the human right to health. If IP causes trade barriers, access to IP-protected products, in this case vaccines and related life-saving

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[119] Sheth *et al* 2008 The Globalization of Markets and the rule of Three 26-41.
[120] WTO - Intellectual property: protection and enforcement https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm
[121] Roach 2014 Yale University Press 1-23.
[122] WTO - Intellectual property: protection and enforcement https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm
[123] Roach 2014 Yale University Press 1-23.
[124] Atkinson 2002 Washington International Law Journal 181-190.
[125] WTO - Intellectual property: protection and enforcement https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm
[126] WTO - Intellectual property: protection and enforcement https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm
[127] WTO - Intellectual property: protection and enforcement https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm

medicines and technologies, can have a detrimental effect on the realization of the universal right to health.

The foundational principles within the TRIPS Agreement found its starting point in the GATT. According to the aforementioned information, it can be inferred that the TRIPS Agreement constitutes an integral component of the WTO, as it is annexed to the GATT. The TRIPS Agreement specifically addresses international aspects of IPRs.[128] Hence, the TRIPS Agreement is a treaty formulated by the Members of the WTO, as previously stated, with the aim of establishing a more streamlined and standardized legal framework pertaining to international commerce, thereby fostering the principles of free trade and globalization. The TRIPS Agreement encompasses an additional crucial objective: the facilitation of technical innovation and technology transfer by protecting IP. As per the provisions of the TRIPS Agreement, it is imperative that both producers and users derive benefits, thereby contributing to the enhancement of economic and social welfare.[129]

2.2 The General Agreement on Tariffs and Trade (GATT)

After the end of the Second World War, governments were resolute in their determination to prevent a recurrence of the atrocities of the war and the collapse of the world order.[130] This entailed avoiding the economic errors of the 1920s and 1930s, particularly resulting in the creation of trade barriers.[131] While such measures were believed to safeguard national economies, the outcome was in fact economic devastation globally as trade between countries dwindled.[132] Consequently, in 1947, a comprehensive overhaul of the economic system was deemed necessary, supplementing the new political order established by the U.N. Charter of 1945.[133]

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[128] Gontijo 2005 Heinrich Böll Foundation 8.

[129] WTO - Intellectual property: protection and enforcement https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm

[130] WTO e-Learning From GATT to WTO https://www.youtube.com/watch?v=rdX3xPSywgU&ab_channel=WTOe-Learning

[131] WTO e-Learning From GATT to WTO https://www.youtube.com/watch?v=rdX3xPSywgU&ab_channel=WTOe-Learning

[132] WTO e-Learning From GATT to WTO https://www.youtube.com/watch?v=rdX3xPSywgU&ab_channel=WTOe-Learning

[133] WTO e-Learning From GATT to WTO https://www.youtube.com/watch?v=rdX3xPSywgU&ab_channel=WTOe-Learning

The pressing need for global stability and a sense of international community led to the establishment of key international organizations tasked with restoring economic cooperation and peace.[134] Governments eventually reached an agreement on a set of rules that would prevent those measures which had resulted in protectionism, epitomized by the resurgence of liberal theories from the nineteenth century.[135] This led to the establishment of the GATT in 1947, following an unsuccessful endeavour to ratify the Charter of the International Trade Organization (ITO).[136] The GATT was a treaty, signed by a coalition of 23 nations, aimed at mitigating impediments to global commerce through the elimination or reduction of quotas, tariffs, and subsidies.[137] Its primary objective was to stimulate economic recuperation in the aftermath of World War II.[138]

The creation of GATT was a reaction to the objectives of developed nations for free trade and multilateralism.[139] The primary objective of the initiative was to foster global commerce by mitigating or abolishing impediments to trade, such as levies (tariffs) or restrictions (quotas).[140]Although only 23 nations affixed their signatures to the GATT, it ultimately emerged as a significant contributor to global economic stability.[141]

GATT is a multinational trade accord that underwent a series of global trade negotiations comprising nine rounds from 1947 to 1995. Its significance in international trade was predominantly superseded in 1995 by the World Trade Organization (hereinafter WTO). GATT was founded upon the fundamental principles of trade liberalisation, namely the most-favoured-nation treatment

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134 WTO e-Learning From GATT to WTO https://www.youtube.com/watch?v=rdX3xPSywgU&ab_channel=WTOe-Learning

135 Kugler and Sucker (Southern) *African Priorities in International Economic Law* 233.

136 Kugler and Sucker (Southern) *African Priorities in International Economic Law* 233.

137 World Trade Organization. "The Text of the General Agreement on Tariffs and Trade https://www.wto.org/english/docs_e/legal_e/gatt47.pdf.

138 World Trade Organization. "The Text of the General Agreement on Tariffs and Trade https://www.wto.org/english/docs_e/legal_e/gatt47.pdf.

139 Kugler and Sucker (Southern) *African Priorities in International Economic Law* 233.

140 Kugler and Sucker (Southern) *African Priorities in International Economic Law* 234.

141 WTO e-Learning From GATT to WTO https://www.youtube.com/watch?v=rdX3xPSywgU&ab_channel=WTOe-Learning

principle (MFN)[142], national treatment (NT),[143] and the reciprocal reduction of trade barriers.[144] It is noteworthy that the majority of developing countries in Africa, Latin America, Central and Asia were either *de facto* or *de jure* colonies at the time when the developed countries formulated these principles.[145] As a result, they were not actively involved in shaping these rules, and they have since endeavoured to integrate into the system.[146] Their objective has been to align with the established rules and regulations.[147]

It is contended that developing nations merely obtained superficial concessions in the GATT that were more decorative, due to their lack of active participation in the early negotiations.[148] As a result of decolonisation during the late 1950s and early 1960s, newly emerged independent States began to disregard and reject the liberal principles that form the foundation of GATT.[149] These States argued that their "less-developed" status necessitated the establishment and protection of their economic independence.[150] In the interest of promoting equitable multilateral trade relations, they sought to gradually modify the GATT regulations to align with their economic realities.[151] These considerations led to the creation of Special and Differential Treatment (S&DT) for developing countries within the GATT, which acknowledges the differentiated legal status of these countries within the global trading system.[152] Subsequently, these deliberations were incorporated into the covered agreements of the WTO.[153]

To fully comprehend how GATT was formative of the IP system we currently know, it is important to understand how countries are classified as developed or

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[142] The policy does not engage in discriminatory practices towards individuals from the nations with which we engage in trade.
[143] The policy regards treating foreign nationals with equal favorability as one's own nationals is imperative.
[144] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 233.
[145] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 234.
[146] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 234.
[147] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 234.
[148] Collier 2006 World Economy 1423-1425.
[149] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 234.
[150] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 234.
[151] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 234.
[152] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 234.
[153] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 234.

developing, what S&DT is, and its impact on IP trading. The proponents of S&DT perceived it as an indispensable measure to promote the progress of developing nations via trade.[154] Conversely, its detractors regarded it as potential peril to the intricately established multilateral trading framework.[155]

2.2.1 The attainment of developed or developing status, and the consequential Special and Differential treatment regime

GATT and the ensuing ITO negotiations acknowledged the challenges encountered by developing nations and, as a result, incorporated clauses aimed at providing preferential treatment to facilitate their developmental endeavours.[156] It was pointed out by Brazil that developing nations could not be expected to achieve the same level of productivity and efficiency as countries that had been engaged in the same activity for several hundred years without allowing for a considerable period of time for this to happen.[157]

The matter at hand pertained to the rate of liberalization and, consequently, the adjustment of regulations in accordance with the developmental requirements of developing nations.[158] Despite the inclusion of the demands for special rights on the agenda and their partial granting during the development of the now-defunct ITO's Charter (Havana Charter),[159] the provisions for Special and Differential Treatment (S&DT) as currently found in WTO-covered agreements are largely the result of efforts conducted under the auspices of the United Nations (hereinafter the UN).[160] While the UN Conference on Trade and Development (UNCTAD) was established only in the immediate aftermath of the 1964 decolonization,[161] its impact on forming

[154] Graham 1978 American Journal of International Law 513.
[155] Graham 1978 American Journal of International Law 513.
[156] Wilkinson 2008 World Trade Review 51–57.
[157] Lamp 2017 World Trade Review.
[158] See Lamp 2017 World Trade Review; and Wilkinson 2008 World Trade Review 482.
[159] Havana Charter for an International Trade Organization, drafted April 1948 https://www.wto.org/english/docs_e/legal_e/havana_e.pdf
[160] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 237.
[161] Establishment of the United Nations Conference on Trade and Development as an organ of the General Assembly.

S&DT, which was subsequently endorsed in the GATT's work, cannot be overstated.[162]

From a legal perspective, the principle of S&DT justifies the deviation from the fundamental principle of non-discrimination in favour of developing nations.[163] This implies that the rights or privileges provided by the covered agreements of GATT/WTO are applicable solely to developing countries and not to developed nations.[164] In determining the status of developed or developing nation, and to claim with it its benefits, Members have adopted the principle of self-selection.[165] This resulted in, apart from the LDCs which are considered the most impoverished nations globally, any nation asserting its developing status could potentially avail itself of the Generalized System of Preferences (GSP).[166] The aim of the GSP was threefold: to enhance the export earnings of developing nations, to foster their industrialisation, and to expedite their rates of economic growth.[167] There are some advantages to having a "developing" country status under the WTO, as it bestows certain rights.[168] This includes some WTO agreements allowing longer transitional periods before fully enforcing such agreements to developing countries and granting developing States technical assistance.[169]

2.3 The Uruguay Round

The Uruguay Round constituted the eighth iteration of multilateral trade negotiations (MTN) held under the auspices of GATT.[170] Spanning the period from 1986 to 1994, the Round involved the participation of 123 countries as "contracting

[162] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 237.
[163] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 237.
[164] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 237.
[165] Yusuf 1980 Journal of World Trade Law 488-494.
[166] Yusuf 1980 Journal of World Trade Law 494.
[167] [167] Kugler and Sucker (Southern) *African Priorities in International Economic Law* 239.
[168]World Trade Organization. "The Text of the General Agreement on Tariffs and Trade https://www.wto.org/english/docs_e/legal_e/gatt47.pdf.
[169]World Trade Organization. "The Text of the General Agreement on Tariffs and Trade https://www.wto.org/english/docs_e/legal_e/gatt47.pdf.
[170] Cline 1995 The World Economy 1.

parties".[171] Its outcome was the establishment of the WTO, with GATT continuing to serve as an essential component of the WTO agreements.[172]

The overarching objective of the Round was to expand the GATT regulations to sectors that were previously excluded due to their complexity in terms of liberalization, such as agriculture and textiles, as well as to encompass emerging and significant areas that were previously not covered, including trade in services, investment policy, trade distortions and most importantly for this discussion, IP.[173] It was sought to not only include IP protection, but additionally formulated a set of regulations aimed at addressing instances of copyright infringement and other types of violations pertaining to IPRs.

The Uruguay Round marked a significant milestone, as it was the inaugural instance of multilateral trade negotiations wherein developing nations actively participated.[174] The Uruguay Round was concluded in 1994, with deadlines expiring in 2000 (and 2004 for developing country contracting parties), under the administrative guidance of the newly established WTO.[175]

2.4 The establishment of the World Trade Organisation

GATT was operative until 1 January 1995, at which point the WTO was instituted subsequent to the accord reached by 123 nations in Marrakesh on 15 April 1994, as an integral component of the Uruguay Round Agreements.[176] The WTO is the successor of GATT, and the initial GATT text (GATT 1947) remains in force within the framework of the WTO, subject to the amendments of GATT 1994.[177] It is however noteworthy that the GATT was a legal instrument, and not an organization as the WTO is. Fifty years subsequent to its establishment, the WTO currently boasts

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[171] Cline 1995 The World Economy 1.
[172] Cline 1995 The World Economy 1.
[173] Cline 1995 The World Economy 1.
[174] " Trade Negotiations Committee "*Multilateral Trade Negotiations the Uruguay Round*" 1994.
[175] World Trade Organization "WTO legal texts: The Uruguay Round agreements" Uruguay Round – General Agreement on Tariffs and Trade 1994.
[176] " World Trade Organization What is the World Trade Organization?, https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm.
[177] " World Trade Organization "WTO legal texts: The Uruguay Round agreements" Uruguay Round – General Agreement on Tariffs and Trade 1994.

a membership of 164 nations. It has assumed the responsibilities of its predecessor, the GATT, while also expanding its purview to encompass novel domains of commerce such as international banking, telecommunications, and high technology innovations. The GATT, in its time, brought a sense of structure and organization to the chaotic realm of global trade.

Various perspectives exist regarding what the WTO is. It serves as an institution aimed at promoting trade liberalization.[178] It provides a platform for governments to engage in negotiations pertaining to trade agreements.[179] Additionally, it serves as a venue for the resolution of trade disputes. Furthermore, the WTO administers a comprehensive framework of trade regulations.[180]

While the GATT primarily focused on the trade in goods, the WTO and its associated agreements currently encompass trade in services, as well as the exchange of IP, including inventions, copyrightable works, trademarks and designs.[181] As explained above, these IP protections have had a severe impact on the equitable availability of vaccines, lifesaving treatments and technologies. It is evident that the development of safe and effective vaccines in an unprecedented timeframe was solely achieved through collaborative efforts across international boundaries by scientists.[182] Therefore, it is imperative that we continue to collaborate across borders in order to address the issues pertaining to vaccine scarcity and equitable access. This predicament is a matter concerning the global community, and it is incumbent upon Members to collectively find a resolution.[183] It is imperative that all barriers to the expansion of supply are eradicated. This dissertation strongly suggests that Members of the WTO accelerate negotiations towards a viable solution

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178 World Trade Organization What is the World Trade Organization?, https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm.

179 World Trade Organization What is the World Trade Organization?, https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm.

180 World Trade Organization What is the World Trade Organization?, https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm.

181 World Trade Organization What is the World Trade Organization?, https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm.

182 World Trade Organization DG Okonjo-Iweala Chair Summary following "COVID-19 and Vaccine Equity: What Can the WTO Contribute?" https://www.wto.org/english/news_e/spno_e/spno7_e.htm.

183 World Trade Organization DG Okonjo-Iweala Chair Summary following "COVID-19 and Vaccine Equity: What Can the WTO Contribute?" https://www.wto.org/english/news_e/spno_e/spno7_e.htm.

regarding IP. Numerous LMICs are actively striving to bolster their domestic manufacturing capacities, a critical endeavour not only in effectively combating the ongoing pandemic, but also in adequately preparing for potential future outbreaks.[184]

It is difficult for governments to realize the human right to health due to obstacles not only created by IP on vaccines, but particularly IP-trade-related obstacles. The issues that need to be addressed encompass increasing production and ensuring fair distribution and administration of vaccines,[185] and it is therefore crucial to explore the potential role of the WTO in supporting these efforts. The facilitation of cross-border trade in raw materials and other essential inputs is imperative for the sustenance and expansion of production. It is crucial to ensure the uninterrupted maintenance of supply chains pertaining to these inputs.[186] Numerous experts have underscored the importance of the upcoming establishment of vaccine supply chains, the establishment of the proper role of IP protections, and the matter of transparency in vaccine agreements as pivotal elements in ensuring just pricing, equitable distribution, and unimpeded accessibility to vaccines.[187] The concerns raised regarding cross-border supply chain operations, encompassing export limitations and the scarcity of proficient personnel, have further solidified the perspective of fellow Members, that the WTO must and has the capacity to assume a pivotal role in addressing this crisis.[188]

Thus, the WTO and its rules are relevant in the current discussion of achieving equitable distribution of vaccines and related essential medicines and treatments during a global health crisis. The rapid development and swift introduction of vaccines have undoubtedly been a triumph. However, this achievement is being

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[184] World Trade Organization Joint statement By Georgieva K, Ghebreyesus TA, Malpass D and Okonjo-Iweala N "A new commitment for vaccine equity and defeating the pandemic" https://www.wto.org/english/news_e/roadmap_igo_01jun21_e.htm.

[185] World Trade Organization DG Okonjo-Iweala Chair Summary following "COVID-19 and Vaccine Equity: What Can the WTO Contribute?" https://www.wto.org/english/news_e/spno_e/spno7_e.htm.

[186] World Trade Organization DG Okonjo-Iweala Chair Summary following "COVID-19 and Vaccine Equity: What Can the WTO Contribute?" https://www.wto.org/english/news_e/spno_e/spno7_e.htm.

[187] World Trade Organization DG Okonjo-Iweala Chair Summary following "COVID-19 and Vaccine Equity: What Can the WTO Contribute?" https://www.wto.org/english/news_e/spno_e/spno7_e.htm.

[188] World Trade Organization DG Okonjo-Iweala Chair Summary following "COVID-19 and Vaccine Equity: What Can the WTO Contribute?" https://www.wto.org/english/news_e/spno_e/spno7_e.htm.

overshadowed by the unfortunate reality of an unequal distribution. The majority of vaccines have been allocated to HMICs, leaving a significant portion of the global population at a disadvantage.[189] In the absence of a globally enforceable agreement to distribute vaccines in a fair and logical manner, leaders will prioritize the well-being of their own citizens rather than focusing on curbing the spread of COVID-19 in other regions or safeguarding healthcare workers and vulnerable populations in different countries. This approach, known as "vaccine nationalism" or a "my country first" mentality, will result in significant and long-lasting repercussions.[190]

This vaccine trend of vaccine nationalism and hoarding pose grave risks to all of us. It not only leads to more fatalities but also exacerbates the strain on healthcare systems, amplifies economic hardships, and creates an ideal breeding ground for the emergence and proliferation of new variants.

2.5 The TRIPS Agreement

During the 1994 negotiations that led to the establishment of the WTO, it was agreed that IP was a part of international trade and should therefore be included in the WTO's ambit.[191] Consequently, the TRIPS was established.[192] TRIPS is a legally binding international accord among all Member States of the WTO. Its primary objective is to establish a set of minimum standards for the regulation of various forms of IP by national governments, as they apply to citizens of other WTO member nations.[193] TRIPS was negotiated during the conclusion of the Uruguay Round of GATT between 1989 and 1990, and its administration is overseen by the WTO.[194] TRIPS mandates that Members of the WTO must incorporate specific fundamental rules for safeguarding IP in their national legislation, encompassing patents and trade secrets.[195] In contrast to other accords pertaining to IP, TRIPS possesses a

[189] See the text of UN Secretary□General António Guterres' video message to the World Health Summit, held in Berlin from 24 to 26 October 2021. https://reliefweb.int/report/world/vaccine-nationalism-hoarding-putting-us-all-risk-secretary-general-tells-world-health.
[190] Bollyky and Bown 2020 Foreign Affairs 97.
[191] Gleeson *et al* 2023 Medical Journal of Australia 46.
[192] Reichman 1995 Int Lawyer 345-388.
[193] See TRIPS Art. 1(3).
[194] Archibugi and Filippetti 2010 Journal of Global Policy 140.
[195] Reichman 1995 Int Lawyer 345-388.

potent enforcement mechanism. The WTO dispute settlement mechanism can be utilized to discipline Member States.

The inclusion of TRIPS was the culmination of a rigorous lobbying program by the U.S.-based International Intellectual Property Alliance, supported by the European Union (EU), Japan, and other developed nations.[196] The tactics were to defeat competing policy positions favoured by developing countries such as Brazil, Thailand, India, and Caribbean Basin States.[197] The United States (US) strategy of linking trade policy to IP standards can be traced back to the entrepreneurial efforts of senior management at Pfizer in the early 1980s.[198] These individuals mobilized corporations in the US and made the maximization of IP privileges the top priority of trade policy in the country.[199]

The TRIPS agreement marked the introduction of IP law into the multilateral trading system, representing the most comprehensive multilateral agreement on IP to date. In 2001, developing nations, apprehensive of the developed nations' insistence on a limited interpretation of TRIPS, instigated a series of discussions that culminated in the Doha Declaration. The Doha Declaration is a statement by the WTO that elucidates the extent of TRIPS flexibilities, affirming, among other things, that TRIPS can and should be construed in the context of the objective "to facilitate access to medicines for all"[200] (discussed in more detail under “the Doha Declaration” below).

Article 28 of TRIPS delineates the proprietary entitlements of patent proprietors, specifically, the exclusive entitlement to manufacture, utilize, proffer for vending, vend, or import the patented commodity.[201] The holder of the patent possesses the sole and exclusive authority to assign, transfer, or license the patent.[202] The

[196] Archibugi and Filippetti 2010 Journal of Global Policy 141.
[197] Archibugi and Filippetti 2010 Journal of Global Policy 141.
[198] Sell 2003 Cambridge University Press 4.
[199] Sell 2003 Cambridge University Press 17.
[200] Declaration on the TRIPS agreement and public health Adopted on 14 November 2001 para 4. https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
[201] TRIPS, *supra* note 32, art. 28(1).
[202] Art. 28(2).

reconciliation and balance between robust IPRs and endeavours to advance public health are commonly observed in provisions such as Articles 6, 7, 8 or 31.

Article 6 pertains to the resolution of disputes within the framework of the TRIPS Agreement, while being subject to the provisions outlined in Articles 3 and 4. It is important to note that this Agreement does not intend to address the matter of the exhaustion of IPRs. Article 7 is of special importance because it deals with the safeguarding and implementation of IPRs and states that Members ought to facilitate the advancement of technological innovation and the exchange and dissemination of technology, for the mutual benefit of creators and consumers of technological knowledge, in a manner that fosters social and economic well-being, and ensures a fair distribution of rights and responsibilities. Article 8(1) states that Members are permitted to adopt measures that are necessary to safeguard public health, as well as to advance the public interest in sectors that are crucial to their socio-economic and technological progress, when they formulate or modify their laws and regulations. However, it is imperative that these measures align with the provisions outlined in TRIPS. Further, article 8(2) allows Members to employ suitable measures, as long as they comply with the terms of TRIPS, as they may be necessary to avoid the misuse of IPRs by their owners or the adoption of practices that unreasonably limit trade or have a negative impact on the international exchange of technology. Each of these provisions in context with the *status quo* will be discussed in more depth below, each under its own heading. The obligations stipulated under TRIPS are equally binding on all Member States.[203]

Nevertheless, developing nations were granted additional time to give effect to the requisite modifications to their domestic legislation, in two stages of transition, based on their respective levels of development.[204] The transition period for developing countries lapsed in 2005.[205] However, the transition period for the least developed countries to comply with TRIPS was extended until 2013, and until 1 January 2016 for pharmaceutical patents, with the potential for further

[203] WTO https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm.
[204] WTO https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm.
[205] WTO https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm.

extension.[206] Inasfar as pharmaceutical patents are concerned, it is important to understand that a change introduced by TRIPS is that patents "shall be available for any inventions, whether products or processes, in all fields of technology".[207] Hence, whereas States could previously, before TRIPS, exclude sectors such as the pharmaceutical sector from patent protection (or strong patent protection for that matter), this is no longer possible under TRIPS.[208]

Consequently, there has been a contention that the TRIPS standard, which mandates all nations to establish rigorous IP frameworks, will impede the progress of economically disadvantaged countries.[209] It has been posited that, on the face of it, it is strategically advantageous for most, if not all, developing nations to leverage the flexibilities afforded by TRIPS to enact the most lenient IP regulations feasible.[210] The flexibilities made available in TRIPS can be integrated into the domestic legislation of Member States. Some of the flexibilities (article 30 and 31 of TRIPS, also reinforced by the Doha declaration) allows for generic manufacturers to obtain an official court order that allows them to manufacture the desired medicine without the prior approval of the patentee, without the threat of being sued for infringing patent rights.[211]

Overall, the reliance on TRIPS flexibilities has been weak. According to a 2005 report by the World Health Organization (WHO), numerous developing nations have failed to integrate TRIPS flexibilities, such as compulsory licensing, parallel importation, limitations on data protection, utilization of extensive research exemptions, and other exceptions to patentability, into their legal frameworks to the extent permitted, or confirmed, under the Doha Declaration.[212] Unfortunately, TRIPS is riddle with complex rules regarding CLs that make the use of it practicably difficult.[213] Furthermore, the implementation of PI could pose challenges for health authorities in various nations in maintaining distinct price controls and regulatory

[206] WTO https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm.
[207] Art. 27 of TRIPS.
[208] WTO https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm.
[209] Morin and Gold 2014 International Studies Quarterly 788.
[210] Blouin *et al* 2007 McGill-Queen's University Press 33.
[211] Gleeson *et al* 2023 Medical Journal of Australia 439.
[212] Musungu and Oh 2005 Commission on Intellectual Property Rights, Innovation and Public Health 181.
[213] Urias and Ramani 2020 A review of the existing evidence J Int Bus Policy 381.

systems, and is strongly contented against by affected parties.[214] Also, something to note is that there is no equivalent "compulsory licensing for trade secrets".[215] Trade secrets encompass a wide range of valuable information, including technical details like manufacturing processes, experimental research data, software algorithms, and commercial aspects such as distribution methods, lists of suppliers and clients, and advertising strategies. Additionally, other types of information that may be safeguarded as trade secrets include financial data, formulas and recipes, and source codes.[216] Article 39 deals with the protection of undisclosed information. Data exclusivity pertains to the safeguarding of clinical test data that is presented to a regulatory agency in order to establish the "safety, effectiveness, and quality" of a novel pharmaceutical.[217] This safeguarding prevents generic drug manufacturers from employing the aforementioned data in their own applications. Data exclusivity functions as a protective mechanism for pharmaceutical companies and extends its coverage to products that are recently introduced to the market and not subject to patent protection.[218] Nations that incorporate a data-exclusivity provision offer varying degrees of protection, ranging from five years (in the US) to a maximum of 10 years (among EU Member States).[219]

Thus, even if a generic manufacturer could get a CL to produce the same pharmaceutical, the information in the patent itself is not sufficient to replicate it. It seems that, in spite of the existing flexibilities, the most crucial barriers during the pandemic, such as patents and trade secrets, are not easily "circumventable" through the use of TRIPS flexibilities. Thus, it seems that current domestic and international IP arrangements provide limited avenues to remove IP barriers to equitable COVID-19 diagnostics, therapies, and vaccines.[220] This will be discussed in more depth below in subsequent chapters.

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[214] Maskus Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries 2.
[215] Gleeson *et al* 2023 Medical Journal of Australia 47.
[216] WIPO What kind of information is protected by trade secrets? https://www.wipo.int/tradesecrets/en/tradesecrets_faqs.html.
[217] WHO Drug Information https://apps.who.int/iris/bitstream/handle/10665/73466/19_3_2005.pdf.
[218] WHO Drug Information https://apps.who.int/iris/bitstream/handle/10665/73466/19_3_2005.pdf.
[219] WHO Drug Information https://apps.who.int/iris/bitstream/handle/10665/73466/19_3_2005.pdf.
[220] Scheibner *et al* 2022 J Law Biosci 20.

2.6 The Doha Declaration

In the context of the prevailing HIV/AIDS public health crisis, particularly in developing nations, the aforementioned flexibilities have had a negligible impact on mitigating the impact of patents on the affordability of medicines.[221] In response to the demands of developing nations, particularly the African Members of the WTO, the fourth Ministerial Conference of the WTO held in Doha, Qatar, affirmed that the TRIPS Agreement should be implemented in a manner that facilitates public health by promoting access to existing medicines and the development of new medicines.[222]

The Ministerial Conference of the WTO held on 14 November, 2001, adopted the Doha Declaration on the TRIPS Agreement and Public Health.[223] The declaration reiterated the flexibility of Member States of TRIPS to "soften" patent rights in order to ensure improved access to vital medicines (including vaccines).[224] In paragraphs 4 to 6 of the Doha Declaration, the participating governments reached an agreement that the TRIPS Agreement ought not to impede Members from implementing measures to safeguard public health.[225] In light of this, the declaration reaffirms Members' dedication to the TRIPS Agreement, but asserts that it is possible and necessary to construe and execute the Agreement in a way that is conducive to the right of WTO Members to safeguard public health, particularly in terms of facilitating access to medicines for all.[226] Members accordingly acknowledge their obligations under the TRIPS Agreement must be upheld. However, under paragraph 5 they also acknowledged that certain flexibilities are available, including the following: Firstly, the customary rules of interpretation of public international law are to be applied when interpreting each provision of the TRIPS Agreement.[227] Such interpretation is to be guided by the Agreement's objectives and principles, as expressed in its stated

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[221] Van der Merwe et al *Law of Intellectual Property in South Africa* 16.
[222] Van der Merwe et al *Law of Intellectual Property in South Africa* 16.
[223] World trade Organization: The Doha Declaration Explained https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm
[224] World trade Organization: The Doha Declaration Explained https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm
[225] Paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health, 2001.
[226] Paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health, 2001.
[227] Paragraph 5(a) of the Doha Declaration on the TRIPS Agreement and Public Health, 2001.

purposes (notably expressed in the preamble and Articles 7 and 8).[228] Secondly, each Member is entitled to grant compulsory licences (as provided for in Article 31) and has the discretion to determine the criteria for granting such licences.[229] Thirdly, each Member possesses the entitlement to determine the definition of a national emergency or other circumstances of extreme urgency.[230] Lastly, Members can rely on parallel imports, which involve the importation of authentic products (vaccines, treatments and equipment) from other countries without the consent of the IP holder.[231]

The Doha Declaration was well-received, with numerous public health officials deeming it a significant stride towards prioritizing public health above IPRs "in specific circumstances."[232] Doha asserts the available courses of action that may be exercised by Members of the WTO, specifically the entitlement to grant CLs and establish the terms upon which said licences may be granted, as well as the prerogative to ascertain what qualifies as a "national emergency or other circumstances of extreme urgency",[233] and further the capacity to allow PIs of cheaper medicine from other markets. Situations that usually constitute a public health emergency are situations where the health consequences are so severe that they have the potential to overwhelm or overburden a state's capabilities to address the emergency[234].

Though the flexibilities of TRIPS that are reinforced by the Doha Declaration in the pursuit of the realization of the right to health sound promising, they remain unobtainable solutions for most underdeveloped countries. Paragraph 6 further acknowledges that WTO Members who possess inadequate or non-existent manufacturing capabilities in the pharmaceutical industry may encounter challenges in effectively utilizing CLs as per the TRIPS Agreement.[235] Alternatively they could rely on PIs, but PIs can be problematic for LMICs who want to introduce the same

[228] Paragraph 5(a) of the Doha Declaration on the TRIPS Agreement and Public Health, 2001.
[229] Paragraph 5(b) of the Doha Declaration on the TRIPS Agreement and Public Health, 2001.
[230] Paragraph 5(c) of the Doha Declaration on the TRIPS Agreement and Public Health, 2001.
[231] WTO Glossary - parallel imports www.wto.org.
[232] Gutner 2017 International Organizations in World Politics 16.
[233] Para. 5(c) of the Doha Declaration.
[234] Nelson *et al* 2007 Am J Public Health 4.
[235] Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, 2001.

