Patents or Patients?

The COVD-19 Pandemic and Intellectual Property Rights

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Abstract

Worldwide inequality in the circulation of vaccines during the outbreak of the COVID-19 pandemic re-ignited the ever-existing turmoil between rich, developed nations and poor, developing nations on the role of intellectual property (IP) against the fundamental right to health. The World Trade Organization (WTO) and the World Health Organization (WHO) contribute to making medicinal products and diagnostic supplies more cost effectively for everyone around the world. A few advanced economies control most of worldwide health regulatory requirements; nevertheless, a large portion of the leading healthcare chain generates from these nations and is produced cheaply in underdeveloped nations before being exported to the rest of the world. Exploring whether or not intellectual property (IP) plays an important role in enabling or restricting nations from fulfilling their responsibilities towards the right to health in light of the current pandemic is the first task in my thesis; this will be followed by a glance at the contribution of IP in today's global pandemic situation, with the goal of providing recommended solutions to the problem.

Forewords

In the first place, I would like to extend heartfelt gratitude to Peter Gottschalk, my thesis supervisor, for his encouragement and support over the months. Learning from such dedicated, an enthusiastic, highly capable but humble individual was a real honour. One of the most memorable aspects of this Master's program has been working under your guidance. Thank you for taking the time to read and revise my research, for all of your insightful suggestions, and for being so supportive of both my writing and my personal well-being over the course of several months.

Thanks to my friends who have made me feel like home even though we were from different countries as well as different background. When I was a whirling ball of depression, you were always there to calm me down and give me the words of encouragement I needed. I would love to meet you soon and thank you all for all of your help and encouragement on this voyage.

I would also like to thank my classmates for putting on such a wonderful program that motivated me to see the world in a new light. Joining this master’s program was one of the best decisions I have ever made, and I will remember it for a long time.

Abbreviations

CDC	Centers for Disease Control and Prevention
CERD	Convention on the Elimination of all forms of Racial Discrimination
CESCR	Committee of the Economic, Social and Cultural Rights
EUCJ	European Union Court of Justice
CL	Compulsory License
ECDPC	European Centre for Disease Prevention and Control
ECHR	European Convention on Human Rights
EMA	The European Medicines Agency
EU	European Union
EPO	European Patent Office
FDA	U.S. Food and Drug Administration
HRC	Human Rights Council (UN)
ICCPR	International Covenant on Civil and Political Rights
ICESCR	The International Covenant on Economic, Social and Cultural Rights
ICJ	International Court of Justice
IHL	International Humanitarian Law
IHRL	International Human Rights Law
IP	Intellectual Property
IPR	Intellectual Property Rights
PCT	Patent Cooperation Treaty
R&D	Research and Development
RoI	Return on Investment
TRIPS	Trade-Related Aspects of Intellectual Property Rights Agreement
UDHR	Universal Declaration of Human Rights
UN	United Nations
WHO	World Health Organization (UN)
WIPO	World Intellectual Property Organization (UN)
WTO	World Trade Organization

Chapter 1: Introduction

1.1 Background

Public healthcare has been heavily impacted by the COVID-19 pandemic.[1] Even though in the past, the mass production of antiretrovirals was permitted in the developing countries of the global south while fighting against HIV, things are clearly not going in the same direction in case of COVID 19 pandemic.[2] Therefore, patent rights and access to medical technologies which fall within the periphery of IPR come into question. Even though patents and copyrights are distinct legal issues[3], they share a similar loop: the difficulty of balancing intellectual property rights with easy accessibility.[4] Limitations to accessibility, as well as the methods employed to decrease them (and their success) are examined in this research.