IP-protected product at cheaper prices to their market due to the expenses associated with transportation and repackaging in parallel trade that can significantly reduce any potential price benefits.[236] And finally, there are known shortcomings in the current reporting and declaration protocol for Public Health Emergencies. Countries may face negative consequences, such as economic impact through restrictions placed on trade and travel, which may deter them from reporting a potential public health emergency.[237] For example, in November 2021 South Africa acted transparently by promptly notifying the global community about the B.1.1.529 variant, which had been discovered by its scientific experts in the preceding week.[238] The South African government was promptly informed that several countries, including Britain, were implementing short-term limitations on travel shortly after receiving the briefing. Moreover, Botswana, where the first sample indicating the variant was identified, was also impacted by these restrictions, as were Namibia, Zimbabwe, Eswatini, and Lesotho.[239] The immediate economic consequences were evident, as the Johannesburg Stock Exchange experienced a decline of nearly 2% by the end of that week, while the Rand dropped to its lowest value in over a year.[240] Another challenge is the political sensitivities associated with declaring a public health emergency that is of international concern. This is partly due to the fact that the decisions of declaring a public health emergency have been unevenly applied by States and are not fully transparent, and therefore it is subject to contention from other Member States.[241]

2.6.1 COVID-19 as an ongoing public health emergency of international concern

A Public Health Emergency of International Concern (PHEIC) is an official declaration issued by the WHO that identifies an extraordinary event as a public health threat to other nations due to the global spread of disease, and may necessitate a coordinated international response.[242] This proclamation is made when a situation

[236] Peiravian 2014 Iran J Pharm Res Fall 1112.
[237] Wilder-Smith and Osman 2020 J Travel Med 8.
[238] WHO World Health Assembly Second Special Session.
[239] Schermerhorn *et al* 2022 BMJ Global Health 2.
[240] Dall and Davies 2021The Guardian.
[241] Mullen *et al* 2020 BMJ Glob Health 1499.
[242] WHO Q&A "International Health Regulations and Emergency Committees".

arises that is considered "serious, sudden, unusual, or unexpected," and has implications for public health beyond the borders of the affected country, which may require immediate global intervention.[243]

On 30 January 2023, Tedros Ghebreyesus, the Director-General of the WHO, made an official declaration that COVID-19 continues to pose a significant PHEIC.[244] This decision comes three years after the initial declaration of the emergency. Tedros, in his announcement, acknowledged the guidance provided by the COVID-19 emergency committee, which stated that the pandemic is likely undergoing a transitional phase and that the termination of the PHEIC remains a subject of considerable speculation.[245]The recent determination made by the Director-General regarding the continued fulfilment of the PHEIC criteria by COVID-19 is accurate. On a global scale, SARS-CoV-2 continues to pose an "extraordinary" health risk, as evidenced by the reported rates of both disease and infection.[246] Additionally, there have been observations of transmission from humans to various mammalian species with minimal adaptation.[247] Given these circumstances, it is highly probable that variants of concern will arise in the near future, which may exhibit greater pathogenicity, increased transmissibility, or the ability to circumvent "public health and medical countermeasures".[248] However, ascertaining the potential hazards posed by variants to environments beyond their origin necessitates endeavours to comprehend transmission and pathogenicity in communities with varying infection and vaccination records.[249] The persistent inequality in global vaccine distribution is a contributing factor to the ongoing discrepancy in health outcomes[250] and perpetuates the likelihood of additional variants of concern.[251]

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[243] WHO Q&A "International Health Regulations and Emergency Committees".
[244] WHO "Statement on the fourteenth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic".
[245] Adam 2023 Nature 1-2.
[246] WHO coronavirus (covid-19) dashboard https://covid19.who.int/.
[247] Tan *et al* 2022 Nature Communications.
[248] Tracking SARS-CoV-2 2023 https://www.who.int/activities/tracking-SARS-CoV-2-variants.
[249] Neherlab https://github.com/neherlab/SARS-CoV-2_variant-reports/blob/main/reports/variant_report_latest_draft.md#variant-report-2023-01-02.
[250] Yamey *et al* 2022 BMJ 2.
[251] 2022 Nature Human Behaviour.

2.7 TRIPS-Plus Agreements

FTAs often face criticism for including TRIPS-Plus rules.[252] One major point of contention is that many of these standards are seen as limiting the policy space and flexibilities that TRIPS provides for implementing its obligations. In 2001, all WTO Members acknowledged the significance of certain flexibilities in the context of public health through the Doha Declaration on TRIPS and Public Health.[253] The emergence of FTAs has resulted in a growing demand to protect the rights of WTO Members to enforce them against TRIPS-Plus obligations in FTAs, particularly in relation to public health.[254] On a global scale, the WHO has stressed that "Bilateral trade agreements should not attempt to include TRIPS-Plus provisions that could limit access to medicines in developing nations."[255] Additionally, the Fifty-seventh World Health Assembly strongly encourages all WHO Members to prioritize the inclusion of the flexibilities outlined in the TRIPS Agreement in their bilateral trade agreements.[256] Additionally, in his report from 2009, the UN Special Rapporteur on the Right to Health emphasized the importance of not implementing TRIPS-Plus standards in the national laws of developing countries and LDCs.[257] Furthermore, he urged developed countries to refrain from encouraging developing countries and LDCs to engage in TRIPS-Plus FTAs. It is crucial for developed countries to be cautious of any actions that could potentially violate the right to health.[258]

In spite of the Doha Declaration, numerous developing nations have encountered mounting pressure in recent years to adopt or enforce patent laws that impose more stringent or restrictive conditions than those mandated by the TRIPS Agreement.[259] These additional provisions, commonly referred to as 'TRIPS-Plus', are not obligatory under international law. However, countries such as Brazil, China, and Central American States have been compelled to incorporate them into their legal

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[252] Drahos 2003 "Expanding Intellectual Property's Empire: the Role of FTAs" http://www.ictsd.org/downloads/2008/08/drahos-fta-2003-en.pdf.
[253] The Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration).
[254] Ruse-Khan *The Protection Of Intellectual Property In International Law* 105.
[255] WHO 2006 http://www.who.int/intellectualproperty/documents/thereport/CIPIHReport23032006.pdf.
[256] WHO 2004 https://apps.who.int/gb/ebwha/pdf_files/WHA57/A57_R14-en.pdf.
[257] Ruse-Khan *The Protection Of Intellectual Property In International Law* 105-106.
[258] Human Rights Council 2000 https://www.refworld.org/pdfid/4538838d0.pdf para 108.
[259] MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha.

frameworks as a result of trade agreements with the US or the EU.[260] Regrettably, these provisions have had a detrimental effect on the accessibility of essential medicines. There exist multiple instances of TRIPS-Plus provisions that entail the extension of patent duration beyond the prescribed minimum of twenty years, coupled with the incorporation of clauses that impede the utilization of compulsory licences or impede generic competition.[261]

One of the provisions presently being scrutinized concerns the concept of "data exclusivity."[262] This term refers to the exclusive rights bestowed upon pharmaceutical companies in relation to the test data they furnish to regulatory bodies for the purpose of securing market approval.[263] Essentially, this provision guarantees that information pertaining to a drug's safety and efficacy remains confidential for a designated period, usually ranging from five to ten years.[264] Consequently, when a generic manufacturer seeks to register a drug in a specific country, it is crucial to recognize that merely demonstrating therapeutic equivalence to the originator product is insufficient.[265] Instead, the manufacturer must either wait for the exclusivity period to expire or undertake the challenging task of conducting extensive clinical trials to establish the drug's safety and efficacy, even if such trials have already been conducted.[266] The repetition of clinical trials is a heavy financial burden that may prove insurmountable and time-consuming,[267] especially for developing countries in the global South.

This requirement remains in effect even if the originator product lacks patent protection.[268] Data exclusivity, simply put, goes beyond the requirements set by the TRIPS agreement, thus a TRIPS-Plus provision, and serves the purpose of prolonging the arrival of generic competition, thus hindering access to affordable

[260] MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha.
[261] MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha.
[262] MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha.
[263] MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha.
[264] MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha.
[265] MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha.
[266] MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha.
[267] Ministry of Public Health, Thailand and the WHO 2006 https://iris.who.int/bitstream/handle/10665/205326/B2072.pdf.
[268] MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha.

medication, especially in cases where patent protection does not exist.[269] Essentially, data exclusivity functions as a covert mechanism for hindering competition, ensuring that pharmaceutical companies can benefit from an extended period of market monopoly during which artificially inflated prices can be imposed.[270] It is a form of "evergreening". Evergreening refers to a range of legal, commercial, and technological tactics employed by producers, particularly those in the pharmaceutical industry, to prolong the validity of their patents that are nearing expiration.[271] This is done with the aim of preserving revenue streams from these patents.

Alternatively, it is more probable that generic manufacturers would be compelled to postpone the release of their product until the conclusion of the exclusivity period.[272] Consequently, data exclusivity reduces the probability of swift marketing of generics, thereby delaying competition and price reductions.[273] It is noteworthy that while TRIPS does mandate data protection, it does not require data exclusivity.[274] Yet, developed countries frequently exercise pressure that FTAs with developing nations incorporate provisions, such as data exclusivity, that surpass the stipulations delineated in TRIPS.[275]

The TRIPS flexibilities, at the time of their adoption, were helpful in theory to promote access to medicines in a time where supply chains were fairly simple and where patent barriers were the only barriers in place.[276] But since the emergence of FTAs, TRIPS-Plus provisions have overridden the use of most TRIPS flexibilities and left developing nations vulnerable while protecting the interests of developed

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269 MSF Southern Africa 2004 https://msfaccess.org/data-exclusivity-international-trade-agreements-what-consequences-access-medicines 4.

270 MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha.

271 Faunce 2004 The age.

272 Ministry of Public Health, Thailand and the WHO 2006 https://iris.who.int/bitstream/handle/10665/205326/B2072.pdf.

273 Ministry of Public Health, Thailand and the WHO 2006 https://iris.who.int/bitstream/handle/10665/205326/B2072.pdf.

274 Ministry of Public Health, Thailand and the WHO 2006 https://iris.who.int/bitstream/handle/10665/205326/B2072.pdf.

275 MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha.

276 Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf 16.

countries. TRIPS-Plus expanded IP protection while further limiting or completely restricting the use of the provided flexibilities.[277]

2.8 A brief overview of the World Intellectual Property Organization

The World Intellectual Property Organization (WIPO) was established by the WIPO Convention, which was signed on 14 July, 1967, in Stockholm.[278] It came into force in 1970 and was later amended in 1979. WIPO, an intergovernmental organization, became one of the specialized agencies of the United Nations system in 1974.[279]

The establishment of WIPO can be traced back to 1883 and 1886 with the conclusion of the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works, respectively. These conventions laid the groundwork for the formation of an "International Bureau". In 1893, the two bureaus were merged, and ultimately, in 1970, the WIPO was created under the WIPO Convention, replacing the previous bureaus.[280]

WIPO is committed to achieving two principal goals. The first encompasses the widespread safeguarding of IP, whilst the second aims to establish administrative links between the IP unions that fall under WIPO's jurisdiction.[281] WIPO carries out various activities to achieve these objectives, which include administrative tasks of the Unions. These activities comprise normative activities, where WIPO sets norms and standards for the protection and enforcement of intellectual property rights through international treaties. Additionally, program activities involve legal and technical assistance to States in the field of intellectual property. WIPO also engages in international classification and standardization activities, which involve cooperation among industrial property offices concerning patent, trademark, and industrial design documentation. Lastly, WIPO provides registration and filing

[277] Bing 2021 Global Economic Governance Initiative 2.
[278] WIPO Summary of the Convention Establishing the World Intellectual Property Organization (WIPO Convention) (1967).
[279] WIPO Summary of the Convention Establishing the World Intellectual Property Organization (WIPO Convention) (1967).
[280] WIPO Summary of the Convention Establishing the World Intellectual Property Organization (WIPO Convention) (1967).
[281] WIPO Summary of the Convention Establishing the World Intellectual Property Organization (WIPO Convention) (1967).

activities, which include services related to international applications for patents for inventions and for the registration of marks and industrial designs.[282]

WIPO plays a significant role in shaping global IP policies and standards, which in turn intersect with issues related to the TRIPS and public health. While WIPO and TRIPS are separate entities with distinct mandates, they are closely related in their efforts to establish international norms and frameworks for IP protection and enforcement. WIPO's involvement in the context of TRIPS and public health can be observed in capacity building and technical assistance, policy dialogue and advocacy, and research and analysis.[283]

2.9 A brief discussion of the vaccine gap between the Global North and South, and it's relevance to IP and trade

The North-South dilemma regarding equitable access to intellectual property (IP) and medicines refers to the stark disparities between high-income countries in the Global North and low- and middle-income countries in the Global South in accessing essential medicines, which are often protected by IP rights. This dilemma encompasses various economic, legal, and ethical considerations surrounding the balance between protecting IP rights and ensuring access to medicines for all.[284]

High-income countries in the Global North, where most pharmaceutical companies are based, typically prioritize the protection of IP rights, including patents, trademarks, and copyrights. These protections incentivize innovation and investment in research and development (R&D) for new medicines. However, strong IP protections can also create barriers to access for people in low- and middle-income countries, as patented medicines may be priced out of reach for many individuals and healthcare systems.[285]

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[282] WIPO Summary of the Convention Establishing the World Intellectual Property Organization (WIPO Convention) (1967).
[283] WIPO Convention 1967.
[284] Sell, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: Seattle, Doha, and Beyond*, 333–352.
[285] Sell, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: Seattle, Doha, and Beyond*, 333–352.

Low- and middle-income countries in the Global South often face challenges in accessing essential medicines, particularly those protected by patents. The high cost of patented medicines can limit their availability in these regions, exacerbating public health crises and contributing to preventable morbidity and mortality. In response, some countries in the Global South have pursued measures such as compulsory licensing, which allows the production of generic versions of patented medicines without the consent of the patent holder, to improve access to essential medicines.[286]

The North-South dilemma raises fundamental questions about global health equity and the right to health. Access to medicines is recognized as a fundamental human right, yet disparities in access persist, driven in part by inequities in IP regimes and pharmaceutical pricing practices. Efforts to address this dilemma involve balancing the need to incentivize innovation with the imperative to ensure access to medicines for all, particularly for diseases that disproportionately affect populations in low- and middle-income countries.[287]

2.10 Conclusion

As globalization continues to advance, the ability to address various policy domains in isolation diminishes. The interconnection between trade, IP and health has sparked extensive discussions. The collaboration between the WHO and the WTO is essential when considering how to prevent and respond to world health crises by eliminating barriers to IP-related trade and fostering global cooperation. This chapter highlights the significant overlap between the domains of IP, trade and health. Moreover, it emphasizes the need for policymakers in these fields to work together to achieve consistency in their respective roles and responsibilities. The approval of the Doha Declaration on the TRIPS Agreement and Public Health by the global community is a clear indication of governments' dedication to guaranteeing that the regulations governing international trade are in harmony with public health

[286] Sell, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: Seattle, Doha, and Beyond*, 333–352.
[287] Sell, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: Seattle, Doha, and Beyond*, 333–352.

concerns. The TRIPS Agreement encompasses various domains that have implications on healthcare. One aspect of great significance is the safeguarding of patent rights for pharmaceutical products. Achieving a delicate equilibrium between two mutually reinforcing public health objectives becomes paramount in this particular realm. On the one hand, it is crucial to incentivize the development of novel drugs through providing appropriate incentives. On the other hand, it is equally vital to guarantee affordable accessibility to pre-existing medications.

The TRIPS Agreement and Public Health section of the WTO Doha Declaration played a crucial role in shaping the IP system within the context of health policy. It emphasized the importance of integrating the TRIPS Agreement into broader national and international efforts to tackle public health challenges faced by developing and least-developed countries. The Declaration outlined various avenues available to governments, referred to as 'flexibilities', to effectively address public health requirements. Public health is an issue that transcends borders and requires collaboration on a global scale. The WHO serves as the central authority for health matters, but the interconnectedness of health with various policy domains necessitates cooperation between the WHO and other international organizations such as the WIPO and the WTO. This dissertation aims to address the growing need, particularly in developing nations, for enhanced capacity in making well-informed policies at the intersection of health, trade, and IP. Specifically, the focus is on improving access to and fostering innovation in medicines and other medical technologies in the face of a global health threat.

The WTO, WIPO, and the WHO are three distinct international organizations with separate mandates and functions. However, they are interconnected in various ways, especially during a global health crisis, where their actions and collaborations can significantly impact global health outcomes.[288] During a global health crisis, the WTO plays a critical role in facilitating trade of essential medical supplies, vaccines, and treatments by ensuring that trade barriers are minimized, and trade rules are followed. The WTO also oversees the TRIPS agreement, which can have implications

[288] WTO *Trade and the COVID-19 pandemic* https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm.

for access to medicines and public health, especially regarding issues like compulsory licensing and the protection of patents during emergencies.[289] During a global health crisis, WIPO may provide technical assistance and support to countries seeking to navigate intellectual property issues related to the development, production, and distribution of vaccines, treatments, and medical technologies. WIPO may also facilitate discussions and initiatives aimed at balancing IP rights with public health objectives, such as technology transfer, knowledge sharing, and access to medicines.[290] The finally during a global health crisis, the WHO provides guidance, expertise, and support to countries in areas such as disease surveillance, outbreak response, healthcare capacity-building, and public health measures. The WHO also collaborates with other organizations, including the WTO and WIPO, to address broader health-related issues, such as access to essential medicines, vaccine equity, and health system strengthening.[291] It is worth exploring all these institutions and their capabilities when considering how a new global health treaty should be formulated.

3 IP legislation's impact on realizing the internationally recognized right to health

3.1 Introduction

Human rights and IP protection are two distinct domains that have developed totally in isolation from one another for a long time.[292] This chapter addresses the various facets of the interrelation between IPRs, human rights, and science and technology-related provisions that are safeguarded in existing human rights treaties. Of particular significance is the reference to the right to health as a human right.[293] The chapter scrutinizes the extant provisions pertaining to access to knowledge and technology protection in human rights treaties and evaluates the effects of prevailing IPR regimes on the attainment of human rights.

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[289] WTO *Trade and the COVID-19 pandemic* https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm.
[290] WIPO and Global Health https://www.wipo.int/global_health/en/.
[291] WIPO and Global Health https://www.wipo.int/global_health/en/.
[292] Gargi and Gupta 2011 Elsevier BV 1.
[293] Gargi and Gupta 2011 Elsevier BV 2.

A comprehensive review of empirical evidence on the impact of IP legal requirements, such as patents and data exclusivity, on access to medicines is yet to be conducted. The WTO's TRIPS Agreement mandates Member States to implement minimum standards of IP protection, including patents for pharmaceutical products, while also providing "flexibilities" to address access barriers. Furthermore, national IP laws may include TRIPS-Plus regulations that exceed TRIPS requirements. This chapter's aim was to systematically review literature measuring the effects of IP rules on access to medicines, whether implemented due to TRIPS, TRIPS-Plus provisions in other trade agreements, or unilateral policy decisions.[294]

3.2 The link between human rights, intellectual property and the pharmaceutical industry

Notwithstanding the unequivocal establishment of right to health as a fundamental human right in international law,[295] the recognition of this right has, in many ways, predominantly remained theoretical.[296] The persistent prioritization by States and multinational corporations of the enforcement of IPRs over the promotion of access to medicines has led to a growing inaccessibility of health technologies.[297] The creation of a medicinal drug constitutes an invention protectable by IP and is intrinsically connected to public health, as it is intended for public consumption and use in the pursuit of health.[298] The significance of IP, in the form of patents and trade secrets, to public health is thus evident. The patent rights and trade secrets in the pharmaceutical industry are the most pertinent forms of IP in relation to this context, as they have a significant impact on the free flow and dissemination of information and technology and impede fair trade between the Global North and the Global South.

Section 5 of TRIPS deals with patents. An invention, whether it be a product or a process, can be granted an exclusive right known as a patent. This exclusive right

[294] Tenni *et al* 2022 Global Health 2.
[295] See for example Universal Declaration of Human Rights, the International Covenant on Economic Social and Cultural Rights.
[296] Yousuf 2021 Access to Medicines and Vaccines 74.
[297] Yousuf 2021 Access to Medicines and Vaccines 74.
[298] Titong 2021 SA Attorneys Journal.

is given to those who offer a new technical solution to a problem or a new way of doing something.[299] In order to obtain a patent, the technical information about the invention must be disclosed to the public through a patent application.[300] (but as discussed above, there is a growing trend that the information disclosed in patents are insufficient for a person skilled in the art to work). The patent owner possesses the exclusive authority to prohibit or halt any commercial exploitation of the patented invention, essentially ensuring that the invention cannot be commercially manufactured, utilized, distributed, imported, or sold by any party without the explicit consent of the owner of the patent.[301] This protection generally lasts 20 years upon the filling of the patent application.[302] Further, protection for undisclosed information, such as know-how or trade secrets, is mandated by the TRIPS Agreement.[303] Article 39.2 specifies that the information must meet certain criteria, including being secret, having commercial value due to its secrecy, and having been kept secret through reasonable measures.[304] The duration, as discussed above, can last up until 10 years.

The providing of affordable medication (including vaccines) is a fundamental prerequisite for the realization of the entitlement to healthcare.[305] The accessibility of such medication is contingent upon their affordability, which is determined by their cost-effectiveness for the end-users.[306] The pricing of pharmaceuticals is influenced by a variety of factors, such as governmental levies, import tariffs, regulatory expenses, and promotional expenditures.[307] The existence of a patent and trade secrets on the medication is often the most important contributing factor.[308]

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[299] WIPO Patents - What is a patent? https://www.wipo.int/patents/en/.
[300] WIPO Patents - What is a patent? https://www.wipo.int/patents/en/.
[301] WIPO Patents - What rights does a patent provide? https://www.wipo.int/patents/en/.
[302] WIPO Patents - How long does patent protection last? https://www.wipo.int/patents/en/.
[303] WTO Overview: the TRIPS Agreement- Protection of undisclosed information. https://www.wipo.int/patents/en/.
[304] WTO Overview: the TRIPS Agreement- Protection of undisclosed information. https://www.wipo.int/patents/en/.
[305] Van der Merwe et al *Law of Intellectual Property in South Africa* 13.
[306] Van der Merwe et al *Law of Intellectual Property in South Africa* 13.
[307] Van der Merwe et al *Law of Intellectual Property in South Africa* 13.
[308] Van der Merwe et al *Law of Intellectual Property in South Africa* 13.

Scholars, theorists, and policymakers have recognized the human impacts of such IP regulations. The acknowledgement of potential conflicts between rights has prompted a discussion on the objectives that IP regimes should strive for. At present, the existing multilateral and minimum standard global trade IP regulations remain focused on personal property rights and economic returns. Patents serve as a mechanism for pharmaceutical manufacturing companies to safeguard their investment in the R&D of novel pharmaceutical drugs.[309] The grant of a patent curtails competition (free riding) from generic drug manufacturers for the duration of the patent, thereby enabling the patent-holder to charge a monopoly price that exceeds what would have been feasible in the absence of the patent, as it were to recover expenses and make a profit.[310] While this could be argued to ensure research and innovation in the pharmaceutical sector, it also results in a reduction of access to the advantages of the patented medicine for a segment of the population that is incapable of affording the price set by the patent-holder.[311]

The primary contention in favour of patents is their indispensability for fostering innovation in the pharmaceutical sector. The exclusive entitlements serve as a motivation for corporations to undertake the financial hazards associated with the exploration and advancement of medicinal remedies, and these scientific and technological breakthroughs ultimately redound to the advantage of the populace.[312] Nevertheless, pharmaceutical enterprises are profit-oriented entities, and patents offer a prospect to optimize returns on their investments. This has a bearing on the promotion of pertinent medical research in at least two interdependent manners. Firstly, it should be noted that pharmaceutical companies tend to structure their R&D initiatives around the prospect of generating profits.[313] Consequently, this approach may result in a deviation from prioritizing research that is necessary, to focusing on research that is financially lucrative.[314] The second concern pertains to the economic gains that can be achieved by capturing a larger

[309] Van der Merwe et al *Law of Intellectual Property in South Africa* 13.
[310] Van der Merwe et al *Law of Intellectual Property in South Africa* 13.
[311] Van der Merwe et al *Law of Intellectual Property in South Africa* 13.
[312] Van der Merwe et al *Law of Intellectual Property in South Africa* 13.
[313] Van der Merwe et al *Law of Intellectual Property in South Africa* 13.
[314] Van der Merwe et al *Law of Intellectual Property in South Africa* 13.

share of the market, which often leads to an increased rate of patenting even in situations where companies lack the incentive to develop new products.[315] Furthermore, this practice encourages the creation of medical inventions that are not genuinely innovative but rather incremental modifications of their existing products (evergreening).[316] The resulting proliferation of patents may impede future medical research in general and research on diseases that disproportionately affect developing countries in particular. This hindrance may arise due to the elevated research costs associated with negotiating licences and similar rights with patent holders, particularly when the development of new medicines depends on access to protected trade secret knowledge.[317]

An example of pharmaceutical companies focussing their research on what is more financially lucrative and attempting to capture more of the market by increasing patents for inventions that are not genuinely innovative, is the COVID-19 booster shot. The Director-General of WHO, Tedros Adhanom Ghebreyesus, expressed his concern over the significant disparity and lack of fairness in the global distribution of COVID-19 vaccines at the time.[318] He highlighted the fact that certain countries and regions had already placed orders for millions of booster doses, while others were still struggling to secure enough vaccines to inoculate their healthcare workers and the most vulnerable populations.[319] Pfizer and Moderna, among others, were specifically identified as vaccine manufacturers that intended to supply additional doses in regions with already substantial vaccination rates.[320] According to Soumya Swaminathan, the chief scientist of the WHO, there was no evidence to suggest that individuals who have completed their full vaccination course require booster shots.[321] By utilizing valuable supplies for booster shots, countries are disregarding the safety of hundreds of millions of individuals, leaving them without adequate protection. This is particularly concerning as vulnerable populations continue to

[315] Van der Merwe et al *Law of Intellectual Property in South Africa* 13.
[316] Van der Merwe et al *Law of Intellectual Property in South Africa* 13.
[317] Van der Merwe et al *Law of Intellectual Property in South Africa* 14.
[318] WHO Press conference.
[319] WHO Press conference.
[320] WHO Press conference.
[321] WHO Press conference.

suffer without access to vaccines in other regions, ultimately exacerbating the global health crisis.

It is clear, that the intention of IP to incentivise innovation has tipped in the favour of economic benefits. It should be questioned if IP should be afforded so much protection, especially if it undermines the realization of the fundamental human right to health, and ultimately life.

3.3 Human Rights vs. Intellectual Property Rights

Human rights are inherent to every individual solely by virtue of being human, and they are not bestowed upon us by any governing body.[322] These rights are universal and apply to all individuals, irrespective of their nationality, gender, ethnic background, race, religion, language, or any other characteristic.[323] They encompass a wide spectrum of rights, ranging from the fundamental right to life to the rights that enhance the quality of life, such as the right to health.[324] IPRs are designed to ensure the protection of the private interests of producers of specific intellectual creations.[325] The concept of human rights operates in a distinctive fashion to promote the public interest (the common good) as opposed to only private interests.[326] It tasks governments with ensuring the protection of basic freedoms and privileges of individuals, such as the right to life, health etc. There are two ways to approach the relationship between IPRs and human rights systems. The first perspective suggests that IPRs should be considered as inherent human rights that everyone is entitled to.[327] The second viewpoint states that enforcing intellectual property rights can impede the achievement of human rights objectives.[328]

The right to health is protected in various domestic and international legal instruments. The fundamental right to health is an essential component of our

[322] UN OHCHR https://www.ohchr.org/en/what-are-human-rights.
[323] UN OHCHR https://www.ohchr.org/en/what-are-human-rights.
[324] UN OHCHR https://www.ohchr.org/en/what-are-human-rights.
[325] Van der Merwe et al *Law of Intellectual Property in South Africa* 3.
[326] Van der Merwe et al *Law of Intellectual Property in South Africa* 4.
[327] Van der Merwe et al *Law of Intellectual Property in South Africa* 4.
[328] Van der Merwe et al *Law of Intellectual Property in South Africa* 4.

inherent human rights and our perception of a dignified existence.[329] "The right to the enjoyment of the highest attainable standard of physical and mental health", is not a novel concept. It was initially articulated on an international level in the 1946 Constitution of the WHO, whose preface defines health as "a condition of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."[330] The preface reaffirms this right by further stating that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."[331] Additionally, incorporated within the 1948 Universal Declaration of Human Rights is the acknowledgement of health as an integral component of the entitlement to a satisfactory standard of living, as outlined in Article 25. Article 25(1) of the UDHR explicitly declares that "Every individual is entitled to an adequate standard of living, including access to food, clothing, housing, medical care, and essential social services, in order to ensure their health and well-being, as well as that of their family." Furthermore, the right to health was once again affirmed as a fundamental human right in the 1966 International Covenant on Economic, Social and Cultural Rights. Among the various international human rights laws, the ICESCR provides the most extensive and comprehensive provisions concerning the right to health. In accordance with Article 12(1) of the Covenant, States parties acknowledge and uphold the right of all individuals to enjoy the utmost level of physical and mental well-being. Furthermore, Article 12(2) outlines a series of measures that States parties should undertake in order to effectively fulfil this right. Furthermore, the right to health is acknowledged, among other things, in article 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination of 1965, in the Convention on the Elimination of All Forms of Discrimination against Women of 1979 the right to health is affirmed in articles

[329] WHO and Office of the United Nations High Commissioner for Human Rights 2008 The Right to Health Fact Sheet No. 31 1.
[330] WHO and Office of the United Nations High Commissioner for Human Rights 2008 The Right to Health Fact Sheet No. 31 1.
[331] WHO and Office of the United Nations High Commissioner for Human Rights 2008 The Right to Health Fact Sheet No. 31 1.

11(1)(f) and 12, and again in article 24 of the Convention on the Rights of the Child of 1989.[332]

Also, numerous regional instruments pertaining to human rights also acknowledge the right to health, including Article 11 of the revised European Social Charter of 1961, Article 16 of the African Charter on Human and Peoples' Rights of 1981, and then in Article 10 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988.[333] Likewise, the Commission on Human Rights has acknowledged the right to health, as well as its recognition in the Vienna Declaration and Programme of Action of 1993 and other global instruments.[334] According to the ICESCR General Comment No. 14, the concept of the right to health should not be misconstrued as a right "to be healthy".[335] This entitlement encompasses the right to a comprehensive health protection system that ensures equal opportunities for individuals to access and enjoy the highest achievable standard of health.[336]

Certain entitlements accompany the right to health, encompassing the entitlement to a comprehensive healthcare system that ensures equal opportunities for all individuals to access the utmost achievable standard of health; the entitlement to preventive measures, medical care, and disease management; and the right to obtain essential medications.[337] Human rights are interconnected, indivisible, and interdependent.[338] This implies that the infringement upon the right to health can frequently impede the realization of other fundamental human rights, such as the rights to education or employment, and life. The ICESCR General Comment No. 14 states that health is an inherent and essential entitlement of every individual, serving as a prerequisite for the fulfilment of other basic human rights.[339] Each person has the right to the utmost achievable level of health that enables them to

[332] CESCR 2000 General Comment No. 14 para 2.
[333] CESCR 2000 General Comment No. 14 para 2.
[334] CESCR 2000 General Comment No. 14 para 2.
[335] CESCR 2000 General Comment No. 14 para 8.
[336] CESCR 2000 General Comment No. 14 para 8.
[337] WHO and Office of the United Nations High Commissioner for Human Rights 2008 The Right to Health Fact Sheet No. 31 3.
[338] Vienna Declaration and Programme of Action.
[339] CESCR 2000 General Comment No. 14 para 1.

lead a life of dignity.[340] The actualization of the right to health can be pursued through various complementary methods, including the establishment of health policies (international legal instruments such as the UDHR AND ICESCR), the execution of health programs devised by the WHO (such as COVAX and C-TAP), and the adoption of specific legal measures (such as the potential IP waiver and a new global health treaty).[341]

Every individual is entitled to the full enjoyment of the utmost achievable level of physical and mental well-being,[342] including the provision of immunization programs targeting prevalent infectious diseases.[343] Furthermore, every individual possesses the right to reap the advantages of scientific advancements,[344] encompassing access to the most optimal applications of scientific progress essential for attaining the highest attainable standard of health.[345] Both of these rights inherently imply that every individual has the right to obtain a COVID-19 vaccine that is secure, efficacious, and grounded in the utilization of the most advanced scientific breakthroughs.[346] States are obligated to implement all necessary measures, utilizing their maximum available resources, in order to ensure equal access to COVID-19 vaccines for all individuals, without any form of discrimination.[347] The responsibility of States to offer immunization against significant infectious diseases and to prevent and manage health crises is a crucial obligation pertaining to the right to health.[348] Consequently, given the present circumstances, States must prioritize the distribution of COVID-19 vaccines to all individuals as a matter of utmost importance.[349]

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[340] CESCR 2000 General Comment No. 14 para 1.
[341] CESCR 2000 General Comment No. 14 para 1.
[342] See article 12 of the International Covenant on Economic, Social and Cultural Rights and article 25 of the Universal Declaration of Human Rights.
[343] CESCR 2000 General Comment No. 14 para 36.
[344] See article 15 of the International Covenant on Economic, Social and Cultural Rights and article 27 of the Universal Declaration of Human Rights.
[345] CESCR 2020 General Comment No. 25 para 70.
[346] CESCR 2020 Statement on universal and equitable access to vaccines for COVID-19 para 2.
[347] See articles 2, 12 and 15of the International Covenant on Economic, Social and Cultural Rights.
[348] See CESCR 2000 General Comment No. 14 para 44.
[349] CESCR 2020 Statement on universal and equitable access to vaccines for COVID-19 para 3.

The right of every person "to enjoy the benefits of scientific progress and its applications" (REBSPA) is created and safeguarded in Article 15(1)(b) of the ICESCR of 1996. But Article 15(1)(c) continues to state that every person has the right "to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." The interpretation of the REBSPA in Article 15(1)(b) should be considered in conjunction with the other clauses of Article 15, which aim to promote wider availability of science and culture for everyone.[350] It is important to note that the safeguarding of creators' moral and material rights, as outlined in Article 15(1)(c), in relation to the progress of science, as outlined in Article 15(1)(b), must be correctly interpreted. The fulfilment of all human rights, particularly economic, social, and cultural rights, is intricately linked to the advancement of science and the accessibility of technologies.[351] As previously mentioned, the primary goal of Article 15 in its entirety is to promote universal access to science and culture.[352] It is crucial to comprehend the essence of Article 15(1)(c) within the context of this objective. The ICESCR, in a separate General Comment from 2006 that specifically addresses this provision, has provided clarification on the purpose of Article 15(1)(c).[353] It was emphasized by the Committee that Article 15(1)(c) safeguards the personal connection between authors and their creations, as well as their fundamental material interests. Another crucial aspect to emphasize is that Article 15(1)(c) exclusively safeguards individuals identified as *human* persons.[354] The Committee appropriately underscores that *legal* persons are not entitled to protection under this provision.[355] Consequently, this explicitly excludes any pharmaceutical company from being recognized as a human rights-holder. Only human beings have the capacity to create and be considered "authors" as defined by Article 15(1)(c).[356] Hence, Article 15(1)(c) is not a right granted to juristic persons (companies). It protects the personal link between creator and work. "Material" interests mean those needed for a dignified living, but

[350] Saul *et al* 2014 Oxford University Press.
[351] Humphreys 2008 Sustainable Dev L. & Pol'y.
[352] Saul *et al* 2014 Oxford University Press 1176-1224.
[353] CESCR 2006 General Comment No. 17.
[354] Beiter 2022 American University International Law Review p 138.
[355] CESCR 2006 General Comment No. 17.
[356] Beiter 2022 American University International Law Review p 138.

not the profits of a company. The purpose of IP regimes (e.g. the TRIPS Agreement) is to protect investments, whereas the right outlined in Article 15(1)(c) pertains to inherent dignity.[357] Protection under Article 15(1)(c) is only granted if it is necessary for the preservation of "human dignity;" claims that are not based on this specific aspect of human rights law are not afforded protection.[358] Therefore, it is crucial to distinguish between IP rights and the human right outlined in Article 15(1)(c) and not to equate them.[359]

The human right to health comprises a number of essential elements, including availability, accessibility, acceptability, quality, participation, and accountability.[360] Accessibility encompasses physical accessibility (within the domestic market) and economic accessibility (affordability). These components are integral to ensuring that individuals have access to adequate healthcare services and that their needs are met in a timely and effective manner. It is imperative that healthcare providers and policymakers prioritize these components in order to uphold the fundamental right to health for all individuals, as IP can hinder the realization of this right. Human rights enjoy precedence above any other rights, such as IPRs.

3.3.1 Intellectual property, a human right or a public good?

All human beings possess inherent rights known as human rights, which are to be granted to every person without any form of discrimination.[361] Human rights are principles that acknowledge and safeguard the integrity and dignity of every individual.[362] The private interests of creators of specific intellectual creations are safeguarded by IPRs.[363]

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[357] Beiter 2022 American University International Law Review p 138.

[358] *See* ICESCR, *supra* note 18, Preamble, Recital 2 ("Recognizing that these Covenant rights derive from the inherent dignity of the human person").

[359] CESCR 2006 General Comment No. 17, *supra* note 217.

[360] CESCR 2000 General Comment No. 14 para 12.

[361] United Nations *Human Rights* https://www.un.org/en/global-issues/human-rights#:~:text=Human%20rights%20are%20rights%20inherent,and%20education%2C%20and%20many%20more.

[362] UNICEF What are Human Rights? https://www.unicef.org/child-rights-convention/what-are-human-rights.

[363] Van der Merwe *Law of Intellectual Property in South Africa* 3.

The universality of human rights is a defining aspect that cannot be solely attributed to the ubiquity of IPRs, even though these rights are considered "universal" due to their incorporation into the legal systems of almost every country through international IP instruments like the TRIPs Agreement.[364] Merely being widespread is inadequate to equate the nature of IPRs to the nature of human rights.

The original intention behind the creation of IP laws was purely driven by commercial interests.[365] However, in modern times, there is a considerable intersection between Human Rights Law and Intellectual Property Law, surpassing the initial expectations. It is noteworthy that IP has become an integral part of Human Rights. The right to IP is enshrined in both the UDHR and the United Nations Declaration for the Right of Indigenous People (UNDRIP).[366] Not explicitly stated, Article 27 (2) of the UDHR affirms that every individual possesses the entitlement to safeguard their moral and material interests arising from their authorship of any scientific, literary, or artistic creation.[367]

According to the UN Committee on Economic, Social and Cultural Rights, General Comment No. 17 (2005), there are "fundamental differences between a system of private rights and the norms of universal human rights". These differences include: 1. Human rights are inherent and universal entitlements that belong to individuals and, in certain circumstances, to communities.[368] On the other hand, IPRs are granted by the State.[369] 2. IPRs have a limited duration, while human rights endure indefinitely and are regarded as "timeless expressions of fundamental entitlements of the human person."[370] 3. Unlike IPRs, which can be sold, leased, and revoked, human rights are inalienable and cannot be transferred or taken away.[371] 5. Juristic persons, including corporations, are eligible to hold IPRs, while human rights are exclusively available to human beings.[372] 6. Furthermore, IPRs are confined to

[364] Van der Merwe *Law of Intellectual Property in South Africa* 4.
[365] Christmann 2018 Adams&Adams.
[366] Christmann 2018 Adams&Adams.
[367] Christmann 2018 Adams&Adams.
[368] Van der Merwe et al *Law of Intellectual Property in South Africa* 5.
[369] Van der Merwe et al *Law of Intellectual Property in South Africa* 5.
[370] CESCR 2006 General Comment No. 17 para. 2.
[371] Van der Merwe et al *Law of Intellectual Property in South Africa* 5.
[372] Van der Merwe et al *Law of Intellectual Property in South Africa* 5.

particular territories, whereas human rights are universally applicable and surpass geographical boundaries.[373]

The cultural rights enshrined in the UDHR and ICESCR serve as the customary foundation for asserting that IPRs are indeed human rights, as acknowledged in these two instruments. The UDHR's Article 27(2) guarantees the entitlement of every individual "to the safeguarding of the moral and material interests arising from any scientific, literary, or artistic creation for which he or she is the author."[374] This entitlement is reiterated in Article 15(1) of the ICESCR, which mandates State parties to acknowledge the right of every person to "derive benefits from the protection of the moral and material interests arising from any scientific, literary, or artistic creation for which he or she is the author."[375]

The current IPRs regime does not appear to be a sufficient means of realizing article 27(2) of the UDHR and article 15(1)(c) of the ICESCR.[376] IPRs are inherently exclusive and limit access to information and knowledge, which conflicts with the right to benefit from scientific advancement and cultural rights.[377] Instead, it may be more appropriate to view articles 27(2) and 15(1)(c) as broader entitlements that could potentially encompass IPRs, but only if they do not infringe upon other human rights.[378] The perspective of the UN's Committee on Economic, Social and Cultural Rights supports the notion that it is crucial to avoid conflating IPRs with the human right acknowledged in article 15, paragraph 1(c).[379]

The development of the existing IP system, based on TRIPS, is a direct response to the social, political, and economic priorities of the most technologically advanced nations.[380] Consequently, the determination of the equilibrium between the private concerns of IP-holders and the public interest in the creation and distribution of

[373] Van der Merwe et al *Law of Intellectual Property in South Africa* 5.
[374] Art 27 of the UDHR.
[375] Art. 15 of the ICESCR.
[376] Torremans 2007 Copyright as a human right 276.
[377] Van der Merwe et al *Law of Intellectual Property in South Africa* 6.
[378] Gana 1996 Law & Policy paras 14 and 15.
[379] CESCR 2006 General Comment No. 17 para. 3.
[380] Van der Merwe et al *Law of Intellectual Property in South Africa* 11.

intellectual products has been influenced by countries with the greatest economic power.[381]

The rise in commodification and privatization of IP has raised concerns about limited public access to information, knowledge, and technology.[382] However, failure by TRIPS Agreement signatory States to comply may result in enforcement through the WTO's dispute settlement process.[383] Member States must either comply with TRIPS or face exclusion from the international trade regime and the WTO. Despite the costs associated with TRIPS, most States prioritize the potential economic benefits of compliance.[384]

A significant number of vaccines that are potentially eligible for approval have been created by private enterprises and may be subject to IP protections. These enterprises anticipate securing a profit, and it is just that they receive equitable remuneration for their investments and research.[385] Nevertheless, State parties are reminded that IP is not a fundamental human right, but rather a societal creation with a social purpose.[386] Therefore, it is the responsibility of States parties to ensure that IP and patent legal frameworks do not hinder the achievement of economic, social, and cultural rights.[387] This situation may arise when vital public goods such as vaccines or medicines become unattainable for developing nations or impoverished communities due to unjustifiably high costs.[388]

The report presented by the Special Rapporteur in the field of cultural rights provides a more detailed analysis of the distinction between a human rights perspective and the current trends observed in the international IP system. The adoption of a public good approach to knowledge innovation and diffusion is proposed by the Special Rapporteur, who also suggests re-evaluating the existing

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[381] Abbott 2003 Oxford University Press.
[382] Helfer 2007 U.C. Davis Law Review 981–982.
[383] Art. 64 TRIPS Agreement.
[384] Van der Merwe et al *Law of Intellectual Property in South Africa* 11.
[385] Committee on Economic, Social and Cultural Rights *Statement on universal and equitable access to vaccines for COVID-19* para 6.
[386] UN GA 2012 HRC Twentieth session paras 1 and 2.
[387] CESCR 2020 Statement on universal and equitable access to vaccines for COVID-19 para 6.
[388] UN GA 2012 HRC Twentieth session para 35.

maximalist IP approach in order to explore the benefits of a more minimalist approach to IP protection. It appears to be imperative to recalibrate the existing IP norms that could potentially hinder the right to science, while simultaneously striving for enhanced coherence among them. The Special Rapporteur emphasizes the importance of vigilance in preventing excessive privatization of knowledge that could limit individuals' engagement in cultural activities and deprive them of reaping the benefits of scientific advancements. This cautious approach is essential to prevent the overall impoverishment of society.[389]

Therefore, in accordance with the provisions outlined in the WTO Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights Agreement TRIPS and Public Health (2001), it is imperative that the IP framework be construed and executed in a manner that upholds the obligation of nations to safeguard public health.[390] It is imperative to note that the right to one's IP is only extended to natural persons, and not corporations, as stated above. It is important that in the context of a global health threat, IP-related products that are introduced into the market to address such a threat, should perceive such an IP as a public good, instead of an exclusive right.

Global public goods are defined as goods that are indispensable for individuals worldwide. Knowledge, whether it pertains to technology or other areas, is widely recognized as a global public good.[391] The task of guaranteeing the worldwide availability and accessibility of knowledge presents a significant challenge, particularly in instances where said knowledge is concentrated and restricted within the global North due to the IPRs held by its proprietors, despite its necessity in the global South.[392] It has been observed that a select group of influential corporate entities in developed nations, who may not necessarily possess significant levels of innovation themselves, wield considerable control over the worldwide dissemination of knowledge.[393] This group effectively operates as a "knowledge cartel".[394] The

[389] UN GA 2012 HRC Twentieth session para 65.
[390] CESCR 2020 General Comment No. 25 para 69.
[391] Beiter 2021 Law and Development Review 311–325.
[392] Beiter 2021 Law and Development Review 235.
[393] Maskus and Rechman 2005 Cambridge University Press 20.
[394] Beiter 2021 Law and Development Review 235.

governments of industrialised countries are known to vigorously safeguard the interests of these corporate entities.[395]The TRIPS Waiver proposal could be useful in this regard, as it broadly interprets trade secrets to encompass know-how, data, and other undisclosed information.

3.4 The equilibrium between private and public interests in the TRIPS Agreement

In the case of developing nations, which typically rely on medical and technology imports, the patent system serves primarily to safeguard the IPRs of foreign entities seeking to establish a foothold in their markets.[396] Due to the prohibition of selective implementation and enforcement of the TRIPS Agreement[397], these countries are unable to address exorbitant pricing by, for instance, exempting pharmaceutical drugs from patent protection in order to fulfil their public health obligations.[398] The implementation of patent and trade secret protection has resulted in the establishment of robust monopolies within the pharmaceutical industry, leading to the pricing of drugs at their maximum market value (monopoly prices).[399] This has rendered them inaccessible to a significant number of countries. In contrast to "ordinary" consumer goods, where pricing strategies may inconvenience affordability due to the elasticity of demand (such as when the prices of coffee goes up, you can substitute it with tea), the demand for pharmaceuticals is inelastic, and the consequences of unaffordability are dire.[400] The escalating demands of public health and the need for affordable access to patented medicines has resulted in a growing conflict with the IP and trade regime.[401] The advent of the COVID pandemic has compelled the world to confront this imbalance head-on, as it has further intensified the pre-existing tensions between international trade and IP, and the vulnerability of public health.[402]

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[395] Beiter 2021 Law and Development Review 236.
[396] Van der Merwe et al *Law of Intellectual Property in South Africa* 14.
[397] Art. 27(1) of the TRIPs Agreement.
[398] Van der Merwe et al *Law of Intellectual Property in South Africa* 14.
[399] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[400] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[401] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[402] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.

Hanns Ullrich posits that there exists a distinct inclination in the IP policies of the countries of the global North towards bolstering the stance on collaborative innovation, while relegating the notion of technology transfer and dissemination to a secondary status.[403] This trend is evident in the IP and competition policies of developed nations and has influenced the interpretation of the TRIPS Agreement.[404] The IPRs outlined in TRIPS are interpreted expansively, while its dissemination, access, and competition regulations pertaining to IP are construed reductively, with the aim of promoting innovation through robust IP protection, even if this has an adverse impact on dissemination and access.[405]

For an extended period, and as mentioned above, there has been a persistent conflict between health and trade.[406] The primary source of this tension has been IP.[407] Although IP was initially promoted as a means to attract foreign direct investment and foster progress, it has also led to increased costs and restricted access to essential healthcare products, such as patented medicines (including vaccines), in certain regions of the world.[408] The TRIPS Agreement had envisioned – this was the political consensus between North and South underlying it – that the protection of IPRs would foster innovation, but also facilitate the transfer and dissemination of technology.[409] In this regard, exceptions and limitations, competition law, and policy space for developing countries to advance socio-economic development were intended to play a role in maintaining a balance between these objectives.[410] However, it is evident that the balance has shifted significantly towards the incentive rationale.[411] To clarify the conflicting legal regimes, a brief explanation of each should be given. On the one hand, there is the international trade and IP regime of the WTO (and WIPO). On the other, there is the international human rights regime of the U.N. and its specialised agencies, such as the WHO, but also including regional human rights organisations in Europe,

[403] Ullrich 2004 Journal of International Economic Law 13.
[404] Beiter 2021 Law and Development Review 236.
[405] Beiter 2021 Law and Development Review 236.
[406] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[407] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[408] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[409] Beiter 2021 Law and Development Review 230.
[410] Beiter 2021 Law and Development Review 230.
[411] Beiter 2021 Law and Development Review 231.

America, and Africa. As discussed above, the economic premise of IP rights is to promote innovation and creativity with the goal that these innovations will lead to long-term economic and other benefits to society.[412] The purpose of the trade regime is to reduce the barriers to global trade in "goods and services" as a mechanism to increase economic productivity.[413] Until recently, global trade and IP seemed to work in tandem, but public health always unfortunately remained uncomfortably incompatible with these regimes.[414] Any attempts at protecting public health have been misconstrued as an attack or creating barriers to trade and IP's promise of innovation.[415] Consequently, a global solution to the COVID-19 pandemic and any other comparable future health crisis would have to establish a balance between IPRs on medicines (including vaccines) and access to these. This may be stated to be a demand of the integration rule contained in Article 31(3)(c) of the Vienna Convention on the Law of Treaties.[416] It requires any treaty, thus also TRIPS, to be read in the light of any other relevant international agreements applicable between the parties. Relevant international agreements include human rights agreements such as the ICESCR, clearly protecting the right to health. However, the notion of a global free trade system is frequently impeded by bilateral free trade relationships between nations,[417] such as TRIPS-Plus agreements.

In this context, Articles 7 and 8 of TRIPS are of paramount importance. These provisions embody public interest considerations, such as the "object and purpose" of TRIPS.[418] Furthermore, it should be noted that these articles also provide a link to the corpus of international human rights law (IHRL).[419] This part of the chapter will have an in-depth look at article 7 and 8 of the TRIPS Agreement and analyse how it attempts to create an equilibrium between both private and public interests, and how it is currently being construed in practice. Furthermore, aside from the innate flexibility in incorporating elements such as the standards for patentability,

[412] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[413] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[414] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[415] Ragavan *Creating a Culture of Health: A Public Health Treaty?* 1.
[416] Vienna Convention on the Law of Treaties (1980).
[417] Stromiedel World Trade Policy and the Game Theory – Overcoming the Prisoner's Dilemma?
[418] Beiter 2021 Law and Development Review 215.
[419] Beiter 2021 Law and Development Review 215.

Member States have at their disposal two key provisions that can mitigate the impact of patents on accessibility and affordability, namely articles 30 and 31. This part of the chapter will examine what these flexibilities entail, and why they remained unused during the COVID-19 Pandemic. Lastly, it will examine if TRIPS is equipped to deal with health emergencies on a global scale, in a fair and equitable manner.

3.4.1 Articles 7 and 8 TRIPS

The central role of ensuring the Members of the WTO the right to implement public health measures is executed by Articles 7 and 8 of TRIPS.[420] The interpretation of any provision of the TRIPS Agreement that may have public health implications is also influenced by the Doha Declaration on the TRIPS Agreement and Public Health.[421] The WTO Panel decision of 2018 on the Australia – Tobacco Plain Packaging dispute is the most recent and prominent example of the use of articles 7 and 8 for interpretation in WTO law.[422]

"Articles 7 and 8, together with the preamble of the TRIPS Agreement, set out general goals and principles underlying the TRIPS Agreement, which are to be borne in mind when specific provisions of the Agreement are being interpreted in their context and in light of the object and purpose of the Agreement."[423] The TRIPS Agreement's drafters formulated articles 7, titled "Objectives," and article 8, titled "Principles," with the intention of ensuring the safeguarding of policy autonomy at the domestic level.[424] These two provisions serve as fundamental components in achieving the necessary equilibrium between incentivizing and fostering technological advancement through IPRs, while simultaneously addressing national imperatives such as public health, food security, and the advancement of domestic industrial and technological capacities.[425] Article 7, titled "Objectives", of the TRIPS agreement states:

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[420] Romero 2020 South Centre Policy Brief 1.
[421] Romero 2020 South Centre Policy Brief 1.
[422] Romero 2020 South Centre Policy Brief 1.
[423] WTO 2022 Implications of the WTO disputes para. 7.2402.
[424] Correa 2016 South Centre Research Paper 5.
[425] Romero 2020 South Centre Policy Brief 1.

> 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.[426]

Article 7 unambiguously stipulates that IPRs do not serve as a sole objective. They are required to facilitate the advancement of technological innovation, as well as the transfer and dissemination of technology.[427] It is imperative to note that IPRs do not inherently foster technological innovation.[428] The correlation between practical innovation and fundamental research carried out in universities and research institutions, which are substantially financed by the government, is more robust than that with innovative initiatives incentivised by any IPRs conferred.[429] Also, the safeguarding of IPRs does not inherently result in the transfer and dissemination of technology.[430] This assertion provides compelling support for the recognition of competition law pertaining to IP as a tool that can facilitate the attainment of transfer and dissemination.[431] It is noteworthy that Article 7 employs the term "should" instead of "shall contribute."[432] Carlos Correa presents a noteworthy perspective regarding the utilization of the term "should".[433] Instead of merely indicating a non-binding obligation, it conveys the notion that the conferment of IPRs alone does not necessarily result in the transfer and dissemination of technology.[434] The term "should" serves to emphasize that the grant of IPRs must be executed in a manner that guarantees such an outcome.[435] This assertion is of utmost significance. Article 7 unequivocally demands the attainment of equilibrium in a manner that fosters economic and social welfare on a broader scale.[436] This provision serves as a comprehensive safeguard against an unbalanced approach to IP protection. Achieving a harmonious coexistence between

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[426] TRIPS, supra note 2, art. 7.
[427] Beiter 2021 Law and Development Review 238.
[428] Beiter 2021 Law and Development Review 238.
[429] Beiter 2021 Law and Development Review 142.
[430] Beiter 2021 Law and Development Review 238.
[431] Beiter 2021 Law and Development Review 238.
[432] Beiter 2021 Law and Development Review 238.
[433] Beiter 2021 Law and Development Review 238.
[434] Beiter 2021 Law and Development Review 238.
[435] Correa 2016 South Centre Research Paper 97.
[436] UNCTAD-ICTSD (2005), supra note 28, p. 126 (emphasis added); Beiter 2021 Law and Development Review 238.

the advancement of innovation and the transfer and dissemination of technology necessitates a delicate balance between the interests of both technology "producers" and "users," as explicitly stated in Article 7.[437]

The significance of maintaining equilibrium between the interests of technological knowledge producers and users is evident when considering that in developing nations (usually in the global South), the majority of individuals fall under the category of technological knowledge users, while the producers are predominantly situated in developed countries (usually the global North).[438] It is important to note that the term "users" encompasses a broad range of individuals, including those who produce goods and services that utilize technology, as well as end consumers.[439] Article 7 aims to promote technological innovation and facilitate the transfer and dissemination of technology, while protecting and enforcing IPRs.[440] This should benefit both producers and users of technological knowledge, and promote social and economic welfare, while maintaining a balance of rights and obligations.[441] "Article 7 reflects the intention of establishing and maintaining a balance between the societal objectives mentioned therein."[442] This interpretation of article 7 indicates that in order to achieve the objectives of the TRIPS Agreement, several factors must align to fulfil the distinct purpose of the contribution of IP to society. It suggests that solely protecting IP does not result in welfare benefits, [443] as mentioned earlier. Instead, it is the exchange and spread of technology, the mutual advantages for both creators and users of technological knowledge, within a framework of balanced rights and responsibilities, that hold equal significance and can be pursued simultaneously through various methods, such as implementing laws and regulations to prevent anti-competitive practices.[444] Article 7 of the TRIPS Agreement emphasizes that the purpose of protecting and enforcing IPRs is not solely for its own sake, but rather to acknowledge and incentivize the efforts of

[437] Beiter 2021 Law and Development Review 238.
[438] Beiter 2021 Law and Development Review 239.
[439] Beiter 2021 Law and Development Review 239.
[440] WTO Analytical Index *TRIPS Agreement – Article 7* (DS reports).
[441] WTO Analytical Index *TRIPS Agreement – Article 7* (DS reports).
[442] WTO 2022 Implications of the WTO disputes para. 7.2403.
[443] Manu 2017 Oxford University Commonwealth Law Journal.
[444] Romero 2020 South Centre Policy Brief.

inventors and creators who contribute to the socio-economic well-being.[445] By doing so, the TRIPS Agreement aims to foster innovation and facilitate the widespread sharing of technology, ultimately benefiting society as a whole.[446]

The principles outlined in Article 8 of this TRIPS Agreement allow for the adoption of measures necessary to safeguard public health, as well as promote the public interest in sectors vital to socio-economic and technological development.[447] These measures must be consistent with the provisions of the Agreement. Additionally, appropriate measures may be required to prevent the misuse of IPRs or practices that unreasonably restrict trade or negatively impact the international transfer of technology, provided they are consistent with the Agreement.[448] Article 8, titled "Principles", of the TRIPS Agreement reads as follows:

> (8)(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.
>
> (8)(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.

Article 8 explicitly states that its provisions do not aim to hinder Members from enacting laws and regulations that serve specific lawful objectives.[449] The drafters of the TRIPS Agreement intended to maintain the capacity of WTO Members to pursue legitimate societal interests, as expressed in Article 8.[450] This principle acknowledges that measures taken by Members for these purposes may affect IPRs, and mandates that such measures must align with the provisions of the TRIPS Agreement.[451]

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[445] Romero 2020 South Centre Policy Brief.
[446] See, e.g., UNCTAD, Reference Guide to IPRs and Pharmaceutical Production in Developing Countries, UNCTAD/DIAE/PCB/2009/19, Geneva, (2011). Available from https:// unctad.org/en/pages/PublicationArchive.aspx? publicationid=437.
[447] TRIPS Article8(1).
[448] TRIPS Article8(2).
[449] WTO 2022 Implications of the WTO disputes para. 7.2402.
[450] WTO 2022 Implications of the WTO disputes.
[451] WTO 2022 Implications of the WTO disputes.

TRIPS articles 7 and 8, along with the Doha Declaration, play a vital role in the achievement of the right to health, despite not explicitly addressing human rights.[452] These provisions are of the utmost importance. The Doha Declaration specifically emphasizes that the TRIPS Agreement should be understood and executed in a manner that supports the right of WTO Members to safeguard public health and, more specifically, to enhance access to medicines for all individuals.

3.4.2 Article 30 of TRIPS

Article 30 of the TRIPS Agreement confers upon Members the prerogative (flexibility) to restrict the exclusive rights of patent-holders by stipulating that in specific circumstances, unauthorized activities pertaining to the patented subject matter shall not be deemed as an infringement of the patent. Article 30 states:

> 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.[453]

Article 30 of the TRIPS Agreement outlines the requirements for an exception to be in line with the Agreement.[454] These requirements, commonly referred to as the 'three-step test',[455] consist of the following criteria:

1. The exception must have limitations in its scope.

2. It should not unreasonably hinder the normal exploitation of the patent.

3. It must not unreasonably harm the legitimate interests of the patent-owner, while also considering the legitimate interests of third parties.[456]

A comprehensive and overall assessment is deemed necessary for the three-step test, rather than conducting a separate and independent assessment of each

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[452] Correa 2016 South Centre Research Paper 97.
[453] Article 30 of TRIPS
[454] Max Planck Institute *Declaration on Patent Protection* 8 para 22.
[455] Max Planck Institute *Declaration on Patent Protection* 8 para 22.
[456] Max Planck Institute *Declaration on Patent Protection* 8 para 22.

criterion.[457] Non-compliance with any of the three conditions does not necessarily lead to the disallowance of the exception.[458]

An exception is considered 'limited' under the TRIPS Agreement if it adheres to the criteria outlined in Article 30.[459] Being 'limited' does not solely depend on having a narrow effect. Instead, it is determined by the reasonable proportionality between the exception's scope and its objective and purpose.[460] The exception must serve a legitimate purpose, be sufficient to achieve that purpose, and not go beyond what is necessary and essential to accomplish it.[461]

An exception is considered not to "unreasonably prejudice legitimate interests" if it is both reasonable and proportionate.[462] In light of this, it is necessary to take into account all interests involved, including:

> …those of the patent holder and their actual and potential licensees, follow-on inventors, competitors, and other market actors who need to operate under conditions of effective competition, scientific and academic researchers who require access to the findings of basic research, consumers who benefit from technological advancement, and the general public, which experiences improved social, cultural, and economic well-being.[463]

Article 30 is not limited to particular medical and technological categories, but rather is expressed in a broader language.[464] Consequently, the provisions may be employed to permit exemptions, such as research and experimental usage, initial implementation of the patent to enable generic drug manufacturers to pursue regulatory clearance for the marketing of a generic version of a medication, or PI of medications that have been legitimately introduced into a foreign market.[465]

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[457] Max Planck Institute *Declaration on Patent Protection* 8 para 22; also see the Declaration on a Balanced Interpretation of the 'Three-Step Test' in Copyright Law (2006), available at http://www.ip.mpg.de/en/pub/news/declaration-threesteptest.cfm.
[458] Max Planck Institute *Declaration on Patent Protection* 8 para 22; also see the Declaration on a Balanced Interpretation of the 'Three-Step Test' in Copyright Law (2006), available at http://www.ip.mpg.de/en/pub/news/declaration-threesteptest.cfm.
[459] Max Planck Institute *Declaration on Patent Protection* 8 para 23.
[460] Max Planck Institute *Declaration on Patent Protection* 8 para 23.
[461] Max Planck Institute *Declaration on Patent Protection* 8 para 23.
[462] Max Planck Institute *Declaration on Patent Protection* 8 para 25.
[463] Max Planck Institute *Declaration on Patent Protection* 8 para 25.
[464] Van der Merwe et al *Law of Intellectual Property in South Africa* 14.
[465] Van der Merwe et al *Law of Intellectual Property in South Africa* 15.