COVID-19's increased access hurdles are clearly not limited to a few particular circumstances, but rather are universal.[5] In my opinion, our current IPR structures are responsible for creating and implementing them. As a result, transparent movement are only able to target a subset of the many access restrictions that must be overcome in order to serve the general public interest.[6] For the purposes of IPR's welfare objectives, these current possibilities are predicated on the concept that somehow there exists a single "public" driven by uniform "interests".[7] This presumption, however, fails to capture the multiplicity and intra-border complexity of public interest.[8] With my findings in mind, I recommend that the current IPR structure (based on strict timely restriction) be redesigned to include limited-IPR restrictions (based on flexible and short-termed restriction with reasonable immunity given to the countries in need) as well as fresh, new and equal legal protections for current societal

[1] World Health Organization. (2020). Overview of public health and social measures in the context of COVID-19: Interim guidance. World Health Organization <http://www.jstor.org/stable/resrep28163> Accessed 10 October 2022.
[2] Torreele, E., & Amon, J. J. (2021). Equitable COVID-19 Vaccine Access. Health and Human Rights, 23(1), 273–288. https://www.jstor.org/stable/27040053, page 275 Accessed 10 October 2022.
[3] How Copyright Differs from Patent Right. (1880). Scientific American, 42(15), 228–228. http://www.jstor.org/stable/26072693 page 228 Accessed 11 October 2022.
[4] Frost, G. E. (1967). Patent and Copyright. Antitrust Law Journal, 33, 63–68. http://www.jstor.org/stable/40839217, page 63-65 Accessed 11 October 2022.
[5] Ibid at 1
[6] Torreele, E., & Amon, J. J. (2021). Equitable COVID-19 Vaccine Access. Health and Human Rights, 23(1), 273–288. https://www.jstor.org/stable/27040053, page 277 Accessed 11 October 2022.
[7] Thrasher, R. D. (2021). Trade-Related Aspects of Intellectual Property, Investment Rules and Access To Medicines. In Constraining Development: The Shrinking of Policy Space in The International Trade Regime (Pp. 41–60). Anthem Press. Https://Doi.Org/10.2307/J.Ctv1qmpd18.7 Page 44-46 Accessed 11 October 2022.
[8] Abbas M.Z. (2022). "Covid-19 and the Issue of Affordable Access to Innovation Health Technologies: An Analysis of Compulsory Licensing of Patents as a Policy Option" page 3-10.

interests. When an international humanitarian crisis occurs, it becomes critical to address the concerns of the general population, not just during the catastrophe, but also on a continuous basis.[9] Therefore, this thesis will evaluate how developing countries in the global south would be able to prefer patient rights of the people over the patent rights in the context of the COVID-19 pandemic.

1.2 Purpose and Research Question

The purpose of this thesis is to provide an introduction to the concepts of right to health recognized as a basic human right and legally analyse how patent rights are intervening with this basic right.

To fulfil this purpose, this master's thesis has two general research questions that need to be answered:

1. Is the Patent system a drawback for a more equitable roll-out of COVID-19 vaccines and human rights to health?

2. What, if any, reforms of the Patent system are needed to advance the right to health?

1.3 Delimitations

This thesis focuses on the human right to health as well as other instruments relating to patent laws; such as The European Convention on Human Rights (ECHR), The Universal Declaration of Human Rights (UDHR), The Convention on the Elimination of all forms of Racial Discrimination (CERD), The WTO TRIPS Agreement; however instruments of International Humanitarian Law (IHL) are not taken into consideration. International Human Right Law (IHRL) and International Humanitarian Law (IHL) are often confused, but they deal with separate legal issues. IHL does not address the fundamental human rights, rather deals with the regulation during armed conflicts. The scope of the thesis excludes issues related to compensation to pharmaceutical company payments or patients.

1.4 Methodology

The thesis follows the legal dogmatic method, which aims to evaluate and justify different areas of patent law and Human Rights Law. Concerning the human right to health and access

[9] Thrasher, R. D. (2021). Trade-Related Aspects of Intellectual Property, Investment Rules and Access To Medicines. In Constraining Development: The Shrinking of Policy Space in The International Trade Regime (Pp. 41–60). Anthem Press. Https://Doi.Org/10.2307/J.Ctv1qmpd18.7 Page 42-43.

to medicine during a global pandemic this thesis takes into account of lex lata and lex ferenda.