In the event that no exception is present, the regulatory approval process mandated by the government for the introduction of a medication into the market commences solely after the expiration of the patent, thereby impeding the availability of the frequently more affordable generic variant.[466] Article 30 may facilitate the conduct of examinations on the generic drug during the patent's duration, thereby enabling the generic product to be introduced into the market expeditiously following the expiration of the patent on the safeguarded subject matter.

In the event that a variation exists between the cost of medicines in a foreign nation and the cost at which the same goods are obtainable in the importing nation, it is plausible to buy the goods at a reduced price compared to the rate stipulated by the patent-holder in the importing nation.[467] In the realm of medicine accessibility, PI can serve as a viable means of enabling access to reasonably priced medication. Public-health authorities in numerous countries contend that it is crucial to have the ability to procure medications from the most cost-effective sources, necessitating an unrestricted PI framework.[468] Regardless of whether these imports materialize, the mere possibility of their occurrence could compel distributors to lower their prices. It is apparent that the policymakers of developing countries, in particular, would prioritize the affordability of medicines over fostering R&D overseas.[469] Article 6 of TRIPS pertains to the exhaustion of IP and asserts that, in relation to the resolution of conflicts under this Agreement, the matter of the exhaustion of IPRs shall not be addressed, except as provided for in Articles 3 and 4.[470] With regards to the exhaustion of IPRs, paragraph 5(d) of the Declaration on the TRIPS Agreement and Public Health, which was approved on 14 November, 2001, states that the TRIPS Agreement's relevant provisions on the exhaustion of IPRs allow each Member to establish its own system for such depletion without opposition,

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[466] Van der Merwe et al *Law of Intellectual Property in South Africa* 15.
[467] Van der Merwe et al *Law of Intellectual Property in South Africa* 15.
[468] Maskus Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries 2.
[469] Maskus Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries 2.
[470] WTO Analytical Index *TRIPS Agreement – Article 6 (Practice) https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art6_oth.pdf.*

provided that it adheres to the MFN and national treatment provisions of Articles 3 and 4.1.

3.4.3 Article 31 of TRIPS

It is imperative to differentiate between the exception outlined in Article 30, which has the potential to be universally applicable to benefit patent-holders and the users of patented inventions, and the stipulations set forth in Article 31, which are specifically targeted towards a particular scenario involving a designated patent and user.[471] According to Article 31 of the TRIPs Agreement, it is permissible for Members States to authorize the use of patented subject matter (in this case medicines, including vaccines) by entities other than the right holder, such as the government or third parties authorized by the government, without requiring the right holder's consent, that is, by granting a CL.[472] Two types of compulsory licences can be categorized: those that uphold the operational effectiveness of the protection system, and those that cater to additional public interests.[473] States have the freedom to utilize CLs as a regulatory tool due to the absence of limitations on the grounds for issuing such licences in both Article 31 of the TRIPS Agreement and Article 5A of the Paris Convention.[474] Though Article 31 does not impose any restrictions on the justifications for granting a CL, it highlights certain circumstances where the granting of a CL might be particularly relevant. It may be granted in the case of a "national emergency" or "other circumstances of extreme urgency", for "public non-commercial use", and to correct anti-competitive practices.[475] As the TRIPS Agreement does not impose any restrictions on the justifications for granting a CL, Article 31 may be invoked by Members to authorize the utilization of protected inventions by manufacturers of generic equivalents for the production of pharmaceutical drugs. The underlying presumption is that the generic manufacturer will be capable of providing the market with drugs at a reduced cost compared to that of the patent-holder, thereby enabling access to reasonably priced

[471] Van der Merwe et al *Law of Intellectual Property in South Africa* 15.
[472] Van der Merwe et al *Law of Intellectual Property in South Africa* 15.
[473] Max Planck Institute *Declaration on Patent Protection* 9 para 29.
[474] Max Planck Institute *Declaration on Patent Protection* 9 para 28.
[475] Article 31(b), (k).

medicines.[476] Hence, a relevant consideration for a CL is lacking availability or accessibility of medicine on the market. The reference to national emergency and situation of extreme urgency indicates that pandemics such as the HIV/AIDS or COVID-19 pandemics are situations where the need for CLs may be particularly acute to secure available and accessible medicines or vaccines. CLs serve as effective policy instruments to maintain a harmonious equilibrium between patent protection and various socio-economic concerns.[477] These licences are granted in the public interest, particularly when there is an insufficient supply or unreasonably restrictive terms for the patented invention. Additionally, they may be issued when the patent-holder refuses to grant a voluntary license, thereby impeding the establishment or growth of domestic industries.[478]

Though no restrictions on the justification for granting CLs are laid down, it should be noted that Article 31 encompasses several prerequisites that a Member remains obligated to fulfil, which includes the requirement stipulated in Article 31(b).[479] This requirement mandates that, prior to utilizing the patented content, the intended user must exert efforts to secure authorization from the rightful patent owner on agreeable commercial terms.[480] Furthermore, these efforts must be undertaken within a reasonable timeframe, and should they prove futile, the user can proceed with their usage.[481] In addition, Article 31(b) further stipulates that a Member has the authority to waive this requirement in situations of a national emergency or other instances of extreme urgency.[482] The practical utilization of CLs may be constrained despite the significant regulatory independence of States in determining the grounds for their issuance.[483] The patent-holder's disciplinary consequences are frequently insignificant due to an excessively stringent execution of the procedural modalities outlined in Articles 31(a) to (l) of the TRIPS Agreement.[484] Consequently, this may incentivize the patent-holder to exploit their advantageous position during

[476] Van der Merwe et al *Law of Intellectual Property in South Africa* 15.
[477] Max Planck Institute *Declaration on Patent Protection* 9 para 29.
[478] Max Planck Institute *Declaration on Patent Protection* 9 para 29.
[479] Kehl 2002 Journal of Intellectual Property Law.
[480] Article 31(b) of TRIPS.
[481] Kehl 2002 Journal of Intellectual Property Law 143.
[482] Kehl 2002 Journal of Intellectual Property Law 143.
[483] Max Planck Institute *Declaration on Patent Protection* 10 para 31.
[484] Max Planck Institute *Declaration on Patent Protection* 10 para 31.

voluntary license (VL) negotiations, potentially resulting in detrimental consequences for the public interest.

VLs refer to private contractual agreements wherein pharmaceutical corporations that hold patents (licensors) establish the conditions for the entry of a generic version of a patented medicine into the market by alternate suppliers (licensees).[485] Although generic manufacturers may be licensed through the use of VLs to provide medications at a lower cost than the pharmaceutical company that holds the patent, they frequently impose covert and limiting terms that hinder access to medicine.[486] By means of licensing agreements, pharmaceutical companies can restrict the sale of their products to certain locations and individuals, regulate the supply of active pharmaceutical ingredients (API), and impose additional limitations on licensees.[487] Since VLs are bilaterally agreed upon, the following issues may arise: lack of transparency, terms and conditions that vary across multiple licences, broadening the scope of patents, geographic limitations, differential treatments toward certain groups, differential treatment towards different health care systems, complex systems of royalty payments, requirements of anti-diversion, restrictions placed upon research and clinical studies, and stringent grant-back terms.[488] Due to the prerequisites bestowed by TRIPS, it can be time consuming to negotiate a VL, and if one is acquired, the latter issues may arise, ultimately defeating the purpose of seeking the licence to produce cheaper generics. It makes more sense to rely on CLs to save time and costs. It is imperative to appropriately adjust the procedural requirements to prevent an undue burden on the petitioner seeking the license.

The employment of CLs as a means to mitigate the exorbitant costs of patented medications can seldom be observed in developing nations.[489] The question at hand pertains to whether the inclusion of a "national emergency or other circumstances

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485 MSF Southern Africa https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf.

486 MSF Southern Africa https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf.

487 MSF Southern Africa https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf.

488 MSF Southern Africa https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf.

489 Van der Merwe et al *Law of Intellectual Property in South Africa* 16.

of extreme urgency" provision extends to encompass a public health emergency like the COVID-19 pandemic.[490] Should this be the case, a member of the WTO could establish a framework, via legislation, to manufacture and distribute pharmaceuticals at a reduced expense, thereby bypassing the arduous process of negotiating with pharmaceutical companies for a specified duration.[491] The rationales for this are multifaceted and may encompass logistical challenges in execution, as well as political coercion.[492] The implementation of CLs has the potential to create trade conflicts with nations that manufacture patented medications. The mere possibility of compulsory licensing can also negatively impact trade partnerships between countries.[493]

3.5 Non-use of TRIPS flexibilities

The mandatory licensing, government usage, and parallel importation flexibilities represent potentially formidable instruments within the framework of the TRIPS Agreement, as reinforced by the Doha Declaration, for the promotion of public health objectives.[494] Nevertheless, numerous countries with lower- and middle-income levels have exhibited a discernible reluctance to integrate these measures into their domestic legislation and subsequently apply them, with only a limited number of exceptions.[495] To understand why these flexibilities have gone unused by developing countries, one must look at the contextual framework and historical origins of compulsory licensing and parallel importation, as well as their incorporation into the TRIPS Agreement.[496] Additionally, one must explore recent instances of their efficacy, specifically in two sub-Saharan nations grappling with the impact of HIV/AIDS[497] that evidenced the shortcomings of TRIPS.

Several additional challenges exist, that encompass political and economic pressures exerted by nations that harbour industries rich in IP, who actively discourage the

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[490] Kehl 2002 Journal of Intellectual Property Law 164.
[491] Kehl 2002 Journal of Intellectual Property Law 164.
[492] Van der Merwe et al *Law of Intellectual Property in South Africa* 16.
[493] Abbas 2013 International Journal of Social Science and Humanity 254-255.
[494] Vawda 2018 South Centre Research Paper 73.
[495] Vawda 2018 South Centre Research Paper 73.
[496] Vawda 2018 South Centre Research Paper 73.
[497] Vawda 2018 South Centre Research Paper 73.

utilization of flexibilities by LMICs.[498] Additionally, there is a shortage of technical, legal, and regulatory capabilities to handle such applications.[499] Lastly, the legal and judicial culture prevalent in numerous countries, whose IP laws originated during the colonial era, poses a significant obstacle.[500] The theory may be examined in practice by discussing the contrasting reactions of two nations situated at the forefront of the HIV/AIDS epidemic in sub-Saharan Africa, specifically Zimbabwe and South Africa.[501] The aim is to comprehend their individual strategies regarding the implementation of CL, government use, and PIs as well as to identify the obstacles that must be addressed.

3.5.1. Zimbabwe

The principal legislation governing the CL regime in Zimbabwe is the Patents Act 57 of 1978,[502] which has undergone three rounds of amendments (in 2001, and twice in 2002) to ensure compliance with the TRIPS agreement. The Act encompasses provisions for compulsory licensing and government use, as well as specific provisions for government use during specific emergencies.[503] The parameters for compulsory licences are restricted to two categories: (1) patents that are reliant on other patents,[504] and (2) various forms of 'patent abuse', including non-functionality, inability to meet reasonable demand, refusal to license, and any anti-competitive behaviour.[505] In the latter group of cases, the petitioner must prove that they were unable to secure a license on reasonable terms within six months of requesting a voluntary license, and that the public's reasonable needs with regard to the invention have not been or will not be met.[506] The aforementioned Act incorporates

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[498] The aforementioned issue has been brought to the forefront in the recent case of Colombia's endeavour to grant a mandatory license for imatinib, as reported by the Minister of Health during a session of the World Health Assembly. Further details can be found in the WIPO (2017) WIPO Standing Committee on the Law of Patents document, accessible at https://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_6.pdf, page 3.

[499] Vawda 2018 South Centre Research Paper 75.

[500] Vawda 2018 South Centre Research Paper 16–18.

[501] Vawda 2018 South Centre Research Paper 76.

[502] Patents (Amendment) Act, 1987 Chapter 26:03 (amended by Acts 26/1971, 39/1973 (ss. 39 and 52), 42/1976 (s. 15), 39/1979, 15/1981, 29/1981, 41/1983, 12/1986 (s. 13), 11/1991 (s. 17), 20/1994 (s. 7), 22/2001, 9/2002, 14/2002.).

[503] Vawda 2018 South Centre Research Paper 82.

[504] Patents (Amendment) Act, 1987 Chapter 26:03, s 30A.

[505] Patents (Amendment) Act, 1987 Chapter 26:03, s 31.

[506] Patents (Amendment) Act, 1987 Chapter 26:03, s 31(1).

"Special Provisions as to State Use During Emergency",[507] which grants the State and authorized parties the authority to manufacture, utilize, implement, and market the invention for purposes deemed necessary or expedient by the Minister to accomplish various public interest objectives.[508] The premise of 'necessity' is deemed credible in cases where the invention pertains to a medicine (including vaccines) or other public necessity that is not readily accessible to the general populace or a substantial cohort of patients.[509] Upon submission of an application, the pertinent tribunal is to bestow a presumptive license, contingent upon the payment of a reasonable and feasible royalty.[510] Utilizing this framework, the government of Zimbabwe has issued what appears to be the initial government usage permit for pharmaceuticals in the post-Doha epoch.[511] During the HIV/AIDS pandemic and the serious shortages of medicines and treatments available, Zimbabwe invoked "General Notice 240 of 2002: Declaration of Period of Emergency (HIV/AIDS)."[512]

Due to the swift spread of HIV/AIDS within the population of Zimbabwe, the Minister therefore proclaimed a state of emergency.[513] The objective of this declaration was to empower the state to grant authority to the state or an individual duly authorized by the Minister to manufacture or utilize any patented drug, including antiretroviral drugs, for the treatment of individuals with HIV/AIDS or HIV/AIDS-related ailments. Additionally, this declaration permitted the importation of any generic drug utilized in the treatment of individuals suffering from HIV/AIDS or HIV/AIDS-related conditions.[514] Nonetheless, the cost of medications remained significantly high in both the private and public sectors in Zimbabwe. A study indicated that the prices of medicines in the public sector exceeded the average prices observed in seven other African nations.[515] However, subsequent to this study, prices for essential medicines in the public sector decreased. In 2006, Brazil, Chile, France, Norway and

[507] Patents (Amendment) Act, 1987 Chapter 26:03, s 35.
[508] Vawda 2018 South Centre Research Paper 85.
[509] Vawda 2018 South Centre Research Paper 84.
[510] Vawda 2018 South Centre Research Paper 84.
[511] Oh 2006 International Journal of Intellectual Property Management.
[512] General Notice 240 of 2002.
[513] General Notice 240 of 2002.
[514] General Notice 240 of 2002.
[515] Vawda 2018 South Centre Research Paper84.

the United Kingdom founded the Unitaid Medicines Patent Pool, hosted by the World Health Organization. The Unitaid Medicines Patent Pool, which now includes all antiretrovirals (ARVs) recommended by the World Health Organization, is directed at LMICs. All sub-Saharan African countries are considered eligible. As a result, the use of flexibilities for such medicines would be unnecessary.[516] However, since there are no licensing arrangements in place for various other essential medicines with excessively high price tags, the need to employ TRIPS flexibilities persists.[517]

3.5.*2. South Africa*

Simultaneously, South Africa encountered a substantial escalation in the prevalence of HIV infection, exacerbating the enormity of the public health issue. As a result, SA swiftly obtained the status of having the greatest quantity of individuals who are afflicted with HIV/AIDS.[518]

The pharmaceutical industry and the South African government were at odds over the reduction of drug prices. The government's emphasis on this issue drew significant criticism from the industry, leading to a media battle between the Pharmaceutical Manufacturers Association of South Africa (PMA) and the Minister of Health. The Minister of Health argued that the shortage of prescription drugs in the public sector and the high prices in the private sector were due to pricing strategies adopted by multinational pharmaceutical companies.[519] These companies held patents in South Africa on most antiretroviral drugs, which contributed to the problem.[520]

The South African Medicines and Related Substances Control Act underwent a modification with the insertion of a new Section 15C. The main objective of this amendment was to provide South Africa with the opportunity to take advantage of reduced prices for identical medications from foreign sources, thus allowing PI under this new provision.[521]The Medicines and Related Substances Act 101 of 1965 was

[516] Vawda 2018 South Centre Research Paper84.
[517] Vawda 2018 South Centre Research Paper87.
[518] Fisher and Rigamonti 2005 The Law and Business of Patents 3.
[519] Attaran and Gillespie-White 2001 Journal of the American Medical Association.
[520] Attaran and Gillespie-White 2001 Journal of the American Medical Association.
[521] Fisher and Rigamonti 2005 The Law and Business of Patents 5.

fiercely contested by multinational pharmaceutical companies during its progression through Parliament.[522] Over 40 pharmaceutical corporations, including some of the most prominent and influential entities globally, were set to initiate legal proceedings against the South African government in an attempt to prevent the implementation of legislation designed to decrease the cost of medication for South African citizens.[523] The enactment of Section 15C faced strong opposition from the U.S. pharmaceutical industry, supported by the U.S. government, due to concerns about a potential domino effect in the developing world. They argued that this section would effectively nullify patent rights and contravene the TRIPS Agreement.[524] It was asserted that CLs and PIs undermine the patent rights of the pharmaceutical industry. Considering the significant financial implications for the patent holders and the alarming number of HIV-infected individuals in South Africa, it can be deduced that the primary target of international opposition lies in the implementation of compulsory licensing for AIDS drugs.[525] But in retrospect, SA successfully contended that Section 15C adhered to TRIPS regulations by asserting that PIs were not prohibited under TRIPS and that the contentious matter of compulsory licensing was not addressed by Section 15C.[526] None of the provisions of the TRIPS Agreement, except those related to non-discrimination, can be utilized to tackle the matter of exhaustion of intellectual property rights in a dispute brought before the WTO.[527] This implies that even if a nation permits parallel imports in a manner that another nation believes infringes upon the TRIPS Agreement, it cannot be contested in the WTO unless principles of non-discrimination are at stake.[528] The Doha Declaration elucidates that this grants Members the freedom to determine how to handle exhaustion according to their own domestic policy objectives.[529] South Africa held the belief that it was being subjected to a "TRIPS-Plus" standard, which entails a higher level of patent protection than what is mandated by TRIPS.

[522] Sidley 2001 BMJ 447.
[523] Sidley 2001 BMJ 447.
[524] Fisher and Rigamonti 2005 The Law and Business of Patents 5.
[525] Marc 2001 NYLS Journal of International and Comparative Law 168.
[526] See WHO & WTO, WTO Agreements & Public Health 106 (2002).
[527] Article 6 of TRIPS and Doha Declaration 5(d).
[528] Article 6 of TRIPS and Doha Declaration 5(d).
[529] Article 6 of TRIPS and Doha declaration 5(d).

This belief was held not only towards the U.S. government but also towards the private plaintiffs involved in the lawsuit against Section 15C.[530]

The South African Treatment Action Campaign (TAC) and other AIDS activists urged for global demonstrations against "drug profiteering" and argued that postponing the implementation of the revised MRSCA would result in more lives lost. However, pharmaceutical companies justified their legal actions by stating that "parallel importation of drugs would weaken the pharmaceutical industry's ability to set varying prices in different regions" and that a "tiered pricing strategy enables wealthier nations to support poorer ones, while still ensuring the drug companies receive the necessary profits for research."[531] (This assertion has proven to be a false during the COVID-19 pandemic, as the contracts for the vaccines were analysed by the Health Justice Initiative (HJI), revealing that Gavi, Pfizer, Johnson & Johnson's subsidiary Janssen Pharmaceutica, and the Serum Institute of India imposed conditions of secrecy, restricted distribution to other nations, and charged prices that were higher than what wealthier countries paid.[532] South African campaigners took legal action against the government to ensure the publication of these contracts.) In addition, a representative from the pharmaceutical industry expressed concerns regarding the influx of PIs, stating that a significant portion of these imports lack active ingredients. This situation poses a grave threat to patients, as it not only leads to ineffective treatments but also contributes to the development of drug resistance. Moreover, it instils false hope in individuals seeking proper medical care.[533]

The former South African Minister of Health, Nkosasana Zuma, has granted permission to pharmaceutical companies to segregate the market by imposing varying prices in different countries. However, the minister reserved the authority to procure from a segment that aligns with the country's financial capabilities.[534] In addition, she made it clear that South Africa had no intention of targeting the drug

[530] See Statement by the South African Delegation, Minutes of the Council for TRIPS Special Discussions on Intellectual Property and Access to Medicines, IP/C/M/31 (July 10, 2001), p. 27.
[531] Lancet 2001 The Lancet.
[532] Dyer 2023 BMJ 2112 1.
[533] Russell The San Francisco Chronicle.
[534] Duke and Zuma 1998 Washington Post 41.

companies' profits. Instead, she proposed that any financial losses incurred due to lower prices could potentially be compensated through increased sales volume.[535] Further, she denied the accusation that she advocated for patent abrogation and emphasized that the lives of their people are of utmost importance. Her priority is to provide health services to the needy without violating any treaties or infringing any patents.[536] Despite her assurance, the pharmaceutical companies were still uneasy about Section 15C, which they perceived as a significant threat to their business. They feared that the implementation of PIs could pave the way for other countries to follow suit.[537]

Ultimately, the US withdrew its lawsuit after the South African government has given its assurance to the industry that in this particular section, it will exclusively import branded medications that are available in other countries at a comparatively lower cost than in South Africa.[538] It has made a commitment to abide by its international responsibilities concerning the safeguarding of IPRs.

Advocates of improved access to cheaper medicines in countries such as South Africa or Botswana have been compelled to pursue alternative flexibilities in order to promote their cause due to a variety of factors, which will be further examined below. These factors include the conclusion of TRIPS-Plus agreements, pressure from the US government, the influence of pharmaceutical industries and the legal challenges associated with obtaining CLs and PIs.[539]

3.5.3 Pressure from the HICs and TRIPS-Plus

The utilization of CLs for local manufacturing in LMICs is progressively limited and seen as a final option due to robust political backlash from HICs and the implementation of more stringent IP frameworks such as TRIPS-plus provisions in recent multinational free trade agreements as seen in the more recent Trans-Pacific

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[535] Sternberg 1999 USA Today 10.
[536] See Transcript No. 98011205-212 of NPR Broadcast Show "All Things Considered" available as audio stream at http://www.npr.org/templates/story/story.php?storyId=1036870.
[537] Fisher and Rigamonti 2005 The Law and Business of Patents 7.
[538] Sidley 2001 BMJ 447.
[539] Vawda 2018 South Centre Research Paper 89.

Partnership Agreement.[540] LMICs, before the outbreak of the global pandemic, faced challenges in issuing CLs for domestic use due to trade pressures. This included the possibility of being added to the annual watch list of the US Trade Representative, which scrutinizes countries that "unfairly issue, threaten to issue, or encourage others to issue compulsory licences." The watch list emphasizes that CLs should be employed only in "extremely limited circumstances."[541]

The initial legal disputes and intimidations directed towards South Africa, Brazil, and Thailand regarding their proposed employment of TRIPS flexibilities have been extensively recorded.[542] Furthermore, within the last twenty years, the United States has issued numerous warnings to countries considering such measures and consistently included them in its Special 301 Reports under the US Trade Act of 1974. The Special 301 List specifically focuses on countries that are actively pursuing compulsory licences, and it includes the potential for investigations and sanctions.[543] Undoubtedly, these warnings have a discouraging impact on nations striving to maintain their trade affiliations with the United States.[544]

The utilization of TRIPS flexibilities has been subjected to mounting criticism in recent bilateral and regional trade agreements (TRIPS-Plus agreements) involving the United States.[545] The United States has endeavoured to restrict the employment of CLs by, for instance, circumscribing the justifications to remedying anti-competitive practices, or instances of public non-commercial use, or national emergencies or other circumstances of extreme urgency (as exemplified in the Australia-US Free Trade Agreement of 2004).[546] This approach has been characterised by a gradual escalation of IP safeguards for pharmaceuticals, featuring clauses designed to extend monopolies, bolster exorbitant pricing, and

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[540] Hoen *et al* 2018 Bull World Health Organ.
[541] Office of the United States Trade Representative 2019 Special 301 Report.
[542] Nattrass 2005 https://www.sahistory.org.za/sites/default/files/nattrass_hivaids_policy.pdf 1.
[543] Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf.
[544] Vawda 2018 South Centre Research Paper 90.
[545] Vawda 2018 South Centre Research Paper 90.
[546] See Lopert and Gleeson (2013), pp. 199–223 http://onlinelibrary.wiley.com/doi/10.1111/jlme.12014/abstract.

impede the introduction of generic drugs, all of which impede the availability of reasonably priced medications.[547]

In conclusion, it is contented that the reduction in the price of medications after the implementation of a CL is too little to justify the significant infringement on patent rights, as even the reduced prices are still too high for the poorest segments of the population to afford.[548] Therefore, the use of CLs are insufficient in addressing availability of costly medicines. The reduction of drug prices has been more successful through market competition and negotiations between major pharmaceutical companies and generic drug manufacturers.[549] An instance of this can be seen with the decrease in the pricing of AIDS medications, which can be attributed to a price war and social pressure rather than the implementation of a CL between the pharmaceutical company and the generic drug makers. In 1996, these medications costed approximately $10,000 per person per year, but by 2001, the price dropped significantly to $295.[550]

3.6 Why TRIPS flexibilities are not equipped for a global health crisis

In spite of the above-mentioned challenges associated with TRIPS flexibilities, they have been beneficial in facilitating access in situations where patent barriers were the main obstacle and, in the times, where supply chains were fairly uncomplicated. However, these flexibilities depend on compulsory licensing on a product-by-product and country-by-country basis, which is a time-consuming and burdensome process. But the IP landscape behind vaccines and technologies are increasingly changing and becoming more complex. Additionally supply chains are becoming more intricate and globalized, production now necessitates global supply chains incorporating contributions from multiple nations. It is important to acknowledge that this framework was not originally intended for, nor does it adequately address, the challenges posed by a worldwide pandemic. Thus, the current regime is ill-suited for a global pandemic scenario, as it struggles to effectively handle the protection

[547] Lopert and Gleeson 2013 The Journal of Law, Medicine & Ethics 199.
[548] Halajian 2013 Brooklyn Journal of International Law 1219.
[549] Halajian 2013 Brooklyn Journal of International Law 1206.
[550] Halajian 2013 Brooklyn Journal of International Law 1206.

of vaccines and other technologies that are safeguarded by various forms of IP and the complex global supply chain challenges we are faced with today. The current TRIPS flexibilities are primarily based on the notion that countries facing a public health crisis can grant CLs to bypass patents, allowing multiple companies to manufacture similar medicines. However, in the context of COVID-19, there are two key reasons why the conventional CLs, which form the core of existing TRIPS flexibilities, are impractical.[551]

3.6.1 The broadening of IP "thickets"

Pharmaceutical companies have implemented measures that impede the efficient utilization of compulsory licensing by constructing extensive "thickets" of IPRs. These include multiple "patents, copyrights, industrial design protections, undisclosed data, and trade secrets for COVID-19 technologies", each necessitating a separate license.[552]

The pharmaceutical industry's approach of building strong IP monopolies through patent thickets is becoming a growing issue for vaccines. Vaccines like PCV (Pneumococcal conjugate vaccine) and HPV (human papillomavirus) vaccines face obstacles due to patent barriers, which can the progress of development, escalate expenses, introduce more unpredictability, and discourage or even prevent other manufacturers from entering the market.[553] In a recent study conducted by Chandrasekharan and his colleagues, it was discovered that there are 106 Patent Cooperation Treaty (PCT) applications that could potentially contribute to the development of pneumococcal vaccines.[554] Additionally, they also identified 93 patent applications directly associated with the manufacturing of HPV vaccines.

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551 Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf 1.

552 Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf 3.

553 Chandrasekharan *et al* 2015 Vaccine.

554 Chandrasekharan *et al* 2015 Vaccine.

The COVID-19 vaccines based on mRNA technology consist of more than 100 essential elements produced in multiple countries, which may be protected by patents and other IPRs.[555] Pfizer/BioNTech and Moderna, for instance, have filed 13 and 12 patent claims respectively for their mRNA vaccines. It is important to note that these patent claims do not cover the all the potential patents for crucial components of these vaccines, like the lipid nanoparticles obtained by Pfizer/BioNTech from Polymun, a pharmaceutical company based in Austria.[556]

3.6.2 The TRIPS Flexibilities were not designed for a global health crisis

The existing flexibilities under the TRIPS agreement were not intended for, and are not effective in, addressing the challenges posed by a global pandemic, especially when vaccines encounter various IP barriers and production depends on intricate global supply chains. The current CL mechanisms, which operate on a product-specific and country-specific basis, are not suitable for products that rely on complex supply chains.[557]

To create a COVID-19 mRNA vaccine using TRIPS flexibilities, a manufacturer would need to acquire CLs for each IP-protected component, of which there are over a 100, from multiple jurisdictions.[558] This would involve gaining cooperation from the exporting country and input producer and applying for licences in the country of manufacture and export. Additionally, in order to import each individual component and produce the vaccine, it would also be necessary to obtain a CL. Moreover, if a producer wanted to export the vaccine to establish a profitable market, they would need to navigate through complex WTO procedures to acquire additional CLs in

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555 Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf 3.

556 Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf 3.

557 Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf 3.

558 Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf 3.

other countries for import and usage of the vaccine.[559] The requirement for licences on a component-by-component and country-by-country basis creates significant challenges in terms of timing and coordination, which are extremely difficult to overcome.

3.7 Conclusion

TRIPS is not suitable to facilitate a global health crisis, and its flexibilities are riddled with complicated procedures and overburdensome admirative procedures. TRIPS-Plus provisions that are integrated in trade agreements, and often forced upon developing countries, override the use of these flexibilities. TRIPS is currently lagging behind the fast and constantly changing IP landscape and its complex supply chains. It is time to consider alternatives to TRIPS, such as an IP waiver and ultimately a pandemic treaty, to achieve health justice in the global South and to ensure equitable access to medicines globally to maintain the right to health.

4 The impact of IPRs on the realization of human rights in the global South during a pandemic and an analysis of the role of politics

As discussed in the previous chapters, international customary law and international treaties presently establish the global rights to life and health.[560] As a result, governments are prohibited from acting in a way that deprives or endangers an individual's right to live or exist.[561] A government's inability to effectively address or take measures to address a threat to life, such as an outbreak of disease, may be considered a violation of the right to life in the sequence of events.[562]

The age-old debate surrounding access to drugs and patents regained international attention during the HIV/AIDS epidemic.[563] Medicines that were made available to

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[559] Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf 4.

[560] Abbott 2003 Oxford University Press 280.

[561] Abbott 2003 Oxford University Press 280.

[562] Abbott 2003 Oxford University Press 280.

[563] Promoting Access to Medical Technologies and Innovation - Intersections between public health,

the market were unfortunately not adequately available to developing, especially African countries with the highest disease burden and medicines were priced so high that they were unaffordable to most patients in those countries.[564] Over twenty years later, after the amendment of the TRIPS Agreement initiated by the Doha declaration, this exact problem has resurfaced in the COVID-19 pandemic. Excessive patent and trade secret protection may limit and diminish healthy competition, create scarcity, reduce the availability of products and finally increase the prices of these products.[565] Therefore, IPRs can potentially create barriers to access life-saving medicines, medical technologies[566] and as seen more recently, vaccines.

This chapter will examine the current vaccine gap between the global South and North with the purpose of addressing the obstacles presented by IP protections and its impact on vaccine equity. This will be crucial to understand what key aspects in the global IP and trade regime must be addressed in order to formulate a comprehensive global health treaty.

4.1 The vaccine gap during the COVID-19 pandemic

There has been massive success in the scientific community in producing COVID-19 vaccines with record speed. However, the global dispersion of vaccines has been very disproportionate. The United States of America has been receiving their vaccines since December 2020,[567] early in the pandemic. The most heavily impacted by the pandemic were the LIC's of the global South, causing them economic devastation and large loss of life due to an increased disease burden.[568] The quantity of vaccines administered in Africa by the end of 2021 has only reached a slightly

intellectual property and trade 8.

[564] Promoting Access to Medical Technologies and Innovation - Intersections between public health, intellectual property and trade 8.

[565] Promoting Access to Medical Technologies and Innovation - Intersections between public health, intellectual property and trade 8.

[566] Promoting Access to Medical Technologies and Innovation - Intersections between public health, intellectual property and trade 8.

[567] COVID-19 vaccination in the WHO African Region - 16 December 2022 https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022 1.

[568] COVID-19 vaccination in the WHO African Region - 16 December 2022 https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022 1.

higher figure than one dose per individual for approximately 2% of the continent's 1.2 billion inhabitants.[569] This circumstance is attributable, among other factors, to the reality that Africa currently imports 99% of its vaccines and that African nations lack the pre-order purchasing capability of more affluent countries.[570] Consequently, the African Union has unveiled a strategy to produce 60% of Africa's vaccines on the continent by 2040.[571]

The fundamental issue at hand pertains to the excessive concentration of vaccine manufacturing, research, and development within a limited number of high- and middle-income nations.[572] These countries, which also hold the primary IPRs, have predominantly supplied their respective governments and those of other affluent nations with the majority of available vaccine doses.[573] By May 2021, approximately 6 billion doses out of the confirmed 8.6 billion purchases have been pre-ordered by governments of high- and middle-income countries (HMICs).[574] It has become apparent that there is a gap between the available vaccines and people who are vaccinated. This causes concerns regarding vaccine production, vaccination rates, coordination between agencies, and finally, global health equity.[575]

Following a two-year and longer struggle against the coronavirus, an old disparity has surfaced between the North and South.[576] Developing nations, which were already economically fragile, were severely impacted by the pandemic due to the absence of resources and policy advancements that the West employed to mitigate the pandemic's detrimental economic consequences. This has resulted in a reversal of decades of progress in poverty reduction, healthcare, and education in certain countries.[577] There are three core social justice and ethical concerns that must be

[569] Nature Editorial 2021 Nature.
[570] Nature Editorial 2021 Nature.
[571] Nature Editorial 2021 Nature.
[572] Nature Editorial 2021 Nature.
[573] Nature Editorial 2021 Nature.
[574] Nature Editorial 2021 Nature.
[575] COVID-19 vaccination in the WHO African Region - 16 December 2022 https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022 2.
[576] Balfour *et al* 2022 Carnegie Europe 3.
[577] Balfour *et al* 2022 Carnegie Europe 1.

addressed regarding IP and access to medicines (including vaccines) and treatments.[578]

Firstly, vaccines hold both economic and health benefits that have historically been proven to help poorer populations. Vaccines promote physical and mental health, they reduce the severity of the diseases and their associated costs, and in turn they promote productivity.[579] A healthy working force means a healthy economy. Unfortunately, the global use of vaccines has historically been higher in wealthier segments of society than in poorer segments, specifically when one looks at the initial rollout stage of the vaccines and treatments.[580] One should learn from history and what COVID-19 exposed during the pandemic. Vaccination programmes in the future must be pro-poor from the start to minimize the economic vulnerability of those who are at higher risk.[581] This has not been the case with either the HIV/AIDS epidemic or the COVID-19 pandemic, 20 years apart.

Secondly, some groups were more affected by COVID-19 than others, and the (lack of) distribution of vaccines for COVID-19 should not have reinforced the severity among the vulnerable. COVID-19 cases were higher and severely more acute in vulnerable populations that are economically disadvantaged.[582] There have also been widespread ethnic and racial disparities seen in infection- and mortality rates.[583] These insights and new information must provide us with valuable learning

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578 COVID-19 vaccination in the WHO African Region - 16 December 2022 https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022 2.

579 COVID-19 vaccination in the WHO African Region - 16 December 2022 https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022 2.

580 COVID-19 vaccination in the WHO African Region - 16 December 2022 https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022 2.

581 COVID-19 vaccination in the WHO African Region - 16 December 2022 https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022 2.

582 COVID-19 vaccination in the WHO African Region - 16 December 2022 https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022 2.

583 COVID-19 vaccination in the WHO African Region - 16 December 2022 https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022 2.

opportunities to prepare for future global health crises by having more equitable vaccination programmes.

Finally, COVID-19 has intensified poverty globally, but vaccines should not exacerbate the same problem. The impact of the pandemic has been felt across all socioeconomic spectrums, no matter one's status, yet people with lower socio-economic status have been affected more profoundly, as the pandemic has resulted in primary breadwinners falling away and the loss of crucial employment opportunities, leading to the depletion of familial savings and exacerbating the plight of impoverished urban communities.[584] The actual ramifications of the financial strain, such as the reduction of healthcare resources, remain uncertain.[585]

As the pandemic starts to slow down, the need to share IP related to COVID-19 remains an urgent matter. As discussed above, two years into the pandemic, people in some high-income countries are already being offered their fourth dose, while fewer than 15% of people from low-income countries have received their first dose.[586] The pandemic has had a significant impact on various sectors, including education, migration opportunities, manufacturing, and trade, the impact expected to be of an enduring nature.[587] The handling of the global crisis has highlighted the disparity between the influential capabilities of the United States, Europe, China, and Russia, and the path dependence of the remaining nations.[588]

4.2. What is the global North vs the global South dilemma?

The notion of Global North and Global South (also referred to as the North-South divide in the global context) is employed as a classification of nations based on their socio-economic and political attributes. As per the United Nations Conference on Trade and Development (UNCTAD), the term "Global South" encompasses countries

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584 COVID-19 vaccination in the WHO African Region - 16 December 2022 https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022 2.

585 COVID-19 vaccination in the WHO African Region - 16 December 2022 https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022 2.

586 Nature Editorial 2022 Nature.

587 Balfour *et al* 2022 Carnegie Europe 1.

588 Balfour *et al* 2022 Carnegie Europe 1.

situated in the regions of Africa, Latin America and the Caribbean, Asia (excluding Israel, Japan, and South Korea), and Oceania (excluding Australia and New Zealand).[589] A significant number of nations situated in the Global South are distinguished by their low income, high population density, inadequate infrastructure, and frequently, political or cultural exclusion.[590] The Global North, on the other hand, encompasses Northern America and Europe, Israel, Japan and South Korea, as well as Australia and New Zealand, as per UNCTAD.[591] Nations that have achieved a high level of development are commonly referred to as Global North countries, whereas those that are in the process of developing are commonly referred to as Global South countries.[592]

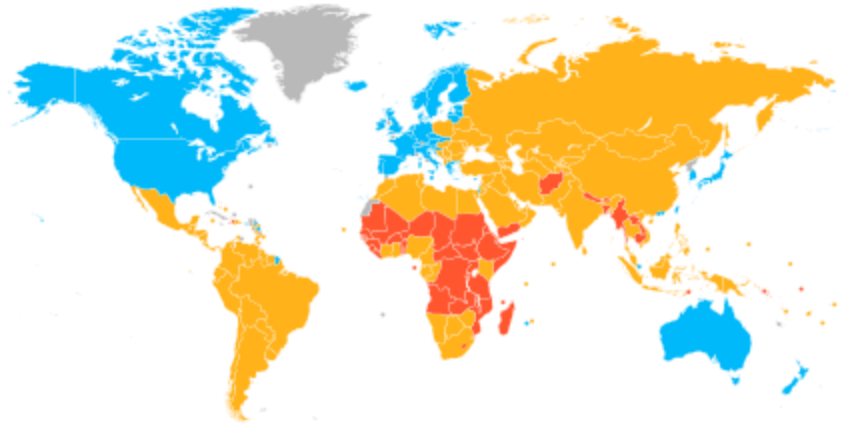
Consequently, the designations Global North and Global South do not pertain to the geographical directions of North and South more concretely, given that numerous countries of the Global South are situated within the Northern Hemisphere, and *vice versa*.[593] The phrase, as employed by governmental and developmental organizations, was initially introduced as a more impartial and unbiased substitute for "Third World Countries"[594] and other potentially subjective terms such as developing countries. The nations of the Global South have been characterized as either newly industrialized or in the midst of industrialization and are often former subjects of colonialism.[595]

The Global North is commonly associated with the Western World, whereas the South is predominantly associated with developing countries and the Eastern World.[596] These two groups are frequently distinguished based on their varying levels of affluence, economic progress, income disparity, democracy, and political and economic autonomy, as determined by freedom indices.[597] Countries that are

[589] UNCTAD 2022 UN Geneva Classification.
[590] Arbab 2019 Perspectives on Global Development and Technology.
[591] " UNCTAD 2022 UN Geneva Classification.
[592] UNCTAD 2022 UN Geneva Classification; Mareï and Savy 2021 Transport Policy; Arbab 2019 Perspectives on Global Development and Technology.
[593] Wolvers *et al* 2015 University of Cologne 7.
[594] Mitlin and Satterthwaite Urban Poverty in the Global South: Scale and Nature.
[595] Mimiko 2012 Carolina Academic Press 47.
[596] Nayak and Selbin Decentering International Relation 48.
[597] Nayak and Selbin Decentering International Relation 48.

typically regarded as constituents of the Global North are generally more prosperous and less unequal. They are developed nations that export technologically advanced manufactured goods.[598] Conversely, Southern States are predominantly impoverished developing nations with nascent democracies that are highly reliant on primary sector exports. Additionally, many Southern States have a shared history of past colonialism under Northern States.[599] Nonetheless, the dichotomy between the North and the South is currently being contested by some.[600]

[598] Nayak and Selbin Decentering International Relation 48.
[599] Mimiko 2012 Carolina Academic Press 47.
[600] Therien 1999 Third World Quarterly.



Developed countries or territories (IMF)

Developing countries or territories (IMF)

Least developed countries (UN)

Data unavailable

World map showing country classifications per the IMF and the UN (last updated April 2023). The countries in light blue form the "Global North", the rest are mostly categorized as belonging to the "Global South", with few exceptions under some listings.[601]

4.3 The North vs The South's IP politics and its impact during the pandemic

The EU has developed a burgeoning interest in investing in the Global South, as the Bloc endeavours to occupy a unique position amidst the geopolitical competition between the US and China.[602] Additionally, the EU seeks to establish new allies in support of multilateralism and diversify its international relations in pursuit of strengthening its norms and interests.[603] However, the policies and aspirations of

[601]UNCTAD https://unctadstat.unctad.org/EN/Classifications.html.
[602] Balfour *et al* 2022 Carnegie Europe 2.
[603] Balfour *et al* 2022 Carnegie Europe 2.

the union are inadequately informed by empirical research on how the Global South perceives the EU and Europe as a whole.

The pandemic presented a pivotal moment for the EU to redefine donor-recipient relations, advance ongoing efforts to eradicate global poverty, and showcase the significance of multilateralism.[604] However, instead of leveraging this opportunity to bolster the resilience of the Global South, the EU was perceived as pursuing inward-looking strategies, including the stockpiling of COVID-19 vaccines and opposition to vaccine waivers.[605] Despite outwardly advocating for international solidarity, the EU failed to implement comprehensive policies to address the structural economic and political disparities in its association with the Global South.[606] This myopic approach resulted in several missed opportunities for the EU to assume a leadership role in supporting the Global South's protracted and arduous recovery from the pandemic. Commendably, particularly in light of the crisis context of the initial months of 2020, the EU demonstrated its commitment to providing resources to assist the rest of the world in managing the repercussions of the coronavirus.[607] However, despite espousing a narrative of international solidarity, the Union missed the opportunity to address certain structural economic and political disparities in its relationship with the Global South.[608] These disparities encompass income and income-distribution disparities, a malfunctioning foreign debt system, impediments to the delivery of goods and services, such as trade barriers, disparities in health and education systems, know-how and R&D, its ongoing competition for access to the Global South's resources and raw materials, and deeply ingrained historical grievances and a lack of trust.[609]

Despite the valuable lessons learned from previous pandemics, particularly in Africa and Asia, the Global North has failed to make adequate efforts to address the "structural reform of the international health services, distribution, and production

[604] Balfour *et al* 2022 Carnegie Europe 2.
[605] Balfour *et al* 2022 Carnegie Europe 2.
[606] Balfour *et al* 2022 Carnegie Europe 14.
[607] Balfour *et al* 2022 Carnegie Europe 14.
[608] Balfour *et al* 2022 Carnegie Europe 6.
[609] Balfour *et al* 2022 Carnegie Europe 6.

capacity system".[610] The distribution of vaccines remains significantly unequal, and there is a lack of debt relief and economic support for lower-income countries (LICs).[611] The proposed modifications to the WTO regulations on patents and permits, which would have enhanced vaccine production capacity, were not implemented due to opposition from the EU, particularly Germany.[612] The aforementioned failure serves to underscore the incongruities that persist between European external and internal policies, thereby exacerbating the disparities between the Northern and Southern regions.[613] This ultimately renders nations susceptible to heightened geopolitical competition and the proliferation of health policies that are weaponized.[614]

In August of 2021, the WHO commenced the construction of the inaugural worldwide vaccine-manufacturing centre in collaboration with the South African government and the biotechnology firm Afrigen, headquartered in Cape Town. However, Moderna and Pfizer, two of the "Northern" companies that had produced a COVID-19 vaccine, declined to share their acquired knowledge.[615] It is noteworthy that Africa accounts for approximately one-quarter of global vaccine consumption, yet it produces less than 1% of its routine vaccinations, thereby exposing Africans to supply-chain and public health hazards.[616] Governments in the Global South are experiencing mounting pressure to allocate greater resources towards safeguarding their most vulnerable populations.[617] However, the available mechanisms at their disposal are severely lacking. Assuming their good intentions, many of the mechanisms initiated by Northern countries, such as debt relief, are increasingly viewed by Southern recipients as inadequate or unattainable due to the extensive list of prerequisites required to access them.[618] Alternatively, they are perceived as

[610] Balfour *et al* 2022 Carnegie Europe 2.
[611] Balfour *et al* 2022 Carnegie Europe 2.
[612] Balfour *et al* 2022 Carnegie Europe 2.
[613] Balfour *et al* 2022 Carnegie Europe 2.
[614] Balfour *et al* 2022 Carnegie Europe 2.
[615] Hassan et al Daily Maverick Citizen OP-ED.
[616] Virtual Conference: Expanding Africa's Vaccine Manufacturing.
[617] Balfour *et al* 2022 Carnegie Europe 2.
[618] Balfour *et al* 2022 Carnegie Europe 2.

delaying tactics, as they merely postpone the inevitable and arduous repayment process.[619]

Through the obstruction of production decentralization and safeguarding of the interests of manufacturers situated in the Global North, the EU together with the US, is exacerbating the socio-economic disparity between affluent and impoverished nations.[620] This political stance is counterproductive for the EU and the US, as it not only overlooks the prospect of reforming the donor-recipient paradigm, but also undermines the progress made in the last decade towards eliminating absolute poverty.[621] Efforts ought to be directed towards financing vaccine production in the least developed countries and ensuring their optimal utilization. Nevertheless, it was not until November 2021 that European Trade Commissioner Valdis Dombrovskis acknowledged the potential for targeted waivers on compulsory licences, which would enable the production of vaccines, moreover at an affordable price.[622] This stance by the EU falls short of the requests made by India and South Africa to lift IP protections for a period of three years and is in contrast to the US's endorsement of a complete waiver of IPRs.[623] These developments have brought to light the inconsistencies in both the EU's and the US's global response narrative of solidarity. This waiver, and the way in which it has the potential to pave a road for a comprehensive global health treaty, will be discussed in more detail in the following chapter.

5 The possible waiver of IPRs during a pandemic

It is clear from the discussion of the previous chapters that the current inadequacy of global provision of medicines (including COVID-19 vaccines), medical equipment, and diagnostics that are crucial in the battle against the pandemic can be attributed to the current structure of the global IP legislation, which is the WTO's TRIPS agreement.[624] The equitable distribution of vaccines is not only a moral imperative

[619] Balfour *et al* 2022 Carnegie Europe 2.
[620] Bounds 2021 Financial Times.
[621] Balfour *et al* 2022 Carnegie Europe 2.
[622] Dombrovskis V European Parliament Plenary Session Statement on Multilateral Negotiations in View of the 12th WTO Ministerial Conference.
[623] Bounds 2021 Financial Times.
[624] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 7.

but also a political, economic, and human rights necessity for the global community.[625] However, the emergence of COVID-19 vaccine nationalism has highlighted the incongruity between existing legal and financial incentives and the imperative to ensure equitable production and distribution of vaccines on a global scale.[626]

The policies of individual Member States must be closely examined to address the urgent requirement for increased scrutiny of vaccine nationalism.[627] Additionally, there is a renewed emphasis on ensuring the equitable distribution of vaccine surpluses among nations, in order to bridge the gap in vaccine access.[628] It is worth noting that, despite the existence of surplus vaccine supplies in certain countries, such as the United States, exportation was prohibited until recently due to domestic prioritization enforced by the US Defence Production Act of 1950 (DPA).[629] In January 2021, President Biden thus utilized the act to ensure the procurement of COVID-19 vaccines.[630]

The comparison made by Trump administration officials regarding the global allocation of vaccines against COVID-19 is similar to oxygen masks dropping in a depressurizing airplane. The priority is to ensure one's own safety first before extending assistance to others. Peter Marks, a senior official at the U.S. Food and Drug Administration, highlighted this concept during a panel discussion in June. However, it is important to note that unlike airplane oxygen masks, vaccines should not be limited to a certain privileged group. If governments delay providing access to vaccines to people in other countries, it would be equivalent to only making vaccines available to those in first class.[631]

LMICs faced the challenges of accessing vaccines as wealthy countries and vaccine manufacturers have already secured early access, even before the vaccines are

[625] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 7.
[626] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 8.
[627] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 9.
[628] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 11.
[629] US Defence Production Act of 1950.
[630] International Energy Agency (IEA) Defense Production Act.
[631] Bown and Bollyky 2022 World Economics 96.

proven to be safe and effective. This trend is expected to continue, given the behaviour of governments during past outbreaks and the current pandemic.[632]

In the absence of worldwide coordination, countries may engage in competitive bidding against each other, resulting in elevated costs for vaccines and associated resources. Even wealthy countries will face a scarcity of proven vaccines initially, but the direst impact will be experienced by LMICs. These nations will be relegated to the sidelines to watch as affluent nations exhaust supplies, leaving them to wait for many months, if not longer, to restock their own.[633] This unfortunate situation will not only prolong the duration of the crisis but also contribute to a higher number of fatalities, while simultaneously posing a threat to already fragile healthcare systems and economies.

The current crisis is a clear indication of the inability of HICs to uphold their commitment made during the TRIPS negotiations in 1994.[634] During that time, they had promised that, by accepting the provisions of TRIPS, LMICs would benefit from technology transfer and the development of productive capacity.[635] As a result, the current crisis not only reveals the inadequacies in addressing global emergencies but also underscores the deficiencies inherent in the international "patent bargain."[636] The undeniable magnitude of the present health crisis caused by COVID-19 is exacerbated by the untenable nature of the global response. The issue at hand pertains to the significant impact that monopolistic market power in the pharmaceutical industry has on the general public, in contrast to market dominance in other industries, "such as mousetraps".[637] It is imperative to acknowledge that IP law plays a crucial role in shaping the pharmaceutical market, and therefore, must be regarded as a pivotal factor when the market yields dysfunctional or inequitable outcomes, as is currently being witnessed during the COVID-19 pandemic.[638]

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[632] Bown and Bollyky 2022 World Economics 96.
[633] Bown and Bollyky 2022 World Economics 97.
[634] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 1.
[635] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 1.
[636] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 1.
[637] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 9.
[638] Matthews and Gurgula 2016 European Intellectual Property Review 661.

The disparities in the production and distribution of vaccines are linked to apprehensions regarding pricing and the profit motive. The current IP framework permits largely monopolistic control over pricing, which may lead to a distorted incentive for COVID-19 vaccine producers, one that does not necessarily prioritize attaining universal and equitable access to vaccines worldwide.[639] From a strictly financial standpoint, the current worldwide pandemic presents significant monetary benefits for corporations engaged in vaccine production and their stakeholders.[640] However, the pursuit of profit and financial gain may potentially conflict with the imperative of expeditiously ending the pandemic on a global scale.[641]

In light of the pharmaceutical industry's insufficient participation in proposed global mechanisms aimed at sharing IPRs, data, and know-how to combat the pandemic,[642] this chapter contends that mandatory mechanisms are imperative. The TRIPS waiver represents a crucial legal instrument in this regard, facilitating a significant boost in manufacturing capacity and, consequently, the supply of COVID-19 vaccines. This, in turn, paves the way for achieving equitable global access,[643] and ultimately creates a path to a global health treaty that can apply to future health crises.

5.1 The TRIPS Waiver proposal

With the increase in COVID-19 related fatalities and the growing vaccine gap, India and South Africa called upon the WTO for the temporary suspension of IPRs that relate to COVID-19 in the pursuit of making medicines, technologies, and treatments accessible for poorer countries,[644] placing emphasis on vaccine equality in the global South. The proposal to temporarily suspend IPRs, specifically patents and trade secrets in the pandemic context, was put before the WTO's Trade-Related Aspects of Intellectual Property Council on 16 October 2020, a few months after COVID-19 was declared a global pandemic. The temporary waiver would help to ensure that

[639] Stoller 2021 Substack.
[640] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 10.
[641] Phillips Nature News Feature.
[642] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 1.
[643] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 1.
[644] Usher 2020 World Report.

access to vaccines, new technologies, and medicines that are needed to control the pandemic, will not only be available and afforded to the wealthiest countries.[645] Although occasionally referred to colloquially as a "patent waiver", the India/South Africa proposal, in both its original and revised iterations, is, in fact, a comprehensive package applicable to diagnostics, treatments, and vaccines.[646] The waiver would pertain to "prevention, containment, or treatment of COVID-19", encompassing not only the temporary suspension of patents (and, where applicable, copyrights) on an international scale but also, crucially, the sharing of IP under the category of "undisclosed information", such as trade secrets and know-how.[647] It was co-sponsored by 62 WTO countries, including India/South Africa.[648]

India and South Africa had proposed that Members of the WTO ought to:

> …work together to ensure that intellectual property [IP] rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19.[649]

India and South Africa's proposal, cites "exceptional circumstances" for a waiver that would remain in effect until there is widespread vaccination globally and the majority of the world's population has acquired immunity.[650]

This proposal received mixed reactions, where over 120 developing nations support the waiver, but more affluent nations feel that such a waiver will not achieve its sought goals and create a president that will be harmful for the industry, as it will disincentivize further innovation. This discourse will be examined closely below.

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[645] Usher 2020 World Report.
[646] Bosse *et al* 2021 The Conversation
[647] Joint Statement of Co-Sponsors to the TRIPS Waiver.
[648] Joint Statement of Co-Sponsors to the TRIPS Waiver
[649] Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19. Communication from India and South Africa.
[650] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 15.

5.1.1 Key components of the proposed TRIPS Waiver

The TRIPS waiver highlights the various levels of property rights that frequently encircle innovation and function as valuable assets in the global economy.[651] Similar to a matryoshka doll, the central core of an invention is frequently enveloped by diverse layers of IPRs, each possessing distinct reasoning, extent, and subject matter.[652] The attention here is directed towards the two primary IPRs for the current objectives: patents and trade secrets (broadly interpreted to encompass know-how, data, and other undisclosed information). The analysis in the following strongly relies on what are, it is submitted, convincing arguments in favour of a COVID-19 waiver.

As previously discussed, a patent confers upon its holder a legal monopoly right[653] to utilize the patented invention for a period of 20 years.[654] As such, it is inherently a restrictive right, with the underlying objective of temporarily impeding competition. Its purpose is to endow the holder with an exclusive right to commercialize the invention and to provide the holder with a competitive advantage that may assist in securing a dominant market position.[655] As a position of dominance is increasingly fortified through IP strategies and its doctrine, the motivation to share technology may diminish.[656] Patent-holders possess the authority to artificially limit the production of the patented product for strategic purposes, for the maximum duration permitted by law.[657] Additionally, the monopoly right customarily empowers the patent-owner to wield unrestricted pricing authority within a given market.[658] The patent is accompanied by specification documentation that is made publicly available.[659] On the other hand, a trade secret, as defined by TRIPS, pertains to undisclosed information, including know-how, and constitutes a significant monopoly. However, owing to its inherent nature, a trade secret is not

[651] Kang 2020 MIT Press.
[652] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 16.
[653] TRIPS Article 28.
[654] TRIPS Article 33.
[655] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 9.
[656] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 9.
[657] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 9.
[658] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 9.
[659] Art 33 TRIPS.

publicly available and is instead safeguarded indefinitely, typically through contractual or non-disclosure agreements (NDAs).[660]

In broad and over-arching terms, it can be observed that the patent-trade secret dichotomy results in the configuration of IP legal incentives in a manner that favours the patenting of inventions that are susceptible to facile replication or reverse engineering.[661] This is because, in the absence of patent protection, such inventions are vulnerable to being readily comprehended, reverse-engineered, and reproduced by competitors. Conversely, if an invention is inherently arduous to replicate, it may be more judicious to safeguard the inventive information as a trade secret, thereby potentially securing protection for a longer duration than the 20-year term afforded by a patent.[662] When corporations manufacture and promote a particular commodity, they depend on the assumption that it cannot be effortlessly comprehended or reverse-engineered.[663] However, insufficient patent disclosures, coupled with formal trade secrets and implicit knowledge, can obscure the situation, rendering it arduous to discern the point at which a lawful incentive terminates and the point at which restrictive practices concerning information-sharing commence.[664]

As an illustration, despite Moderna's announcement in 2020 that it would refrain from enforcing its patents pertaining to COVID-19 vaccines throughout the pandemic, it is noteworthy that this determination did not extend to all IP, including trade secrets and know-how, and it also excluded tech transfer.[665] In actuality, Moderna has recently acknowledged that the absence of this pertinent know-how and technology transfer would pose considerable obstacles for other entities endeavouring to produce their vaccine, particularly in terms of manufacturing scalability.[666]

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[660] Art 39 TRIPS.
[661] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 17.
[662] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 17.
[663] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 17.
[664] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 17.
[665] Brennan 2021 EndPoints News.
[666] O'donnell and Mishra 2021 Healthcare & Pharmaceuticals.

The advantage of implementing a universal waiver of IPRs on COVID-19 vaccines and health technologies is that it would grant manufacturers the liberty to conduct their operations without the apprehension of legal action or the possibility of exported vaccines being confiscated during transit and detained on the grounds of purported IP violation.[667] This study contends that, in light of the inadequacy of voluntary measures aimed at achieving vaccine equity, the waiver represents a requisite and appropriate legal mechanism for removing IP barriers in a direct, uniform, and expeditious manner.[668] If implemented, it would furnish companies with the liberty to engage in the manufacture and distribution of COVID-19 vaccines (as well as other COVID-19-related health technologies) without the apprehension of violating the IP rights of another party and the attendant risk of litigation.[669] The waiver engenders optimism, not only in the short term, but also in laying the foundation for bolstering pandemic preparedness in LIMCs more generally.[670] The discussion below examines the waiver which was eventually adopted and assesses it critically. The argument is developed through an initial analysis of the major COVID-19 vaccines with regard to their "development, production, distribution, and pricing".[671] The analysis reveals that the IP framework, exemplified by TRIPS, has enabled IP-holders to exert exclusive rights, leading to an artificial scarcity and inequitable supply of vaccines.[672] This is in addition to delays caused by the original "shortage of raw materials and the scaling of production capacity."[673] IP as interpreted under TRIPS has played a pivotal role in facilitating an oligopolistic market in vaccines, particularly in mRNA vaccines, with rights-holders exercising significant control over access to such vaccines.[674]

Hilty and colleagues contend that the effective implementation and enforcement of the waiver of trade secret protection to compel companies to divulge all pertinent know-how is exceedingly improbable.[675] In light of the insufficient collaboration

[667] Reuters 2009 Reuters Government.
[668] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 2.
[669] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 2.
[670] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 2.
[671] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 2.
[672] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 2.
[673] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 2.
[674] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 2.
[675] Hilty *ed al* 2021 Max Planck Institute for Innovation & Competition Research.

among industries in voluntarily sharing confidential business information, the aforementioned negative and unproductive perspective would amount to endorsing a current state of affairs that has proven inequitable for LMICs.[676] While the circumstances that may compel entities to divulge proprietary or implicit technical knowledge may be restricted, they are by no means unprecedented.

5.1.2 This type of waiver/sharing of information is not novel

In essence, this form of "sharing" is not novel. The 2011 WHO Pandemic Influenza Preparedness (PIP) Framework explicitly alludes to technology transfer, albeit within the restricted context of benefit-sharing (in exchange for obtaining biological materials), and it provides verbiage that falls short of a legal mandate.[677] Nevertheless, certain aspects of it are worth reiterating at this juncture. According to Section 6.13.4, the following is stipulated:

> Influenza vaccine manufacturers who receive PIP biological materials may grant, subject to any existing licensing restrictions, on mutually agreed terms, a nonexclusive, royalty-free license to any influenza vaccine manufacturer from a developing country, to use its intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of influenza vaccine development and production, in particular for pre-pandemic and pandemic vaccines for use in agreed developing countries.

In accordance with this premise, it can be contended that the TRIPS waiver has the potential to facilitate the development of capacity in LMICs.[678] As previously mentioned, the implementation of TRIPS in 1995 has impeded LMICs' industrial and pharmaceutical capabilities due to the absence of technology transfer from HICs.[679] Furthermore, even when technology transfer has occurred, undisclosed licensing terms pertaining to patents and other IPRs have typically imposed limitations on the utilization of transferred technologies and the extent to which resulting products, such as vaccines, can be disseminated within and across national borders.[680]

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[676] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 16.
[677] Kapczynski 2017 Cornell Law Review 1584.
[678] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 16.
[679] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 16.
[680] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 16.