For the matter in the field of IPRs the thesis rely on the TRIPS Agreements. In regard to human rights to health, Committee of the Economic, Social and Cultural Rights (CESCR) and The International Covenant on Economic, Social and Cultural Rights (ICESCR) is analyzed with complementary books and articles.

On the other hand, for the Covid-19 situation this thesis primarily rely on TRIPS waiver proposal, NGOs reports, WTO documents, pharmaceutical companies declaration along with newspaper and online articles, academic and legal sources to provide better understanding and support the findings.

It is important to note that, sources that are used in this thesis are mostly non-binding as this is comparatively a new area of law that needs to be explored. It must also be noted that these non-binding sources plays an important role as they define and argue the concepts and sometimes can be interpreted by courts.

1.5 Structure

This thesis is divided into four chapters. The second chapter focuses on the background of Human Rights to health and IPRs with theories and practice between these two concepts. Chapter three is built upon within the conflict between patent law and ‘access to medicine’, where at the same time it analysed procedures that are undertaken to seek a balance. This chapter is also dedicated to locate problems that require attention during a global pandemic, and tried to provide recommendations. The final chapter of this thesis presents summery of the investigated issues and findings, also the possibilities of future work.

Chapter 2: Concepts of Right to Health and Intellectual Property Rights

2.1 Introduction

In recent years, intellectual property rights (IPRs) have risen to prominence as a massive macroeconomic, investment, and capital market issue, as evidenced by substantial growth in licensing fees and royalty payments in practically every part of the globe, as well as the inclusion of copyright clauses in regional and bilateral market and investment agreements (trade and investment agreements). Many countries have expressed concern that the intellectual property system is no longer serving its intended intent of advancing technology and transferring and disseminating technology to benefit the community, or that preferential rights are increasingly being used to protect preferential interests at the expense and reduce competition.

The introduction of COVID-19 vaccines a year after the virus that causes COVID-19 first appeared was a significant scientific accomplishment. However, the manner in which the program was implemented revealed significant disparities. As of the authoring of this research, just over 10% of people in low-income nations had at least one dose of vaccination, compared to 67% in high-income ones.[10] While a large percentage of people in developing economies continue to lack sufficient access to full vaccination against COVID-19, a number of countries that have vaccinated the majority of their populations are now administering booster shots, and some are introducing vaccine mandates and stockpiling vaccines.

Given that 11.2 billion doses of vaccines were produced by the end of 2021,[11] it is expected that production efforts will more than double to 24 billion doses by June 2022.[12] That would be quantitatively sufficient to fully vaccinate the entire world population, but most of the doses in the production queue are already allocated to high-income countries.[13] Even some vaccines produced in Africa, where only 10 per cent of population have been vaccinated,[14] have been shipped to countries that have already vaccinated the majority of their

[10] <https://data.undp.org/vaccine-equity/> (data as at 13 January 2022). Accessed on 18 April 2022.
[11] The 11 billion COVID-19 vaccines produced in 2021 has resulted in the largest immunization campaign in human history, and more and better vaccine redistribution and innovation will be required in 2022, according to the International Federation of Pharmaceutical Manufacturers Associations.
[12] International Federation of Pharmaceutical Manufacturers Associations; see also <https://www.imf.org/external/NP/Res/GHP/dashboardv2.html>. Accessed on 18 April 2022.
[13] <https://news.un.org/en/story/2021/09/110019>2 Accessed on 18 April 2022.
[14] <https://africacdc.org/covid-19-vaccination/> Accessed on 18 April 2022.

populations.[15] In all countries, serious cases of COVID-19 and deaths are predominantly occurring among those who are unvaccinated.[16]

Reducing the circulation of the virus still requires a combination of effective measures, including wearing protective face masks, physical distancing and testing, yet vaccines remain a particularly strong determinant to controlling the impact of the pandemic by limiting the risk of severe symptoms, hospitalization and death.[17] If a considerable proportion of the world population remains unvaccinated, vaccination's efficiency as a public health approach will be jeopardized, posing a serious threat to human rights, such as the rights to life, healthcare, employment, knowledge, social welfare, justice, and non-discrimination. The right to health of all persons is indeed undermined when vaccines are not available to everyone, given that variants, including more dangerous ones, may continue to develop and affect public health, as evidenced by the recent emergence of the Omicron variant and its rapid spread.