Throughout the nineteenth and twentieth centuries, a number of significant nations, such as the Netherlands, opted to temporarily eliminate patent rights as a means of fostering domestic industry.[681] Additionally, certain countries intentionally diminished IPRs in order to bolster their own technological capabilities. Notably, several nations, including those that currently boast prominent pharmaceutical corporations, such as Germany and Switzerland, were initially reluctant to permit the patenting of medicines.[682]

5.1.3 Analysis of the discourse surrounding the TRIPS Waiver

This part of the chapter seeks to examine the discourse surrounding the TRIPS Waiver among the Members of the WTO, civil society organizations, and stakeholders in the pharmaceutical industry. The objective is to analyse the diverse viewpoints and opinions held by these groups in relation to the TRIPS Waiver. The outcomes of this investigation offer valuable insights into assessing the TRIPS Waiver finally agreed on and its potential ramifications for the global trade and pharmaceutical sectors.

As of June 2022, an estimated 59% of Members belonging to the WTO had demonstrated their support for a waiver concerning the TRIPS.[683] This support had been expressed either through direct sponsorship or favourable endorsement. Conversely, approximately 21% of Members had expressed their opposition to the TRIPS waiver.[684] Notably, out of the 35 opposing Members, 28 are affiliated with the EU or its delegation.[685] The remaining 20% of Member positions were unclear at the time, as some had chosen to abstain from publicly commenting on the TRIPS waiver, while others had refrained from expressing a definitive stance on the matter.[686] Various arguments had been presented by both the advocates against the waiver and advocates for the waiver, in support and against the possibility of a waiver of IPRs. The interests of the pharmaceutical industry as well as the broader

[681] Dutfield That High Design of Purest Gold 3.
[682] Dutfield That High Design of Purest Gold 3.
[683] Kohler *et al* 2022 Health Hum Rights 162.
[684] Kohler *et al* 2022 Health Hum Rights 162.
[685] Kohler *et al* 2022 Health Hum Rights 162.
[686] Kohler *et al* 2022 Health Hum Rights 162.

public must be taken into consideration when these arguments are evaluated, as set out below.

5.1.3.1 The lack of manufacturing capacity argument

Notwithstanding the insufficiency of production and the uneven allocation of COVID-19 vaccines, producers have declined proposals to collaborate and augment production in the global South, citing the lack of capacity in LMICs.[687] This commonly held argument against the TRIPS waiver asserts that it may not adequately tackle the problem of vaccine inequality, owing to the prolonged time required to establish domestic production capabilities in LMICs.[688] Additionally, during this transitional phase, existing facilities in HICs and LMICs may already be functioning at or close to full capacity.[689]

Significantly, the assertion that there is no additional production capacity for HIC/LMIC, has been refuted.[690] Throughout the year 2021, various companies situated in both HICs and LMICs, namely Biolyse in Canada, Teva in Israel, Bavarian Nordic in Denmark, and Incepta in Bangladesh, proffered their manufacturing capabilities, yet were either turned away or were unable to secure a license.[691] Additionally, in October of 2021, the New York Times identified ten production sites located in LMICs, specifically in Brazil, Argentina, Indonesia, India, and South Africa, which have the potential to commence manufacturing mRNA vaccines within a few months.[692] Furthermore, a subsequent expert study identified over one hundred potential mRNA vaccine manufacturers across Africa, Asia, and Latin America.[693] These findings contradicted the assertions of numerous industry sources and certain IP commentators who have contended that all appropriate manufacturing facilities

[687] Furlong 2021 Politico.
[688] Furlong 2021 Politico.
[689] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 19.
[690] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 19.
[691] Furlong 2021 Politico 19.
[692] Nolen New York Times.
[693] Prabhala and Alsalhani 2021 MSF Southern Africa 3.

are currently in use or that there is minimal manufacturing capacity and expertise beyond HICs.[694]

Notwithstanding the fact that there are a significant number of manufacturers in LMICs with the capacity to produce vaccines, the expeditious establishment of new production capacities is also feasible. At the onset of 2020, Moderna lacked a vaccine manufacturing facility, yet in less than a year, it emerged as a prominent producer of COVID-19 vaccines.[695] The former director of chemistry at Moderna, Suhaib Siddiqi, asserts that with a blueprint and technical guidance, a contemporary factory can manufacture mRNA vaccines within a span of three to four months.[696] It should also be reminded that one of the TRIPS obligations bestowed upon developed Member States is to provide incentives to businesses and organizations within their regions, with the aim of fostering and motivating the transfer of technology to the least developed countries.[697] This support enables developing countries to establish a robust and sustainable technological foundation.

It is indisputable that a larger number of corporations in developing regions of the world would have been able to participate in the production of COVID-19 vaccines at present, if the technology had been shared.[698]

5.1.3.2 The lack of know-how and concern of vaccine quality and safety argument

The possession of know-how and trade secrets is of the utmost importance in the manufacturing process of pharmaceuticals or vaccines that exhibit superior quality, safety, and efficiency.[699] The transfer of such valuable information through compulsory licences is highly improbable, as discussed above. It is argued by the pharmaceutical industry that it is challenging to envision any government enforcing such a transfer, even with a waiver. Hence, they contend that, instead of endorsing production in regions with inadequate safety and efficacy standards, which would lead to a substantial inflow of substandard vaccines and result in catastrophic

[694] Thambisetty *et al* 2022 Camb Law Journal 19.
[695] Thambisetty *et al* 2022 Camb Law Journal 19.
[696] Cheng and Hinnant 2021 AP News.
[697] Article 66.2 of TRIPS.
[698] Furlong 2021 Politico.
[699] Mercurio 2021 Bad Precedent IIC Int Rev Ind Prop Copyright Law 987.

consequences, it is more judicious to identify potential manufacturing capabilities, and devise strategies to harness and enhance them, in the global North.[700] The latter statement is problematic, because this will result in said knowledge being concentrated and restricted within the global North due to the IPRs held by its proprietors, despite its necessity in the global South. This further supports the need to rely on voluntary licences to access lifesaving medicines (including vaccines). It further undermines the responsibility afforded to HIC to support the transfer of technology and related know-how to support the development of LMICs.

Further, it has been contended that the production of vaccines in nations where IPRs are deemed "weak" poses a risk, as the resultant vaccines may not be authentic or secure.[701] However, numerous instances spanning several decades have demonstrated that vaccines and intricate medications can be manufactured safely and securely in the global South.[702] In 2005, Tamiflu was safely manufactured in Asia despite assertions that the process involved was highly intricate and not readily replicated.[703] Likewise, in 2009, Shanta Biotechnics, also an Indian company, successfully produced a dependable and secure recombinant hepatitis-B vaccine.[704] In 2020, Hetero and Cipla, also based in India, produced Remdesivir following comparable concerns regarding safety.[705] Significantly, the WHO holds the perspective that the manufacture of COVID-19 vaccines in the global South of the world can be executed in a secure and effective manner.[706]

For instance, despite Moderna's declaration in 2020 that it would not enforce its COVID-19 vaccine patents during the pandemic, this undertaking was subject to notable limitations. It could be revoked at any moment, and it did not encompass trade secrets, know-how, or technology transfer.[707] As recently acknowledged by Moderna, the absence of this pertinent know- how and technology transfer would

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[700] Mercurio 2021 Bad Precedent IIC Int Rev Ind Prop Copyright Law 987.
[701] Gottlieb 2021 Wall Street Journal.
[702] Douglas and Samant 2017 Plotkin's Vaccines 41.
[703] Amin 2021 Foreign Affairs.
[704] Chakma *et al* 2011 Global Health 9.
[705] "BBC News 2020 https://www.bbc.co.uk/news/world-asia-india-52659052.
[706] Aizenman 2021 https://www.npr.org/sections/goatsandsoda/2021/10/19/1047411856/the-great-vaccine-bake-off-has-begun?ft=nprml&f=1047411856.
[707] Thambisetty *et al* 2022 Cambridge University Press 20.

pose considerable obstacles for other entities endeavouring to produce their vaccine. However, notwithstanding Moderna's reluctance to collaborate with manufacturers in the global South, in February 2022, Afrigen Biologic and Vaccines, a South African-based company that is part of the WHO mRNA hub, declared that it had reached the final stages of creating an mRNA vaccine that is comparable to the NIH-Moderna vaccine.[708] Moderna's public declaration of non-enforcement of its patents, along with the increased accessibility of public information pertaining to the NIH-Moderna vaccine in comparison to other contenders, prompted Afrigen to opt for the replication of this particular vaccine.[709] Scientists hailing from various parts of the globe, including those at NIH, extended their support to Afrigen in this endeavour.[710] The fact that Afrigen had to undertake the reverse-engineering of the vaccine without the aid of Moderna's know-how, data or technology transfer undoubtedly resulted in a significant delay in the Afrigen development process, spanning several months.[711] Additionally, the absence of shared regulatory data from Moderna (or as previously posited, from US government agencies) may result in a further delay of 12-18 months in the rollout of the vaccine by Afrigen, in the absence of such data-sharing.[712]

In light of the current protectionist measures, the TRIPS waiver, in a comprehensive version, would have presented a viable solution by promoting production efforts in the global South, such as the commendable work undertaken by Afrigen. This waiver would have offer legal assurance with respect to the utilization of patents and trade secrets in the development process, as well as the eventual transfer of doses and knowledge to other countries in the global South.[713]

5.1.3.3 "Bottlenecks are caused by a shortage of raw material" argument

It has been contended that the insufficiency of raw materials on a global scale is more to blame than IPRs for the predicament of an unsteady supply of COVID-19

[708] Furlong 2021 Politico.
[709] Thambisetty *et al* 2022 Cambridge University Press 20.
[710] Thambisetty *et al* 2022 Cambridge University Press 20.
[711] Thambisetty *et al* 2022 Cambridge University Press 20.
[712] Roy and Kasolowsky 2022 Reuters.
[713] Thambisetty *et al* 2022 Cambridge University Press 20.

vaccines.[714] It is held that the surge in capacity expansion leads to a substantial increase in the demand for input supplies, including raw materials and specialized equipment.[715] This has resulted in significant pressure on the raw material supply chain, creating challenges throughout the entire vaccine manufacturing process. The scarcity of various materials, such as "flacons, lipids, syringes, cell cultures, filters, and single-use bioreactor bags", has been frequently reported by Contract Development and Manufacturing Organizations (CDMOs) and documented in literature.[716] These shortages not only present significant compounded risks but also have the potential to disrupt the entire production chain of vaccines.[717]

However, it must be noted that IP impediments have contributed to the scarcity of raw materials and consumables, thus restricting alternative solutions.[718] For example, the scarcity of plastic single-use bioreactor bags can be attributed to the worldwide reliance on a limited number of providers for these resources. In fact, the existence of over 2,000 patents pertaining to these bags, renders arduous, the prospect of entering the market as a new supplier.[719]

The TRIPS waiver would be required to have a broader scope, encompassing not only vaccine end-products but also mechanical equipment and components.[720] Furthermore, constructive international negotiations regarding the waiver could facilitate the coordination of the worldwide supply of ingredients.[721]

5.1.3.4 The profit, price, and public purse problem/arguments

With regard to pricing, the current IP legal framework maintains a system in which LMICs, such as South Africa, Uganda and Bangladesh, have allegedly been subjected to higher vaccine prices than HICs.[722] Additionally, Pfizer-BioNTech

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[714] Bourla 2021 https://www.linkedin.com/pulse/today-i-sent-letter-have-candid-conversation-our-drivers-bourla/.
[715] Bown and Bollyky 2022 World Economics 472.
[716] Bown and Bollyky 2022 World Economics 472.
[717] Bown and Bollyky 2022 World Economics 472.
[718] Thambisetty *et al* 2022 Cambridge University Press 22.
[719] Stoller 2021 Substack.
[720] Thambisetty *et al* 2022 Cambridge University Press 22.
[721] Thambisetty *et al* 2022 Cambridge University Press 22.
[722] Paun and Furlong 2021 Politico.

possesses the ability to raise vaccine prices at their discretion in order to augment profitability.[723] Hilty and colleagues assert that there was undoubtedly a potential for exorbitant pricing during the developmental phase of vaccines.[724] Governments should have taken measures to mitigate such risks within the ambit of contracts that subsidized vaccine research.[725]

However, in cases where disparities in pricing exist, it has been argued that it is insufficient to concentrate solely on contractual matters, disregarding the significance of IP. The argument presented by Hilty and colleagues is based solely on hindsight. The issue of pricing and distribution inequalities is of utmost concern and cannot be dismissed as unrelated to IP law.[726] To depict the issue of vaccine affordability in LMICs as solely a matter of private contractual decisions is to deliberately overlook the role of IP in enabling asymmetry.[727] Hilty and colleagues could be argued not to have presented a satisfactory resolution for the current and forthcoming pandemic scenarios in LMICs with their current argument. From pragmatic and ethical standpoints, legal scholarship should propose a path towards progress instead of advocating for the current *lex lata*, which has demonstrated its detrimental constraints.[728] As emphasized by advocates for access to medicines and patent experts, through various means, IP serves as the foundational framework that supports and facilitates such disparities, as it grants IP proprietors exclusive authority.[729]

To shift the *onus* of the current inequity of vaccines from the current structure of IP on the shortcomings of contracts, is a way to avoid remodelling the current IP framework, and to keep the *status quo*, with the looming threat of profit maximization over global welfare. The stratification of IPRs pertaining to inventions and the safeguarding of regulatory data cannot be dissociated from pricing and profiteering.[730] The culture of trade secrecy cannot be separated from the lack of

[723] Thambisetty *et al* 2022 Cambridge University Press 22.
[724] Hilty *et al* 2021 Max Planck Institute for Innovation & Competition Research 3.
[725] Hilty *et al* 2021 Max Planck Institute for Innovation & Competition Research 3.
[726] Thambisetty *et al* 2022 Cambridge University Press 22.
[727] Dyer 2021 BMJ 1.
[728] Thambisetty *et al* 2022 Cambridge University Press 22.
[729] Thambisetty *et al* 2022 Cambridge University Press 22.
[730] Thambisetty *et al* 2022 Cambridge University Press 23.

transparency.[731] It is not feasible to depend on free market to ensure fair distribution of vaccines worldwide, just as we did not rely on the free market to finance the essential R&D or shoulder the entire risk of creating such vaccines initially.[732]

Regarding the public purse argument, the disparities that impact the worldwide population are particularly conspicuous, especially in light of the fact that an unprecedented amount of public funding has been allocated towards vaccine research during the pandemic. Several vaccines have relied on significant breakthroughs that have occurred at universities and public institutions, such as the University of Pennsylvania (Penn), Oxford University, and the US National Institutes of Health (NIH).[733] As per a recent preprint published on medRxiv, the research and development of ChAdOx[734] and the Oxford-AstraZeneca vaccine received a significant proportion of its funding from public sources, ranging from 97.1% to 99.0%.[735] Additionally, it was reported in January 2021 that the global public sector had invested a minimum of €93 billion towards the development of COVID-19 vaccines and therapeutics, with €85.6 billion being allocated specifically towards vaccine development.[736] And in some countries, people have to pay out of their pocket to receive a jab. As discussed above, the creation of the vaccine through public funding should make the vaccine a public good that should be accessible to the public to advance social and economic welfare.

5.1.3.5 The diminishing incentive argument

Opponents of the TRIPS waiver argue that it would hinder the drive for pharmaceutical innovation,[737] and there are those who go as far as to claim that such a waiver would spell the end of the industry.[738] It is argued that a comprehensive waiver of IPRs is likely to have an adverse impact on the motivation

[731] Thambisetty *et al* 2022 Cambridge University Press 23.
[732] Thambisetty *et al* 2022 Cambridge University Press 23.
[733] McDonagh 2020 https://blogs.lse.ac.uk/covid19/2020/09/10/could-university-patents-stand-in-the-way-of-universal-global-access-to-a-covid-19-vaccine/.
[734] Oxford 2020 https://www.dictionary.com/e/tech-science/chadox1-ncov-19/.
[735] Cross *et al* 2021 BMJ Global Health 7.
[736] Thambisetty *et al* 2022 Cambridge University Press 23.
[737] Hilty *ed al* 2021 Max Planck Institute for Innovation & Competition Research 9.
[738] Gupta and Ramachandran 2021 Bloomberg Law.

for drug innovation, resulting in IP-holders discontinuing their R&D efforts for vaccines.[739] This assertion suggests that any attempts to diminish the stringency of IP regulations with the aim of augmenting vaccine production in the current pandemic could potentially result in the pharmaceutical industry refraining from developing vaccines and treatments in the event of a future pandemic.[740] It was felt by rich countries that this would lead to diminished incentivisation to continuously improve the vaccine portfolio, which is extremely important as we see a rapid rise in variants across the globe.

This is a conjectural statement that seems to regard the existing market conditions as the most favourable circumstance. Upon critical analysis, it could be construed as an acknowledgement that the existing system's incentives are misaligned to such an extent that pharmaceutical companies can leverage their IPRs as a form of ransom against governments, thereby perpetuating their strength indefinitely.[741] [742]

As COVID-19 transitions from a pandemic to an endemic situation in HICs, it is likely that a profit-maximizing private market will prioritize the production of costly vaccine booster doses for these countries, where they are required, over initial doses for LMICs.[743] This prioritization is expected, due to the need for booster doses to address new variants of COVID-19, which will exacerbate the already limited vaccine supplies and manufacturing capacities.[744] This is due to the way in which the current incentivisation framework is structured, and can prolong the pandemic due to stagnation in reaching global immunity.

In recent times, the prevailing market conditions have exhibited a deficiency in effectively addressing the demands for pandemic preparedness, primarily due to the functioning of IP incentives.[745] This has been demonstrated by notable instances of market failures in the production of vaccines for LMICs,[746] as well as inadequate

[739] Hilty *ed al* 2021 Max Planck Institute for Innovation & Competition Research 9.
[740] Thambisetty *et al* 2022 Cambridge University Press 28.
[741] Rizvi 2021 PublicCitizen 128.
[742] Thambisetty *et al* 2022 Cambridge University Press 28.
[743] Thambisetty *et al* 2022 Cambridge University Press 10.
[744] Thambisetty *et al* 2022 Cambridge University Press 10.
[745] Rutschman 2020 Journal of International Affairs.
[746] Kaslow 2018 Nature 334.

responses to outbreaks such as Zika and Ebola.[747] As the conventional incentives offered by IP tend to be insufficient in meeting the needs of the impoverished, it is crucial that one refrains from uncritically defending such incentives during the current global pandemic.[748]

5.1.3.6 The argument that TRIPS encompasses adequate flexibilities to avert adverse impacts of IPRs.

In addition to its political significance, one may present arguments that the TRIPS waiver presents considerable practical and legal advantages over the arduous array of "TRIPS flexibilities," specifically those delineated in Articles 31 and 73 of TRIPS.[749]

With regard to the subject of CL as provided for in Article 31, TRIPS allows for the exemption from the requirement to engage in negotiations for a voluntary license (VL) with the IPRs holder before a CL in cases of a "national emergency," instances of "extreme urgency," or for "public non-commercial use" is granted.[750] The COVID-19 situation can be considered as an emergency scenario. However, the intricate and disjointed IP landscape pertaining to COVID-19 renders the current CL system under TRIPS unsuitable for effectively addressing the issue of vaccine inequality.[751]

CL is associated with six noteworthy disadvantages.[752] The initial drawback is that the application of a CL can only be executed on a "product-by-product" and "country-by-country" basis.[753] A comprehensive CL for COVID-19 vaccines across all States is not feasible under the TRIPS agreement.[754] Secondly, the WTO framework stipulates minimum standards for a CL under Article 31 in TRIPS; however, nation-States can enact supplementary prerequisites for a CL, resulting in protracted procedures at the national level.[755] Thirdly, certain States have historically exhibited hesitancy in initiating the procedure for granting a CL owing to apprehensions of

[747] Herder *et al* 2020 Journal of Law and the Biosciences 1.
[748] Lezaun and Montgomery 2015 Science, Technology, & Human Values 3.
[749] Thambisetty *et al* 2022 Cambridge University Press 24.
[750] Thambisetty *et al* 2022 Cambridge University Press 24.
[751] Thambisetty *et al* 2022 Cambridge University Press 24.
[752] McMahon 2021 Journal of Medical Ethics 142.
[753] Thambisetty *et al* 2022 Cambridge University Press 24.
[754] Thambisetty *et al* 2022 Cambridge University Press 24.
[755] Thambisetty *et al* 2022 Cambridge University Press 24.

diplomatic discord, a potential challenge from a more dominant nation at the WTO, or trade-related intimidations, such as the imposition of sanctions.[756] Fourthly, there are supplementary obstacles that impede the utilization of a CL for vaccines, which include regulatory barriers.[757] As previously stated, in regions where data and marketing exclusivities are in place, generic manufacturers are unable to utilize such data to obtain regulatory approval for a generic product within a specific timeframe.[758] Consequently, the obtaining of generic approval may not be feasible within a reasonable period. It is noteworthy that a CL does not provide any additional incentive for data-sharing.[759] Fifthly, when a CL is granted, the proprietor of the rights must receive "sufficient" compensation, and this may lead to complex conflicts.[760]

Lastly, according to Article 31(f) of TRIPS, commodities produced under a CL must be utilized primarily for the provision of the domestic market. In principle, a CL for both import and export is now feasible under Article 31 *bis*.[761] [762] However, impediments exist to the utilization of Article 31 *bis*, notably the decision of certain countries/regions (such as the EU) to exclude themselves as importing Members from its application.[763] The prerequisites for invoking Article 31 *bis* are arduous. Thus far, this provision has been efficaciously employed only once, when Rwanda procured generic HIV TriAvir by importing it from the Canadian enterprise Apotex.[764] In spite of this, Rwanda did not receive its initial consignment of pharmaceuticals until 15 months following their notification.[765] Furthermore, in May of 2021, Bolivia submitted a statement to the WTO expressing its intention to procure the J&J vaccine from the Canadian enterprise Biolyse through a CL under Article 31 *bis*.[766] The submission made by Bolivia evinces the arduousness in ascertaining the

[756] 't Hoen *et al* 2018 WHO Bulletin 85.
[757] 't Hoen *et al* 2017 Journal of Pharmaceutical Policy and Practice; Thambisetty *et al* 2022 Cambridge University Press 25.
[758] Thambisetty *et al* 2022 Cambridge University Press 25.
[759] Thambisetty *et al* 2022 Cambridge University Press 25.
[760] Thambisetty *et al* 2022 Cambridge University Press 25.
[761] Amendment of the TRIPS Agreement. WTO Doc. WT/L/641 (Dec. 8, 2005) (hereafter Article 31 bis).
[762] Thambisetty *et al* 2022 Cambridge University Press 25.
[763] WTO Unknown https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm.
[764] Hestermeyer 2007 American Society of International Law Insights.
[765] Anderson 2010 Case Western Reserve Journal of Law, Technology & the Internet 168.
[766] Bolivia Outlines Vaccine Import Needs in Use of WTO Flexibilities to Tackle Pandemic.

pertinent patents and patent applications for a CL procedure.[767] Furthermore, the persistent postponements in the handling of the Bolivia/Biolyse petition reiterate the constraints of Article 31 *bis* when employed in a swiftly developing and extensively patented technological domain.[768]

Ultimately, Article 73 of TRIPS furnishes Member States of the WTO with legal protection to suspend the implementation of customary TRIPS obligations during periods of national emergency. Although Article 73 is advantageous, its applicability is restricted in comparison to the TRIPS waiver.[769] Specifically, Article 73 permits independent (unilateral) action by a WTO Member, which is nevertheless subject to judicial review under the WTO Dispute Settlement Understanding.[770] Conversely, the waiver diverges from Article 73 in that its ratification would clarify its lawful availability to the entire WTO membership.[771]

5.1.3.7 The argument that encourages the use of alternative means to the waiver

There exist two pertinent and noteworthy global initiatives by the WHO for pandemic response, namely the COVID-19 Technology Access Pool (C-TAP) and COVAX. Each initiative encompasses distinct approaches and perspectives on the significance of intellectual property (IP) and knowledge sharing in the battle against COVID-19.

The origins of the C-TAP initiative can be traced back to Costa Rica's appeal for a voluntary pool of IP, data, and know-how as far back as March of 2020.[772] In response, the WHO, in collaboration with the Costa Rican government, launched C-TAP in May of the same year as an internationally coordinated mechanism for the voluntary sharing of IP, data, and know-how in the battle against the pandemic.[773] C-TAP has been designed based on the Medicines Patent Pool, which is supported by the United Nations and aims to guarantee fair and impartial access to HIV

[767] Blanco With One Simple Decision, the Canadian Government Can Save Lives.
[768] Blanco With One Simple Decision, the Canadian Government Can Save Lives.
[769] Thambisetty *et al* 2022 Cambridge University Press 26.
[770] Thambisetty *et al* 2022 Cambridge University Press 26.
[771] Thambisetty *et al* 2022 Cambridge University Press 26.
[772] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 13.
[773] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 13.

medication and treatment, among other ailments.[774] Despite this, the pharmaceutical industry has largely disregarded C-TAP, and vaccine rights-holders have not formally cooperated with the initiative.[775]

COVAX facilitates global collaboration to ensure that LMICs have fair and equal access to COVID-19 tests, treatments, and vaccines.[776] Regarding COVAX, the overreliance on a sole producer, namely the Serum Institute of India (SII), to cater to the global voluntary COVAX initiative, spearheaded by WHO, CEPI, and Gavi, was grossly insufficient.[777] Due to the severe COVID-19 crisis in India, the SII had been prohibited from exporting any vaccine doses for the COVAX program, in order to prioritize the domestic requirements of India.[778]

5.2 The acceptance of a watered-down TRIPS Waiver

It is clear from the previous discussions that the proposition elicited both endorsement and dissent. It is apparent that it was also met with substantial acclaim, 105 WTO Members conveyed their support for the waiver, while 65 of those Member States acted as co-sponsors, .[779] The opposition primarily emanated from the pharmaceutical sector and affluent nations, where accessibility has been considerably less of an issue owing to their financial prowess and the presence of pharmaceutical corporations within their borders. The divergent perspectives gave rise to a protracted period of deliberations and bargaining that resulted in a 20-month long deadlock.

Ultimately, on 17 June 2022, at the 12th Ministerial Conference (MC12) of the WTO, the Ministerial Resolution on the TRIPS Agreement, commonly known as the TRIPS Waiver, was officially adopted.[780] The resolution involves a significantly diluted rendition of the initial TRIPS Waiver formulated by India and South Africa. It solely

[774] Bosch 2020 https://www.who.int/initiatives/covid-19-technology-access-pool.
[775] Thambisetty *et al* 2021 LSE Legal Studies Working Paper 13.
[776] Berkley 2020 Gavi https://www.gavi.org/vaccineswork/covax-explained.
[777] Reuters 2021 https://www.reuters.com/business/healthcare-pharmaceuticals/who-urges-countries-donate-10-mln-doses-covid-19-vaccines-poorest-2021-03-26/#
[778] Findlay *et al* The Irish Times.
[779] Wemos date unknown https://covid19response.org/.
[780] Wemos date unknown https://covid19response.org/.

pertains to vaccines and excludes any other medical products related to COVID-19. The decision made by the WTO scarcely grants exemptions and solely reiterates or elucidates current avenues for overriding patents through CL.[781] In contrast to the proposed waiver of 35 TRIPS provisions, the resolution only exempts one provision, namely Article 31 (f), which permits the export of vaccines under a compulsory licence. Lastly, the duration of the resolution is restricted to a period of five years. The resolution will undergo reassessment within six months of its implementation in May 2024.[782]

It is crucial to recognize that a narrow focus on patents alone is inadequate. To ensure the production and distribution of high-quality products like vaccines, it is imperative to acquire a comprehensive range of information that goes beyond what is encompassed by patents.[783] This includes knowledge concerning processes, machinery, quality control standards, and other relevant factors.[784] Such knowledge is essential to guarantee that products meet the necessary safety and efficacy requirements and are promptly brought to market.[785] Achieving this necessitates the transfer of technology and expertise, which can present challenges when one attempts to enforce measures like compulsory licensing. Opting for a universal waiver is more likely to yield effective results.

The decision made by the WTO could be argued to indicate that the commercial interests of affluent nations have superseded the objective of promoting fair and equal access to COVID-19 innovations. The original proposition put forth by India and South-Africa sought to rectify the power asymmetry between governments and pharmaceutical corporations, as well as between HICs and LMICs. However, the WTO's verdict does not seem to significantly advance either of these objectives.[786] Additionally, the complete ramifications of the WTO's verdict may be impeded by FTAs that certain nations have ratified.[787] Finally, a potential hazard exists that this

[781] Wemos date unknown https://covid19response.org/.
[782] Wemos date unknown https://covid19response.org/.
[783] Wemos date unknown https://covid19response.org/.
[784] Wemos date unknown https://covid19response.org/.
[785] Wemos date unknown https://covid19response.org/.
[786] Wemos date unknown https://covid19response.org/.
[787] Wemos date unknown https://covid19response.org/.

determination could establish a precedent for pandemic agreement discussions, thereby jeopardizing the formulation of substantial provisions aimed at ensuring fair and impartial access to medical commodities in forthcoming frameworks.[788]

Decision-making in the WTO involves a combination of consensus-based negotiations, formal meetings, and institutional procedures. Since every country has their own interest that they aim to protect, it is difficult to achoieve the full willing participation from all Members unless a consensus about how things should be is reached. Due to over accommodation to ensure participation, we see a watered-down instrument that has little value to achieve the original goal.

6 An analysis of the current Pandemic prevention, preparedness and response accord

6.1 Introduction

While the WTO addresses trade-related aspects of intellectual property rights and access to medicines, the WHO has a primary mandate focused explicitly on public health. Public health imperatives, such as ensuring equitable access to healthcare, promoting disease prevention and control, and addressing global health disparities, are central to the WHO's mission. The COVID-19 pandemic has caused significant upheaval, prompting the 194 WHO Member States to engage in negotiations for an international treaty.[789] The objective of this accord is to enhance countries' preparedness to manage future health crises or prevent them from occurring altogether. Although the process is in its nascent stages, the goal is to achieve a consensus by May 2024.[790]

In December 2021, the World Health Assembly[791] made a momentous resolution to create an Intergovernmental Negotiating Body (INB) tasked with drafting and

[788] Wemos date unknown https://covid19response.org/.
[789] News24 2023 https://www.news24.com/news24/world/news/critics-say-pandemic-treaty-text-is-step-backwards-20230530
[790] News24 2023 https://www.news24.com/news24/world/news/critics-say-pandemic-treaty-text-is-step-backwards-20230530
[791] The World Health Assembly serves as the platform for the governance of the World Health Organization by its 194 Member States. It is the preeminent global body responsible for establishing health policies and is comprised of health ministers representing Member States.

negotiating a global instrument focused on pandemic prevention, preparedness, and response.[792] During its inaugural session, the International Health Regulations (IHR) Review Committee, also known as the INB, conducted an election to appoint members of the INB Bureau.[793] The selection was based on geographical equilibrium and developmental stages, resulting in the appointment of two co-chairs hailing from the Netherlands and South Africa, and four vice-chairs from Brazil, Egypt, Japan, and Thailand. The INB Bureau is responsible for overseeing the INB process, which is further aided by the WHO secretariat.[794]

As negotiations gain momentum towards a novel pandemic treaty, caution has been expressed by observers that endeavours to guarantee equitable access to the requisite medical products for combating future hazards, are being diluted.[795]

6.2 Analysis of the current proposed global health treaty

The newly negotiated accord is the outcome of a rigorous consultation process that spanned the entirety of 2022. Contributions were made by the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies, which took into account inputs from various sources, Member States, and other stakeholders' written submissions. In addition, there were two rounds of public consultations, WHO Regional consultations, four meetings with interested stakeholders, and four informal focused consultations with experts across multiple domains.[796] To date, the INB Bureau has convened 28 times, in addition to meeting with the Bureau of the Working Group on Amendments to the International Health Regulations (2005). The aforementioned meetings and consultations have yielded a Zero Draft, which has been produced by the Bureau with the backing of the WHO Secretariat.[797] This draft was released on 1 February 2023 and was slated for discussion at INB meetings (INB4 from 27 February to 3 March and INB5 from 3 to 6 April). The INB has been

[792] WHO The First meeting of the Intergovernmental Negotiating Body to draft and negotiate a WHO Convention.
[793] Matsoso *et al* 2023 BMJ 1.
[794] Matsoso *et al* 2023 BMJ 1.
[795] News24 2023 https://www.news24.com/news24/world/news/critics-say-pandemic-treaty-text-is-step-backwards-20230530.
[796] Matsoso *et al* 2023 BMJ 1.
[797] WHO The fourth meeting of INB 2023.

tasked with finalizing the negotiation process in a timely manner, so that the Accord may be submitted to the World Health Assembly by May 2024.

However, detractors caution that the modifications being made to the preliminary negotiating text are diluting the language, particularly in a critical area aimed at preventing the widespread inequality observed in the distribution of vaccines and other medical supplies during the COVID-19 pandemic.[798] The elimination of a provision that required publicly funded, private sector research and development to adhere to transparent pricing of their products and technology transfer to underprivileged nations, was met with disapproval from public-interest organizations.[799] Suerie Moon, the co-director of the Global Health Centre at the Geneva Graduate Institute, said in this regard, "I think it is a real step backwards." She cautioned that if less affluent nations do not encounter concrete provisions that guarantee enhanced protection during the next pandemic, "there is a genuine possibility that countries may withdraw" from the negotiations.[800]

The initial version of the treaty, commonly referred to as the Zero Draft of WHO CA+, was released on 1 February 2023 and deliberated upon during the fourth session of the Intergovernmental Negotiating Body from 27 February to 3 March 2023.[801] As the Zero Draft serves as the foundation for negotiations, the specific provisions and substance of the treaty may undergo modifications.[802] However, the fundamental framework and overarching themes that the treaty is expected to tackle are anticipated to remain unchanged.[803] At present, negotiations are underway between the parties regarding several matters, including but not limited to:

[798] News24 2023 https://www.news24.com/news24/world/news/critics-say-pandemic-treaty-text-is-step-backwards-20230530.
[799] News24 2023 https://www.news24.com/news24/world/news/critics-say-pandemic-treaty-text-is-step-backwards-20230530.
[800] News24 2023 https://www.news24.com/news24/world/news/critics-say-pandemic-treaty-text-is-step-backwards-20230530.
[801] WHO The fourth meeting of INB 2023.
[802] Butchard and Balogun What is the proposed WHO Pandemic Preparedness Treaty?.
[803] Butchard and Balogun What is the proposed WHO Pandemic Preparedness Treaty?.

- The definition, means, and procedure for declaring a pandemic, and the practical implications thereof for States.
- The compatibility of the treaty with the International Health Regulations.
- The fundamental international principles that will inform the treaty, including human rights, sovereignty, equity, solidarity, transparency, accountability, and others.
- The establishment of equitable global supply chains for pandemic-related products and access to relevant technologies.
- The enhancement of the resilience and responsiveness of healthcare systems.
- The coordination and cooperation between States and the World Health Organization in pandemic preparedness and response.
- The financing of initiatives for pandemic preparedness and response.
- The creation of a new Governing Body for the treaty, such as a COP or Conference of the Parties.
- Other general legal issues pertaining to the treaty, such as amendments, withdrawal, and dispute resolution.[804]

There is no clear reference as to how the IP regime must be adjusted to accommodate the above set out objectives. There are significant shortcomings in the current pandemic accord. There are no clear obligations that will bind Members of the new treaty to act in global public health emergencies. Also, the way in which the current accord is being structured, still provides a veil for big pharmaceutical companies to continue with exorbitant pricings and anti-competitive behaviour, and to keep a hold on their own discretion as to when and with whom they will share their know-how and technology. The current state of the accord does not bring the global South and the global North onto an equal footing, effectively making it an accord with no teeth and with no legitimate consideration for the wellbeing of the greater world population, but rather the private interests of these companies.

[804] Butchard and Balogun What is the proposed WHO Pandemic Preparedness Treaty?.

6.3 Recommendations to forming an equitable global health treaty

A pandemic treaty offers a chance to tackle the difficulties of future pandemics and construct an improved framework, founded on unity, for the worldwide management of medical countermeasures. The analysis pinpoints crucial elements of a potential treaty that focuses on the global distribution of IP, medical technologies, and knowledge. These components are essential to guarantee fair and equal access to medical countermeasures during future pandemics.

In order to ensure effective and fair access to medical countermeasures during a pandemic, this thesis proposes that a pandemic treaty should address seven key areas. These recommendations take into account the existing constraints of international law, as well as the varying economic circumstances of potential state parties to the treaty.

6.3.1 Government-led biomedical R&D funding

Government-led initiatives must be implemented to provide financial support, subsidies, incentives, and risk reduction for the development of effective medical countermeasures.[805] It is widely recognized that private investments in vaccines and therapeutics for potential pandemic pathogens are insufficient, especially prior to the occurrence of a catastrophic event.[806]

The establishment of a pandemic treaty should aim to establish worldwide standards that guarantee and improve funding for relevant R&D, both before and during a pandemic crisis. Additionally, the treaty should define guidelines for effectively managing the allocation of resources towards R&D. An essential aspect of this treaty would involve implementing measures to ensure an adequate availability of resources from all sources, including public and private sectors, at every stage of the research and development process.[807] A comprehensive pandemic treaty should encompass a range of management frameworks that enable nations to adhere to the established R&D funding standards. These frameworks may include national

[805] Perehudoff *et al* 2022 BMJ Global Health 2.
[806] Perehudoff *et al* 2022 BMJ Global Health 2.
[807] Perehudoff *et al* 2022 BMJ Global Health 2.

R&D programs, international collaborations, contributions to global initiatives, and a diverse array of funding mechanisms such as direct funding, subsidies, and incentives.[808]

The attainment of such a level of cooperation could be facilitated by the implementation of a pandemic treaty that offers incentives for collaboration and the resolution of crucial public health concerns. This treaty should strive to strike a balance between decentralized decision-making and control, while also incorporating mechanisms for cooperation and maximizing the advantages gained.

6.3.2 Establish prerequisites for government-funded R&D

One significant drawback of the R&D process for COVID-19 countermeasures is the imbalance in financial risks between public funders and private companies, where the former bears a substantial burden while the latter maintains control over the access to the predominantly publicly funded knowledge required for developing the resulting products.[809]

A pandemic treaty needs to establish guidelines for conditions and enforceable clauses (in contracts) when a government has financially supported the R&D of pandemic countermeasures. It is crucial to secure adequate rights to guarantee the sharing of "patents, data, know-how, and biological resources" as necessary to reproduce the innovative solutions by qualified entities.[810] This sharing should be subject to suitable safeguards and conditions, which may include remuneration for pharmaceutical and research industries when applicable. The UN-supported Medicines Patent Pool, which strives to enhance medication accessibility through patent licensing, could offer valuable examples for such licensing agreements.[811]

The guidelines must mandate the public disclosure of various information, such as clinical trial data, research outcomes, and expenses, on open-access platforms (refer to transparency below). These measures would facilitate the achievement of

[808] Perehudoff *et al* 2022 BMJ Global Health 2.
[809] Perehudoff *et al* 2022 BMJ Global Health 2.
[810] Perehudoff *et al* 2022 BMJ Global Health 2.
[811] Perehudoff *et al* 2022 BMJ Global Health 2.

the worldwide agreement for enhanced transparency of R&D expenditure, units sold, the revenue of sales, and the net prices by country.[812]

6.3.3 Obligate technological transfers

The absence of technology sharing between vaccine manufacturers in high-income nations and their counterparts in LMICs has posed a significant challenge in scaling up the global vaccine production.[813] To ensure effective pandemic preparedness and response, it is imperative for technology transfer to become a standard practice rather than an isolated occurrence. In order to accomplish this, the establishment of a pandemic treaty is paramount, which would impose two distinct obligations on governments as soon as a PHEIC is declared. Firstly, governments should mandate that public funding for R&D of medical countermeasures is contingent upon agreements to facilitate significant technology transfer (as outlined in the aforementioned conditions for government-led funding of R&D). Secondly, in order to promote technology transfer to eligible entities, it is crucial for governments to cooperate and offer mandates, incentives, and subsidies to the private sector. This support should be extended regardless of whether the public sector finances the knowledge to encourage innovation and transfer of technology. Governments can facilitate this through voluntary or non-voluntary buy-outs, cost-sharing arrangements between the public and private sector, or by mandating technology transfer in government procurement contracts.[814] If the transfer of technology is highly dependent on the background IP and expertise (know-how), the government may have the option to buy-out the IPRs of an asset to achieve a particular policy goal.[815]

6.3.4 Mandate the sharing of knowledge and IP

The COVID-19 pandemic has highlighted the inadequacy of existing voluntary methods for sharing IP and knowledge related to medical countermeasures. To tackle this problem, it is imperative to establish a pandemic treaty that would require

[812] Perehudoff *et al* 2021 Health Evidence Network Synthesis Report 13.
[813] Perehudoff *et al* 2022 BMJ Global Health 2.
[814] Garrison 2021 Medicines Law & Policy Briefing Note.
[815] Love 2021 Medium.

governments to proactively revise their national laws concerning the sharing of rights to "inventions, data, know-how, and biological resources" when a pandemic arises.[816] It is imperative to incorporate mandatory measures in the form of legal tools that are immediately activated when a PHEIC is declared. These tools should enable the swift, streamlined, and successful elimination of monopolies on essential technology required for managing a pandemic.[817] It is crucial for a pandemic treaty to recognize the increasing significance of knowledge exchange, especially considering the advancements in the technological aspects of countermeasures, making them more complex.

The pandemic treaty must address the possible conflicts that may arise when balancing the necessity of the public to swiftly share IP of medical countermeasures during a crisis and the obligations to protect IP as stated in different international trade and investment agreements by taking into account various bilateral and plurilateral agreements pertaining to such obligations.[818] In pursuit of this, the treaty must specify that countries are required to abstain from enforcing provisions in such agreements if they contradict the treaty's obligation to promote knowledge sharing and enable the widespread production of affordable countermeasures.[819]

6.3.5 Enhance the regulatory framework by making it more streamlined and straightforward.

Governing the quality, effectiveness and the safety of medical countermeasures holds significant importance in achieving worldwide vaccine and related IP protected products accessibility. Typically, pharmaceutical regulation occurs at either a national or regional level, which in turn poses a considerable risk of division, redundancy, and inefficiency when new medications are introduced to combat a pandemic.[820]

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[816] Perehudoff *et al* 2022 BMJ Global Health 3.
[817] Reuters 2020 https://www.reuters.com/article/us-health-coronavirus-greece-pm-idUSKBN21O1LJ/.
[818] Perehudoff *et al* 2022 BMJ Global Health 3.
[819] Perehudoff *et al* 2022 BMJ Global Health 3.
[820] Perehudoff *et al* 2022 BMJ Global Health 4.

In order to effectively address the challenges posed by pandemics, the treaty must establish a centralized repository of regulatory standards and procedures that can be applied globally.[821] Additionally, transparency and sharing of regulatory data should be prioritized to ensure that all parties have access to the most up-to-date information. In order to effectively address the challenges posed by pandemics, the treaty must create an international repository of regulatory standards and procedures, as well as promote transparency and the sharing of regulatory data.[822] Additionally, the treaty must establish a process for addressing known issues in regulation, such as inconsistent approval standards for applying provisions regarding emergency use and the overly restrictive pathways for new technologies. Finally, the treaty should identify and create financing mechanisms to support these efforts.[823] By taking these steps, a pandemic treaty can help ensure that safe and effective products are available in a timely manner during emergencies.

6.3.6 Mandate enhanced transparency

Global health crises suffer from a lack of international cooperation due to inadequate sharing of information throughout the entire process of developing, funding, acquiring, and implementing medical countermeasures.

A comprehensive pandemic treaty must include a transparency chapter that covers various aspects such as pathogens, scientific research, and regulatory standards and procedures.[824] The transparency chapter should also address issues related to R&D funding agreements, patent landscapes, licensing of inventions, data, know-how, and biological resources.[825] Other important areas that should be covered in the transparency chapter include clinical trial designs, outcomes, costs, subsidies, and manufacturing costs.[826] Information pertaining to the ongoing crisis is currently available to the public via some channels, while certain data remain undisclosed and are guarded by government bodies and private institutions. Establishing a pandemic

[821] Perehudoff *et al* 2022 BMJ Global Health 4.
[822] Perehudoff *et al* 2022 BMJ Global Health 4.
[823] Perehudoff *et al* 2022 BMJ Global Health 4.
[824] Doshi *et al* 2022 BMJ 102.
[825] Doshi *et al* 2022 BMJ 102.
[826] Doshi *et al* 2022 BMJ 102.

treaty must be aimed at putting forth protocols that mandate the disclosure and sharing of sensitive information.

6.3.7 Encouragement for more inclusive global governance

A treaty should provide financial support for low-resourced States to effectively participate in negotiations. The resulting governance mechanism should provide for the meaningful representation of States by region and by level of development. The governance mechanism should not advantage early ratifiers or States with greater capacity and financial resources. A pandemic treaty should be dynamic (allowing for changes and amendments as needed) and have effective incentives and enforcement provisions, including accountability mechanisms for State parties and, ideally, non-State actors.

Global cooperation to address these six foregoing recommendations would be aided by an ongoing process to build a stepwise global framework with three levels. On the first level, a global framework should bind all governments to harmonise their existing mechanisms related to areas of the strongest consensus. The second level should provide an opt-in for harder-to-agree provisions. These provisions would be legally binding for those countries who join. The third level should develop best practices or soft norms for more novel or experimental provisions, where these norms could be moved 'up' to level two or one over time as support grows.

It is essential for the treaty to offer financial assistance to States that are low-resourced to ensure their active and continued involvement in negotiations. Additionally, the resulting governance structure should ensure the appropriate representation of States based on their geographical region and by their level of development.[827] It is crucial that this mechanism does not favour States that ratify the treaty early or have higher capacity and greater financial means.[828] The newly proposed pandemic treaty must be flexible nature, enabling it to accommodate changes and amendments as required (it should be dynamic, as the world structure, technology, and health threats are). Additionally, it should incorporate robust

[827] Perehudoff *et al* 2022 BMJ Global Health 4.
[828] Perehudoff *et al* 2022 BMJ Global Health 4.

enforcement provisions and incentives, along with mechanisms to hold state parties accountable.[829]

The WHO should play a central role in driving the development and implementation of a global health treaty. As the leading international health agency, the WHO possesses the expertise, authority, and mandate to coordinate global responses to health emergencies, including pandemics. Dispute resolution mechanisms in a pandemic treaty could be structured to ensure timely and effective resolution of conflicts or disagreements that may arise among parties regarding the interpretation or implementation of treaty provisions. Overall, the design of dispute resolution mechanisms in a global health treaty should prioritize fairness, transparency, and efficiency, with the ultimate goal of promoting cooperation and solidarity among parties in addressing global health challenges.[830]

To enhance global cooperation in addressing the aforementioned recommendations, it is crucial to establish a progressive global framework consisting of three tiers. At the first level, all governments should be obligated to align their current mechanisms pertaining to areas where a strong consensus exists. The second level should offer an optional inclusion for provisions that are more challenging to agree upon. These provisions would carry legal obligations for the countries that choose to participate. Lastly, the third level should focus on developing best practices and flexible norms for innovative or experimental provisions. As support for these norms grows, they can be elevated to level two or even level one.[831]

6.3.8 Incentivising participation of the global North

Countries and pharmaceutical companies ("Big Pharma") can be incentivized to agree to a global health treaty through a combination of economic, political, and

[829] Perehudoff *et al* 2022 BMJ Global Health 4.

[830] While a direct source cannot be provided, you can find support for these points in WHO publications, such as its constitution, strategic plans, reports on pandemic responses, and statements from WHO officials advocating for a global health treaty. Additionally, academic articles and policy papers discussing the role of the WHO in global health governance and pandemic management may provide further insights and references.

[831] Perehudoff *et al* 2022 BMJ Global Health 4.

public health considerations.[832] A global health treaty could facilitate market access for pharmaceutical companies by standardizing regulatory requirements and streamlining approval processes for vaccines, treatments, and medical technologies.

Harmonized regulations and procedures would reduce the administrative burden and costs associated with seeking approval for products in multiple countries, thus expanding market opportunities for pharmaceutical companies.[833]

The treaty could incorporate mechanisms for providing financial incentives, subsidies, or grants to pharmaceutical companies to develop vaccines, treatments, and diagnostics for priority diseases. Funding mechanisms such as advance market commitments, pooled procurement, and public-private partnerships could incentivize R&D and production of health products that address global health needs.[834] Participation in a global health treaty demonstrates a commitment to corporate social responsibility and public health objectives, which can enhance a company's reputation and brand value. Pharmaceutical companies can benefit from positive public perception, stakeholder engagement, and partnerships with governments, international organizations, and civil society in addressing global health challenges.[835]

7 Conclusion

The COVID-19 pandemic has highlighted the difficulties that intergovernmental organizations have encountered in their efforts to ensure that nation States adhere to international regulations during public health crises. The global South's reliance on the global North, particularly for crucial diagnostics and vaccines, has left the LICs susceptible to vulnerabilities. Furthermore, it is noteworthy that some of the primary advocates for the treaty negotiations are the very same HICs that have imposed excessive travel restrictions, stockpiled vaccines, and have persistently opposed the IP Waiver put forth by India and South Africa in 2020 for the past two

[832] Del Lano *et all* 2022 NIH 18.
[833] Del Lano *et all* 2022 NIH 19.
[834] Del Lano *et all* 2022 NIH 19.
[835] Del Lano *et all* 2022 NIH 19.

years.[836]As argued by Moon and Kickbusch, the difficulties associated with guaranteeing the adherence of States to international regulations underscore a persistent characteristic of the global system: the self-interested conduct of sovereign States, particularly when their perceived interests diverge.[837]

It is essential that IP products created to address a public health threat, that has the potential to cross borders, to be seen as a public good instead of an exclusive right held by pharmaceutical giants. The right to health necessitates the dissemination and exchange of technology and knowledge to be able to improve equitable access to required treatments globally. We cannot keep relying on the excuse that the global South does not have the capacity to manufacture their own treatments. This reasoning will keep LMICs forever reliant on importation and in turn, keep them in debt and with their poor footing pre-purchasing wars between them and more affluent States in the North, they will always be at a loss in acquiring treatments at affordable rates and in time. Capacity building and the lowering of IP-related barriers surrounding access and fair trade of life-saving treatments is of utmost importance to achieve health justice in the global South, having the highest disease burden and suffers the most during times of crisis.

The pursuit of an international instrument on pandemics, as decided by Member States of the WHO, offers an opportunity for the global community to enhance its readiness and collaboration in the face of future health crises. This dissertation proposes that the pandemic treaty should encompass the seven crucial aspects discussed in the previous chapter to ensure equitable access to IP, technology, and knowledge for the required medical countermeasures to combat global health threats. The main aim of incorporating these elements into the pandemic treaty should be to foster a more efficient collective response to pandemics, in accordance with established international law, robust public health principles, and political commitments.

[836] Dentico *et al* 2022 G2H2.
[837] Moon and Kickbusch 2021 Lancet Public Health.

Bibliography

Literature

Abbott 2003 Oxford University Press

Abbott FM, "*The 'Rule of Reason' and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS*" 2003 Oxford University Press 279-300

Achiume United Nations OHCHR *UN expert urges States to end 'vaccine apartheid'.*

Achiume E United Nations Human Rights Office of the High Commissioner (OHCHR) *UN expert urges States to end 'vaccine apartheid'.* 2022 GENEVA

Adam 2023 Nature

Adam D "When will covid stop being a global emergency?" 2023 Nature Volume 614 Article number 7947 1-2

Akonumbo 2022 Pretoria University Law Press

Akonumbo AN "*Intellectual property, trade, human rights and access to medicines in Africa: A Reader*" 2022 Pretoria University Law Press 218-270

Amin 2021 Foreign Affairs

Amin T "*Folly of Hoarding Knowledge*" 2021 Foreign Affairs

Anderson 2010 Case Western Reserve Journal of Law, Technology & the Internet

Anderson B "*Better Access to Medicines: Why Countries Are Getting 'Tripped' Up and Not Ratifying Article 31 Bis*" 2010 Case Western Reserve Journal of Law, Technology & the Internet 166-182

Archibugi and Filippetti 2010 Journal of Global Policy

Archibugi D and Filippetti A "*The globalization of intellectual property rights: Four learned lessons and four theseis*" 2010 Journal of Global Policy Volume 1 Issue 2 137-143

Balfour *et al* 2022 Carnegie Europe

Balfour R, Bomassi L, Martinelli M "*Coronavirus and the Widening Global North-South Gap*" 2022 Carnegie Europe 1-21

Bown and Bollyky 2022 World Economics

Bown CP and Bollyky TJ "*How COVID-19 vaccine supply chains emerged in the midst of a pandemic*" 2022 World Economics Volume 45 Issue 2 337-589

Brennan 2021 EndPoints News

Brennan Z "*Moderna CEO brushes off US support for IP waiver, eyes more than $19b in covid-19 vaccine sales in 2021*" 2021 EndPoints News

Butchard and Balogun What is the proposed WHO Pandemic Preparedness Treaty?

Butchard P and Balogun B What is the proposed WHO Pandemic Preparedness Treaty? the WHO is negotiating a treaty on pandemic preparedness. The briefing outlines what has been proposed, where negotiations are up to, and what comes next.

Chakma *et al* 2011 Global Health

Chakma J, Masum H, Perampaladas K *et al* "*Indian vaccine innovation: the case of Shantha Biotechnics*" 2011 Global Health Volume 7 Issue 9 1-10

Chandrasekharan et al 2015 Vaccine

Chandrasekharan S, Amin T, Kim J, Furrer E, Matterson AC, Schwalbe N, Nguyen A "*Intellectual property rights and challenges for development of affordable human papillomavirus, rotavirus and pneumococcal vaccines: Patent landscaping and perspectives of developing country vaccine manufacturers*" 2015 Vaccine Volume 33 Issue 46 6366–6370

Cheng and Hinnant 2021 AP News

Cheng M and Hinnant L "*Countries Urge Drug Companies to Share Vaccine Know-how*" 2021 AP News

Cline 1995 The World Economy

Cline W "*Evaluating the Uruguay Round*". 1995 The World Economy. Volume 18 Issue 1 1-23

Correa 2016 South Centre Research Paper

Correa CM "*Is the right to use trademarks mandated by the TRIPS Agreement?*" 2016 South Centre Research Paper Volume 72 1-36

Cowart *et al* Laws 2023

Cowart T, Rashi T, Bock GL. "*Should Pharma Companies Waive Their COVID-19 Vaccine Patents? A Legal and Ethical Appraisal*" Laws 2023; 12(3):47. https://doi.org/10.3390/laws12030047 2-11

Cross *et al* 2021 BMJ Global Health

Cross S, Rho Y, Reddy H, Pepperrell T, Rodgers F, Osborne R, Eni-Olotu A, Banerjee R, Wimmer S, Keestra S "*Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine?*" 2021 BMJ Global Health Volume 6 Issue 12 1-11

Dall and Davies 2021 The Guardian

Dall N and Davies L "South Africa accuses UK and others of 'knee-jerk' reaction to new variant" 2021 The Guardian (26 November 2021)

Llano et all 2021 Eur J Health Econ

Del Llano J, Mestre-Ferrandiz J, Espin J, Gol-Montserrat J, Del Llano A, Bringas C. *"Public health policies for the common interest: rethinking EU states' incentives strategies when a pandemic reshuffles all interests."* Eur J Health Econ 19-23Dentico *et al* 2022 G2H2

Dentico N, Aye B, Meurs M "*Financial justice for pandemic prevention, preparedness and response*" 2022 G2H2

Doshi *et al* 2022 BMJ

Doshi P, Godlee F, Abbasi K "*Covid-19 vaccines and treatments: we must have RAW data, now*" 2022 BMJ Volume 376 issue 102 100-108

Douglas and Samant 2017 Plotkin's Vaccines

Douglas RG and Samant VB "*The Vaccine Industry*" 2017 Plotkin's Vaccines Volume 41 Issue 50 41-50

Dutfield That High Design of Purest Gold

Dutfield G That High Design of Purest Gold: A Critical History Of The Pharmaceutical Industry, 1880-2020 (University of Leeds, UK 2020) 1-21

Dyer 2021 BMJ

Dyer O "*Covid-19: Countries Are Learning What Others Paid for Vaccines*" 2021 BMJ Volume 372 Issue 281 1-2

Faunce 2004 The age

Faunce T 2004 "*The awful truth about evergreening*" The Age

Findlay *et al* The Irish Times

Findlay S, Peel M and Mancini DP "*India's block on vaccine exports deals blow to dozens of nations*" The Irish Times (26 March 2021)

Fisher and Rigamonti 2005 The Law and Business of Patents

Fisher III WW and Rigamonti CP "*The South Africa AIDS Controversy A Case Study in Patent Law and Policy*" 2005 The Law and Business of Patents 1-56

Furlong 2021 Politico

Furlong A, "*Big Vaccine Makers Reject Offers to Help Produce More Jabs*" 2021 Politico

Gargi and Gupta 2011 Elsevier BV

Gargi R and Gupta R "Intellectual Property Rights vs. Human Rights: A Need to Re-Examine the Relationship between the Two to Enhance Social Being" 2011 Elsevier BV 1-21

Garrison 2021 Medicines Law & Policy Briefing Note

Garrison C "Lessons for a pandemic preparedness treaty from previous successes and failures with treaty-based technology transfer" 2021 Medicines Law & Policy Briefing Note

Gleeson *et al* 2023 Medical Journal of Australia

Gleeson D, Scheibner J, Nicol D "*Proposals to waive intellectual property rights for pandemic response products in the World Health Organization pandemic accord need Australia's support*" 2023 Medical Journal of Australia 46-48

Gottlieb 2021 Wall Street Journal

Gottlieb S "*Covid Lessons from Bush's Effort Against AIDS*" 2021 Wall Street Journal

Gupta and Ramachandran 2021 Bloomberg Law

Gupta R and Ramachandran R "*A Covid-19 Vaccine IP Waiver Won't Kill Pharma Innovation*" 2021 Bloomberg Law

Gutner 2017 International organizations in world politics

Gutner T "International organizations in world politics" 2017 199

Halajian 2013 Brooklyn Journal of International Law

Halajian D "*Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem*" 2013 Brooklyn Journal of International Law Volume 38 Issue 3 1192-1230

Hallo De Wolf and Toebes 2016 Health Human Rights

Hallo De Wolf A and Toebes B "*Assessing Private Sector Involvement in Health Care and Universal Health Coverage in Light of the Right to Health*" 2016 Health Human Rights Volume 18 Issue 2 79-92

Hassan et al Daily Maverick Citizen OP-ED

Hassan F, Akram R and Gonsalves G "The TRIPS fandango: Don't water down the waiver – lives depend on it" Daily Maverick Citizen OP-ED (12 May 2021)

Helfer 2007 U.C. Davis Law Review

Helfer LR "*Toward a Human Rights Framework for Intellectual Property*" 2007 U.C. Davis Law Review Volume 40 981-982

Hemel and Ouellette 2019 Yale Law Journal

Hemel DJ and Ouellette LL "*Innovation Policy Pluralism*" 2019 Yale Law Journal Volume 128 544-613

Herder *et al* 2020 Journal of Law and the Biosciences

Herder M, Graham JE and Gold R "*From Discovery to Delivery: Public Sector Development of the rVSV-ZEBOV Ebola Vaccine*" 2020 Journal of Law and the Biosciences Volume 7 Issue 1 1-14

Hestermeyer 2007 American Society of International Law Insights

Hestermeyer HP "*Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines*" 2007 American Society of International Law Insights Volume 11 2-6

Hilty *ed al* 2021 Max Planck Institute for Innovation & Competition Research

Hilty R, Batista PHD, Carls S, Kim D, Lamping M, Slowinski, Peter PR "*COVID-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition*" 2021 Max Planck Institute for Innovation & Competition Research Paper No. 21-13

Kang 2020 MIT Press

Kang HY "*Patents as Assets: Intellectual Property Rights as Market Subjects and Objects*" 2020 MIT Press

Kapczynski 2017 Cornell Law Review

Kapczynski A "*Order Without Intellectual Property Law: Open Science in Influenza*" 2017 Cornell Law Review Volume 102 Issue 6 1539-1639

Kaslow 2018 Nature

Kaslow DC et al "*Vaccine Candidates to Poorer Nations Are Going to Waste*" 2018 Nature Volume 564 Issue 334 337-339

Kehl 2002 Journal of Intellectual Property Law

Kehl J "*Trips Article 31(b) and the HIV/AIDS Epidemic*" 2002 Journal of Intellectual Property Law Volume 10 Issue 1 143-171

Kleyn 2021 les Nouvelles - Journal of the Licensing Executives Society

Kleyn, Madelein and Harmelen, Joanne, "Trade Secrets - South Africa" les Nouvelles - Journal of the Licensing Executives Society, Volume LVI No. 2 6-13

Kohler *et al* 2022 Health Hum Rights

Kohler J, Wong A, Tailor L "*Improving Access to COVID-19 Vaccines: An Analysis of TRIPS Waiver Discourse among WTO Members, Civil Society Organizations, and Pharmaceutical Industry Stakeholders*" 2022 Health Hum Rights Volume 24 Issue 2 159-175

Lezaun and Montgomery 2015 Science, Technology, & Human Values

Lezaun J and Montgomery CM "*The Pharmaceutical Commons: Sharing and Exclusion in Global Health Drug Development*" 2015 Science, Technology, & Human Values Volume 46 3-29

Love 2021 Medium

Love J "Buying Know-How to Scale Vaccine Manufacturing" 2021 Medium

Marc 2001 NYLS Journal of International and Comparative Law

Marc P "*Compulsory Licensing And The South African Medicine Act Of 1997: Violation Or Compliance Of The Trade Related Aspects Of Intellectual Property Rights Agreement?*' 2001 NYLS Journal of International and Comparative Law Volume 21 Issue 1 168-199

Maskus 2001 Final Report to World Intellectual Property Organization

Maskus KE "*Parallel Imports In Pharmaceuticals: Implications For Competition And Prices In Developing Countries*" 2001 Final Report to World Intellectual Property Organization 1-11

Matsoso *et al* 2023 BMJ

Matsoso P, Driece R, da Silva Nunes T, Soliman A, Taguchi K, Tangcharoensathien V "*Negotiating a pandemic accord: a promising start*" 2023 BMJ Volume 380 Issue 506 1-2

McMahon 2021 Journal of Medical Ethics

McMahon A "*Global Equitable Access to Vaccines, Medicines and Diagnostics for COVID-19: The Role of Patents as Private Governance*" 2021 Journal of Medical Ethics Volume 47 Issue 142 142-148

McManis CR and Contreras J American University, WCL Research Paper No. 2014-16

McManis CR and Contreras J "*Compulsory Licensing of Intellectual Property: A Viable Policy Lever for Promoting Access to Critical Technologies?"* 2014 American University, WCL Research Paper No. 2014-16 109-131

Mercurio 2021 Bad Precedent IIC Int Rev Ind Prop Copyright Law

Mercurio B "*The IP Waiver for COVID-19: Bad Policy*" 2021 Bad Precedent IIC Int Rev Ind Prop Copyr Law Volume 52 Issue 8 983-988

Mimiko 2012 Carolina Academic Press

Mimiko NO "*Globalization: The Politics of Global Economic Relations and International Business*" 2012 Carolina Academic Press 47-52

Moon and Kickbusch 2021 Lancet Public Health

Moon S and Kickbusch I "*A pandemic treaty for A fragmented global polity*" 2021 Lancet Public Health Volume 6 355-356

Morin and Gold 2014 International Studies Quarterly

Morin F and Gold R "*An Integrated Model of Legal Transplantation: The Diffusion of Intellectual Property Law in Developing Countries*" 2014 International Studies Quarterly Volume 58 Issue 4 781-791

Mukherjee *et al* 2023 PLOS Glob Public Health

Mukherjee S, Kalra K, Phelan AL "*Expanding global vaccine manufacturing capacity: Strategic prioritization in small countries"* 2023 PLOS Glob Public Health Volume 3 Issue 6 1-15

Mullen et al 2020 BMJ Glob Health

Mullen L, Potter C, Gostin LO, Cicero A, Nuzzo JB "*An analysis of international health regulations emergency committees and public health emergency of international concern designations*" 2020 BMJ Glob Health 1499-1500

Musungu and Oh 2005 Commission on Intellectual Property Rights, Innovation and Public Health

Musungu SF and Oh C "The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?" 2005 Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) 181

Nayak and Selbin Decentering International Relation

Nayak M and Selbin E Decentering International Relations (Zed Books London 2010) 48-260

Nkengasong and Tessema 2020 Cell

Nkengasong JN and Tessema SK "*Africa needs a new public health order to tackle infectious disease threats*" 2020 Cell Volume 183 296-300

Nkengasong *et al* 2017 Lancet Glob Health

Nkengasong J, Djoudalbaye B, Maiyegun O "*A new public health order for Africa's health security*" 2017 Lancet Glob Health Volume 5 1064-1065

Nolen New York Times

Nolen S "Here's Why Developing Countries Can Make the Top Covid Vaccines" New York Times (22 October 2021)

O'donnell and Mishra 2021 Healthcare & Pharmaceuticals

O'donnell C and Mishra M "*Moderna sees no impact on COVID-19 vaccine from potential patent waiver' Reuters*" 2021 Healthcare & Pharmaceuticals 1–33

Oehler and Vega 2021 Open Forum Infectious Diseases

Oehler RL, Vega VR. "*Conquering COVID: How Global Vaccine Inequality Risks Prolonging the Pandemic*" 2021 Open Forum Infectious Diseases Volume 9 Issue 10 1-3

OHCHR General comment No. 25 on A 15 of the science and economic, social and cultural rights

OHCHR General comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights)

Ouellette 2012 Harvard Journal of Law & Technology

Ouellette L "*Do Patents Disclose Useful Information?*" Harvard Journal of Law & Technology Volume 25 545-545

Paun and Furlong 2021 Politico

Paun C and Furlong A "*Poorer countries hit with higher price tag for Oxford/AstraZeneca vaccine*" 2021 Politico

Peiravian 2014 Iran J Pharm Res Fall

Peiravian F "*Parallel import: is it worth?*" 2014 Iran J Pharm Res Fall Volume 13 Issue 4 1112-1113

Perehudoff *et al* 2021 Health Evidence Network Synthesis Report

Perehudoff K, 't Hoen E, Mara K "What is the evidence on legal measures to improve the transparency of markets for medicines, vaccines and other health products (World Health Assembly resolution WHA72.8)?" 2021 Health Evidence Network Synthesis Report No. 73 1-55

Perehudoff *et al* 2022 BMJ Global Health

Perehudoff K, 't Hoen E, Mara K "*A pandemic treaty for equitable global access to medical countermeasures: seven recommendations for sharing intellectual property, know-how and technology*" 2022 BMJ Global Health Volume 7 Issue 7 1-5

Prabhala and Alsalhani 2021 MSF Southern Africa

Prabhala A and Alsalhani A "*Pharmaceutical manufacturers across Asia, Africa and Latin America with the technical requirements and quality standards to manufacture mRNA vaccines*" 2021 MSF Southern Africa 1-9

Ragavan *Creating a Culture of Health: A Public Health Treaty?*

Ragavan S "*Creating a Culture of Health: A Public Health Treaty?"* 1-9

Reuters 2009 Reuters Government

Reuters "*Brazil to object to Dutch seizure of generic drug*" 2009 Reuters Government

Rizvi 2021 PublicCitizen

Rizvi Z "*Pfizer's Power*" 2021 PublicCitizen

Roffe 1974 World Development

Roffe P "*Abuses of patent monopoly: A legal appraisal*" World Development, Volume 2, Issue 9,1974 15-26

Romero 2020 South Centre Policy Brief

Romero T "*Articles 7 and 8 As the Basis for Interpretation of the Trips Agreement*" 2020 South Centre Policy Brief Volume 79 1-8

Roy and Kasolowsky 2022 Reuters

Roy M and Kasolowsky R "*Approval of COVID Vaccine Made in South Africa Could Take 3 Years, WHO Says*" 2022 Reuters

Rutschman 2020 Journal of International Affairs

Rutschman AS "*The Mosaic of Coronavirus Vaccine Development: Systemic Failures in Vaccine Innovation*" 2020 Journal of International Affairs 1-6

Saul et al 2014 Oxford University Press

Saul B, Kinley D and Mowbray J "*The International Covenant on Economic, Social and Cultural Rights: Commentary, Cases and Materials*" 2014 Oxford University Press 1175-1232

Scheibner et al 2022 J Law Biosci

Scheibner J, Nielsen J, Nicol D "An ethico-legal assessment of intellectual property rights and their effect on COVID-19 vaccine distribution: an Australian case study" 2022 J Law Biosci Volume 9 1-36

Schermerhorn et al 2022 BMJ Global Health

Schermerhorn J, Case A, Graeden E "*Fifteen days in December: capture and analysis of Omicron-related travel restrictions*" 2022 BMJ Global Health Volume 7 1-5

Sell 2003 Cambridge University Press

Sell S "Private Power, Public Law: The Globalization of Intellectual Property Rights (Cambridge Studies in International Relations)" 2003 Cambridge University Press 1-17

Shang *et al* 2021 Frontiers in public health 9

Shang Y, Li H, and Zhang R "*Effects of pandemic outbreak on economies: evidence from business history contex*t" Frontiers in public health 9 2021 146-146

Sidley 2001 BMJ

Sidley P "*Drug companies sue South African government over generics*" 2001 BMJ Volume 322 447-447

Sinha *et al* 2023 Cambridge University Press

Sinha MS, Bostyn SJR and Minssen T "*Addressing Exclusivity Issues During the COVID-19 Pandemic and Beyond*" 2021 Glenn Cohen IG, Gluck AD, Kraschel K and Shachar C "*COVID-19 and the Law: Disruption, Impact, and Legacy*" 2023 Cambridge University Press 237-252

Sternberg 1999 USA Today

Sternberg S "*Victims lost in battle over drug patents*" 1999 USA Today 1-55

Stoller and Barclay The Big News Letter

Stoller M and Barclay D "Why Are There Shortages of Plastic Bags Needed for Vaccine Production? Monopolies and Patents" The Big News Letter (11 May 2021)

Stromiedel World Trade Policy and the Game Theory – Overcomming the Prisoner's Dilemma?

Stromiedel D World Trade Policy and the Game Theory – Overcomming the Prisoner's Dilemma? (GRIN Verlag 2005) 63-80

Venkatapuram 2011 Polity Press

Venkatapuram S Health Justice: An argument from the capabilities approach Polity Press 13-16.

Tenni et al 2022 Global Health

Tenni B, Moir HVJ, Townsend B "*What is the impact of intellectual property rules on access to medicines? A systematic review*" 2022 Global Health Volume 18 Issue 40 1-40

't Hoen *et al* 2017 Journal of Pharmaceutical Policy and Practice

't Hoen EFM, Boulet P, Baker BK "*Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation*" 2017 Journal of Pharmaceutical Policy and Practice Volume 10 Issue 1 2-9

't Hoen *et al* 2018 WHO Bulletin

't Hoen E and others "*Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-related Aspects of Intellectual Property Rights, 2001–2016*" 2018 WHO Bulletin Volume 96 Issue 85 185-193

Thambisetty *et al* 2021 LSE Legal Studies Working Paper

Thambisetty S, McMahon A, McDonagh L, Kang HY, Dutfield G "*The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic*" 2021 LSE Legal Studies Working Paper No. 06/2021 2-43

Thambisetty *et al* 2022 Cambridge University Press

Thambisetty S, McMahon A, McDonagh L, Kang HY, Dutfield G "*Addressing Vaccine Inequity During the Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond*" 2022 Cambridge University Press 1-33

Titong 2021 SA Attorneys Journal

Titong M "*The balance between Intellectual Property and public health*" 2021 SA Attorneys Journal 123–132

Torremans 2007 Copyright as a human right

Torremans PLC "Copyright as a human right" 2007 Mich. St. L. Rev. 271 276-276

Van der Merwe *et al Law of Intellectual Property in South Africa*

Van der Merwe APS, Klopper H, Pistorius T, Koornhof PGJ, Kelbrick R, Sutherland P, Tong L-A, Geyer S, Van der Spuy P *Law of Intellectual Property in South Africa* 2nd ed (LexisNexis 2016) 3-29; 359-392

Voice of America News

Voice of America "*As monkeypox drops in the west, still no vaccines for Africa*" Voice of America News (14 September 2022)

WHO The First meeting of the Intergovernmental Negotiating Body to draft and negotiate a WHO Convention

WHO The First meeting of the Intergovernmental Negotiating Body to draft and negotiate a WHO Convention, Agreement or other international instrument on pandemic prevention, preparedness and response (24 February 2022 14 and 15 March 2022)

WHO The fourth meeting of INB 2023

WHO The fourth meeting of INB 2023. Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting (1 February 2023)

Wilder-Smith and Osman 2020 J Travel Med

Wilder-Smith A and Osman S "*Public health emergencies of international concern: a historic overview*" 2020 J Travel Med 1-10

WIPO *et al Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual Property and Trade*

World Intellectual Property Organization; World Health Organization; World Trade Organization "*Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual Property and Trade*" (Geneva, Switzerland: World Intellectual Property Organization, 2013)

Wolvers et al 2015 University of Cologne

Wolvers A, Tappe O, Salverda T, Schwarz T "*Concepts of the Global South – Voices from around the world*" 2015 University of Cologne 1-19

Ulrich 2004 Journal of International Economic Law

Ulrich H "*Expansionist Intellectual Property Protection and Reductionist Competition Rules: A Trips Perspective*" 2004 Journal of International Economic Law Volume 7 Issue 2 1-34

Urias and Ramani 2020 A review of the existing evidence J Int Bus Policy

Urias E and Ramani SV "Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices?" 2020 A review of the existing evidence J Int Bus Policy 367-384

Yamey et al 2022 BMJ

Yamey G, Garcia P, Hassan F, et al "*It is not too late to achieve global covid-19 vaccine equity*" 2022 BMJ Volume 376 Article number 070650 1-6

Case law

Brazil vs. Merck & Co. 2007

India vs. Pfizer 2020

South Africa vs. Pharmaceutical Manufacturers Association 1997 2 SA 647 (CC)

Legislation

Medicines and Related Substances Act (previously Drugs Control Act) 101 of 1965

International instruments

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 1994

CESCR 2000 General Comment No 14

Committee on Economic, Social and Cultural Rights, General Comment No 14: The Right to the Highest Attainable Standard of Health (Art 12 of the ICESCR), UN Doc E/C.12/2000/4 (11 August 2000)

CESCR 2006 General Comment No 17

Committee on Economic, Social and Cultural Rights, General Comment No 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He or She Is the Author (Art 15(1)(c) of the ICESCR), UN Doc E/C.12/GC/17 (12 January 2006)

CESCR 2006 General Comment No 25

Committee on Economic, Social and Cultural Rights, General Comment No 25: Science and Economic, Social and Cultural Rights (Art. 15(1)(b), (2), (3), and (4) of the ICESCR), UN Doc E/C.12/GC/25 (30 April 2020)

Doha Declaration on the TRIPS Agreements and Public Health of 2001

International Covenant on Economic, Social and Cultural Rights of 1966

Universal Declaration of Human Rights of 1948

United States International Trade Commission

The Economic Effects of Significant U.S. Import Restraints: Eighth Update 2016

WIPO Summary of the Convention Establishing the World Intellectual Property Organization (WIPO Convention) 1967

Internet sources

AccessIBSA initiative https://accessibsa.org/about/

AccessIBSA initiative https://accessibsa.org/about/ accessed 13 June 2023

African Development Bank https://www.afdb.org/en/news-and-events/press-releases/african-development-banks-board-approves-landmark-institution-establishment-african-pharmaceutical-technology-foundation-transform-africas-pharmaceutical-industry-52727

African Development Bank African development bank's board approves landmark institution: establishment of African pharmaceutical technology foundation to transform Africa's pharmaceutical industry, African development bank - building today, a better Africa tomorrow 2022 available at https://www.afdb.org/en/news-and-events/press-releases/african-development-banks-board-approves-landmark-institution-establishment-african-pharmaceutical-technology-foundation-transform-africas-pharmaceutical-industry-52727 accessed 14 Jan 2023

African Union Africa's New Public Health Order

African Union Call to action: Africa's New Public Health Order (2022) Africa CDC https://africacdc.org/news-item/call-to-action-africas-new-public-health-order/ accessed 22 Dec 2022

Union Africa. Call to action: Africa's new public health order, Africa CDC. 2022. Available at https://africacdc.org/news-item/call-to-action-africas-new-public-health-order/ accessed on 22 Dec 2022

Aizenman 2021 https://www.npr.org/sections/goatsandsoda/2021/10/19/1047411856/the-great-vaccine-bake-off-has-begun?ft=nprml&f=1047411856

Aizenman N Moderna won't share its vaccine recipe. WHO has hired an African startup to crack it https://www.npr.org/sections/goatsandsoda/2021/10/19/1047411856/the-great-vaccine-bake-off-has-begun?ft=nprml&f=1047411856 accessed 15 Feb 2022

BBC News 2020 https://www.bbc.co.uk/news/world-asia-india-52659052

BBC News Remdesivir: Five Indian and Pakistani Firms to Make Drug to 'Fight Coronavirus' https://www.bbc.co.uk/news/world-asia-india-52659052 accessed 18 January 2021

Berkley 2020 Gavi https://www.gavi.org/vaccineswork/covax-explained

Berkley S "COVAX explained" 2020 Gavi https://www.gavi.org/vaccineswork/covax-explained accessed 18 January 2021

Blanco With One Simple Decision, the Canadian Government Can Save Lives

Blanco B With One Simple Decision, the Canadian Government Can Save Lives available at https://www.aljazeera.com/opinions/2021/9/28/the-canadian-government-can-save-bolivian-lives# accessed 14 February 2022

Bolivia Outlines Vaccine Import Needs in Use of WTO Flexibilities to Tackle Pandemic

WTO Bolivia Outlines Vaccine Import Needs in Use of WTO Flexibilities to Tackle Pandemic available at

https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm accessed 14 February 2022

Bosch 2020 https://www.who.int/initiatives/covid-19-technology-access-pool

Bosch R 2020 WHO COVID-19 Technology Access Pool https://www.who.int/initiatives/covid-19-technology-access-pool accessed 14 February 2022

Bourla 2021 https://www.linkedin.com/pulse/today-i-sent-letter-have-candid-conversation-our-drivers-bourla/

Bourla A Today I Sent This Letter to Have a Candid Conversation with Our Colleagues about the Drivers of COVID-19 Access and Availability https://www.linkedin.com/pulse/today-i-sent-letter-have-candid-conversation-our-drivers-bourla/ accessed 17 February 2022

CDC Africa 2021 https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/

CDC Africa Partnerships for African vaccine manufacturing (PAVM) framework for action, africa CDC. 2021 available at https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/ accessed 14 Jan 2023

COVID-19 vaccination in the WHO African Region - 16 December 2022 https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022

COVID-19 vaccination in the WHO African Region - 16 December 2022 available at https://www.afro.who.int/publications/covid-19-vaccination-who-african-region-16-december-2022 accessed 14 Jan 2023

Dombrovskis V European Parliament Plenary Session Statement on Multilateral Negotiations in View of the 12th WTO Ministerial Conference

Dombrovskis V European Parliament Plenary Session Statement on Multilateral Negotiations in View of the 12th WTO Ministerial Conference available at

https://ec.europa.eu/commission/presscorner/detail/en/speech_23_6091 accessed on 25 June 2023

Drahos 2003 "Expanding Intellectual Property's Empire: the Role of FTAs" http://www.ictsd.org/downloads/2008/08/drahos-fta-2003-en.pdf

Drahos P "Expanding Intellectual Property's Empire: the Role of FTAs" 2003 available at http://www.ictsd.org/downloads/2008/08/drahos-fta-2003-en.pdf accessed on 20 June 2023

Duke and Zuma 1998 Washington Post (News Art)

Duke L and Zuma N "Activist Health Minister Draws Foes in S. Africa" 1998 Washington Post, https://www.washingtonpost.com/archive/politics/1998/12/11/activist-health-minister-draws-foes-in-s-africa/613ba0dd-202e-4311-a6c3-59cf6ce408a8/

Establishment of the United Nations Conference on Trade and Development as an organ of the General Assembly

Establishment of the United Nations Conference on Trade and Development as an organ of the General Assembly (1965) available at https://digitallibrary.un.org/record/203700?ln=en accessed 12 Augustus 2023

ETO Consortium date unknown https://www.etoconsortium.org/en/what-are-etos/

ETO Consortium date unknown https://www.etoconsortium.org/en/what-are-etos/ accessed 13 June 2023

General Notice 240 of 2002

General Notice 240 of 2002 available at https://wipolex-res.wipo.int/edocs/lexdocs/laws/en/zw/zw030en.pdf

Global Trade Watch date unknown https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf

Global Trade Watch https://www.citizen.org/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf accessed 24 June 2023

Havana Charter for an International Trade Organization, drafted April 1948 https://www.wto.org/english/docs_e/legal_e/havana_e.pdf

Havana Charter for an International Trade Organization, drafted April 1948 https://www.wto.org/english/docs_e/legal_e/havana_e.pdf accessed 14 June 2023

Intellectual property and trade

Intellectual property and trade (2013) available at https://www.wipo.int/publications/en/details.jsp?id=305

Joint Statement of Co-Sponsors to the TRIPS Waiver

Joint Statement of Co-Sponsors to the TRIPS Waiver (2021) available at https://www.pmindiaun.gov.in/public_files/assets/pdf/Cosponsors'_Joint_Statement_17_May_2021.pdf accessed on 12 February 2023

Maskus Parallel Imports In Pharmaceuticals: Implications For Competition And Prices In Developing Countries

Maskus KE "*Parallel Imports In Pharmaceuticals: Implications For Competition And Prices In Developing Countries"* available at https://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf accessed on 14 June 2023 2-50

McDonagh 2020 https://blogs.lse.ac.uk/covid19/2020/09/10/could-university-patents-stand-in-the-way-of-universal-global-access-to-a-covid-19-vaccine/

McDonagh L 2020 Could university patents stand in the way of universal global access to a COVID-19 vaccine? https://blogs.lse.ac.uk/covid19/2020/09/10/could-university-patents-stand-in-the-way-of-universal-global-access-to-a-covid-19-vaccine/ accessed 18 January 2022\

Ministry of Public Health, Thailand and the WHO 2006 https://iris.who.int/bitstream/handle/10665/205326/B2072.pdf

Ministry of Public Health, Thailand and the WHO 2006 https://iris.who.int/bitstream/handle/10665/205326/B2072.pdf accessed 21 June 2023

Mpox (monkeypox) 2023 https://www.who.int/news-room/fact-sheets/detail/monkeypox

Mpox (monkeypox) https://www.who.int/news-room/fact-sheets/detail/monkeypox accessed on June 13 2023

MSF Southern Africa 2004 https://msfaccess.org/data-exclusivity-international-trade-agreements-what-consequences-access-medicines

MSF Southern Africa 2004 https://msfaccess.org/data-exclusivity-international-trade-agreements-what-consequences-access-medicines accessed 21 June 2023

MSF Southern Africa https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf

MSF Southern Africa *Voluntary Licenses And Access To Medicines* 3. https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf accessed 25 June 2023

MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha

MSF Southern Africa Unknown https://msfaccess.org/spotlight-trips-trips-plus-and-doha accessed 20 June 2023

Nattrass 2005 https://www.sahistory.org.za/sites/default/files/nattrass_hivaids_policy.pdf

Nattrass 2005 https://www.sahistory.org.za/sites/default/files/nattrass_hivaids_policy.pdf accessed on 19 June 2023

Neherlab https://github.com/neherlab/SARS-CoV-2_variant-reports/blob/main/reports/variant_report_latest_draft.md#variant-report-2023-01-02

Neherlab. Variant report 2023 https://github.com/neherlab/SARS-CoV-2_variant-reports/blob/main/reports/variant_report_latest_draft.md#variant-report-2023-01-02 accessed 02 January 2023

News24 2023 https://www.news24.com/news24/world/news/critics-say-pandemic-treaty-text-is-step-backwards-20230530

News24 2023 https://www.news24.com/news24/world/news/critics-say-pandemic-treaty-text-is-step-backwards-20230530 accessed 20 June 2023

Office of the United States Trade Representative 2019 Special 301 Report

Office of the United States Trade Representative 2019 Special 301 Report. available at: https://ustr.gov/about-us/policy-offices/press-office/reports-and-publications/2019/2019-special-301-report accessed on 1 December 2021

Oxford 2020 https://www.dictionary.com/e/tech-science/chadox1-ncov-19/

University of Oxford 2020 https://www.dictionary.com/e/tech-science/chadox1-ncov-19/ accessed 6 March 2022

Reuters 2020 https://www.reuters.com/article/us-health-coronavirus-greece-pm-idUSKBN21O1LJ/

Reuters 2020 https://www.reuters.com/article/us-health-coronavirus-greece-pm-idUSKBN21O1LJ/ accessed 25 February 2022

Reuters 2021 https://www.reuters.com/business/healthcare-pharmaceuticals/who-urges-countries-donate-10-mln-doses-covid-19-vaccines-poorest-2021-03-26/#

Reuters 2021 https://www.reuters.com/business/healthcare-pharmaceuticals/who-urges-countries-donate-10-mln-doses-covid-19-vaccines-poorest-2021-03-26/# accessed 16 February 2022

Russell The San Francisco Chronicle (News Art)

Russell S "World Trade Showdown" The San Francisco Chronicle (Nov. 24, 1999), https://www.sfgate.com/health/article/World-Trade-Showdown-Activists-Industry-Split-2894099.php

Statement by the South African Delegation, Minutes of the Council for TRIPS Special Discussions on Intellectual Property and Access to Medicines

Statement by the South African Delegation, Minutes of the Council for TRIPS Special Discussions on Intellectual Property and Access to Medicines (July 10, 2001) available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/M31.pdf

Third World Network 2020 https://twn.my/title2/resurgence/2020/345-346/cover01.htm

Third World Network 2020 https://twn.my/title2/resurgence/2020/345-346/cover01.htm accessed 12 November 2021

Tracking SARS-CoV-2 2023 https://www.who.int/activities/tracking-SARS-CoV-2-variants

Tracking SARS-CoV-2 variants https://www.who.int/activities/tracking-SARS-CoV-2-variants accessed 13 June 2023

UN OHCHR https://www.ohchr.org/en/what-are-human-rights

UN OHCHR "*What are human rights?"* https://www.ohchr.org/en/what-are-human-rights# accessed 20 June 2023

UNCTAD https://unctadstat.unctad.org/EN/Classifications.html

UNCTAD Global South https://unctadstat.unctad.org/EN/Classifications.html accessed 13 August 2023

UNICEF 2015 https://www.unicef.org/child-rights-convention/what-are-human-rights.

UNICEF What are Human Rights? 2015 https://www.unicef.org/child-rights-convention/what-are-human-rights accessed 20 June 2023

Virtual Conference: Expanding Africa's Vaccine Manufacturing

Virtual Conference: Expanding Africa's Vaccine Manufacturing available at https://africacdc.org/event/virtual-conference-expanding-africas-vaccine-manufacturing/ accessed 12 June 2023

Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19. Communication from India and South Africa

Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19. Communication from India and South Africa (2020) available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True accessed 12 February 2023

Wemos date unknown https://covid19response.org/

Wemos Unknown Review of initiatives for access to Covid-19 innovations https://covid19response.org/ accessed 17 November 2022

Who are the developing countries in the WTO? https://www.wto.org/english/tratop_e/devel_e/d1who_e.htm

Who are the developing countries in the WTO? https://www.wto.org/english/tratop_e/devel_e/d1who_e.htm accessed 13 June 2023

WHO coronavirus (covid-19) dashboard https://covid19.who.int/

WHO coronavirus (covid-19) dashboard https://covid19.who.int/ accessed 28 February 2023

WHO Covid-19 shows why united action is needed for more robust international health architecture, World Health Organization

WHO "*Covid-19 shows why united action is needed for more robust international health architecture, world health organization"* World Health Organization 2021 available at https://www.who.int/news-room/commentaries/detail/op-

ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture accessed 22 Dec 2022

WHO Drug Information https://apps.who.int/iris/bitstream/handle/10665/73466/19_3_2005.pdf

WHO Drug Information https://apps.who.int/iris/bitstream/handle/10665/73466/19_3_2005.pdf accessed 20 May 2022

WHO 2006 http://www.who.int/intellectualproperty/documents/thereport/CIPIHReport23032006.pdf

WHO, Report of the Commission on Intellectual Property Rights, Innovation and Public Health (Geneva, 2006) available at http://www.who.int/intellectualproperty/documents/thereport/CIPIHReport23032006.pdf accessed on 18 June 2023

WIPO Patents - How long does patent protection last? https://www.wipo.int/patents/en/

WIPO Patents - How long does patent protection last? https://www.wipo.int/patents/en/ accessed 24 June 2023

WIPO Patents - What is a patent? https://www.wipo.int/patents/en/

WIPO Patents - What is a patent? https://www.wipo.int/patents/en/ accessed 24 June 2023

WIPO Patents- What rights does a patent provide? https://www.wipo.int/patents/en/

WIPO Patents - What rights does a patent provide? https://www.wipo.int/patents/en/ accessed 24 June 2023

WIPO What kind of information is protected by trade secrets? https://www.wipo.int/tradesecrets/en/tradesecrets_faqs.html

WIPO What kind of information is protected by trade secrets? https://www.wipo.int/tradesecrets/en/tradesecrets_faqs.html accessed 13 June 2023

World Bank 2021 Reporthttps://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups

World Bank 2021 Reporthttps://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups accessed on 20 February 2024

World Intellectual Property Organization IP and International Trade https://www.wipo.int/export/sites/www/sme/en/documents/pdf/ip_panorama_9_learning_points.pdf

World Intellectual Property Organization IP and International Trade https://www.wipo.int/export/sites/www/sme/en/documents/pdf/ip_panorama_9_learning_points.pdf accessed on 14 June 2023

World Trade Organization DG Okonjo-Iweala Chair Summary following "COVID-19 and Vaccine Equity: What Can the WTO Contribute?" https://www.wto.org/english/news_e/spno_e/spno7_e.htm

World Trade Organization DG Okonjo-Iweala Chair Summary following "COVID-19 and Vaccine Equity: What Can the WTO Contribute?" https://www.wto.org/english/news_e/spno_e/spno7_e.htm accessed on 13 June 2023

WTO World Trade Organization joint statement

World Trade Organization joint statement by Georgieva K, Ghebreyesus TA, Malpass D and Okonjo-Iweala N "A new commitment for vaccine equity and defeating the pandemic" (2021) available at https://www.wto.org/english/news_e/roadmap_igo_01jun21_e.htm accessed 13 June 2023 accessed on 13 June 2023

World Trade Organization What is the World Trade Organization?, https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm

World Trade Organization What is the World Trade Organization?, https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm accessed on 13 June 2023

World Trade Organization. "The Text of the General Agreement on Tariffs and Trade https://www.wto.org/english/docs_e/legal_e/gatt47.pdf

World Trade Organization. "The Text of the General Agreement on Tariffs and Trade, https://www.wto.org/english/docs_e/legal_e/gatt47.pdf accessed on 14 June 2023

World Trade Organization: The Doha Declaration Explained https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm

World Trade Organization: The Doha Declaration Explained https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm accessed 13 June 2023

WTO Unknown https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm

WTO "Annex and Appendix to the TRIPS Agreement (Note 3)", available at https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm accessed 14 February 2022

WTO e-Learning From GATT to WTO https://www.youtube.com/watch?v=rdX3xPSywgU&ab_channel=WTOe-Learning

WTO e-Learning From GATT to WTO https://www.youtube.com/watch?v=rdX3xPSywgU&ab_channel=WTOe-Learning accessed 14 June 2023

WTO Glossary - parallel imports www.wto.org

WTO Glossary - parallel imports www.wto.org accessed 6 June 2023

WTO Intellectual property: protection and enforcement https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm

WTO Intellectual property: protection and enforcement https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm accessed on 14 June 2023

WTO on TRIPS and Pharmaceutical Products 2006 https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm

WTO on TRIPS and Pharmaceutical Products 2006 https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm accessed on 13 June 2023

WTO Overview: the TRIPS Agreement- Protection of undisclosed information. https://www.wipo.int/patents/en/

WTO Overview: the TRIPS Agreement - Protection of undisclosed information. https://www.wipo.int/patents/en/ accessed 24 June 2023

WTO https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm

WTO https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm accessed 12 Augustus 2023