Accessibility to a COVID-19 vaccine that is both safe and reliable is a critical component of everyone's right to the best possible mental and physical health and wellbeing.[18] In interpreting that and other rights laid out in the International Covenant on Economic, Social, and Cultural Rights, the Committee on Economic, Social, and Cultural Rights has stated that Nations have a responsibility to take all appropriate steps, as a matter of practicality and to the best of their ability, to ensure equal entry to COVID-19 vaccines for all people, without unequal treatment.[19]

Given that the virus knows no borders, investment in one country is inherently insufficient, if other countries lack the resources to effectively address COVID-19. The global nature of the pandemic makes it incumbent upon all States to fulfil their obligations to support, to the maximum of their available resources, efforts to make vaccines available globally.[20] States with the ability to give technological and economic help should collaborate worldwide and believe in the right to healthcare as required, strongly in the context of the epidemic. This

[15] <https://www.nytimes.com/2021/08/16/business/johnson-johnson-vaccine-africa-exported-europe.htm>l Accessed on 18 April 2022.
[16]<https://www.who.int/news-room/questions-and-answers/item/coronavirus-disease-(covid-19)-vaccines;> <https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm>; and <https://ourworldindata.org/covid-deaths-by-vaccination> Accessed on 18 April 2022.
[17] <https://www.who.int/news-room/questions-and-answers/item/coronavirus-disease-(covid-19)-vaccines> Accessed on 18 April 2022.
[18] E/C.12/2021/1.
[19] E/C.12/2021/1.
[20] Ibid.

includes exchanging information, expertise, hospital instruments, and materials, as well as adopting concerted action to mitigate the health crisis' negative social and economic effects and support world economic restoration.[21]

According to the Committee on Economic, Social and Cultural Rights, providing national identity to vaccines violates States' transboundary commitments to refrain from making choices that restrict other States' capacity to make vaccines obtainable to their people and, as a consequence, to enforce their commitments regard to the right to health, since it results in a vaccine shortfall for the world's poorest people.[22] The Committee emphasized that States should ensure that no decision or unilateral measure obstructed access to vaccines and that any restriction geared towards secure national supply must be proportionate and the urgent needs of other countries must be taken into consideration.[23]

States also have a responsibility to take steps to eliminate obstacles to the effective production and distribution of vaccines. Currently, intellectual property rights present obstacles not only to sufficiently expanded vaccine production, but also to other critical elements of COVID-19 response, including testing and treatments. But those barriers are not immutable. On October 2, 2020, a large group of countries, led by India and South Africa, proposed an exemption under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) for COVID-19 preventative measures, quarantine, or therapeutic interventions that would last until widely spread vaccination is in spot and most of the world's total population has evolved their immune system and protection.[24] With the emergence of the Omicron variant of COVID-19 and related travel restrictions, the twelfth Ministerial Conference of the World Trade Organization, at which further negotiations should have been held, has been postponed indefinitely.[25] In supporting that call, the WHO has pointed out that emergency exemption to trade restrictions exist; a worldwide disease outbreak that has compelled many nations to close down and caused significant damage to firms of all kinds certainly qualifies.[26]

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[21] Ibid.
[22] Ibid.
[23] Ibid.
[24] Guardian News and Media. (2021, March 5). Who chief: Waive covid vaccine patents to put world on 'war footing'. The Guardian. <https://www.theguardian.com/world/2021/mar/05/covid-vaccines-who-chief-backs-patent-waiver-to-boost-production> Accessed on 8 June 2022.
[25] General Council decides to postpone MC12 indefinitely. WTO. (n.d.). <https://www.wto.org/english/news_e/news21_e/mc12_26nov21_e.htm> Accessed on 8 June 2022.
[26] Ghebreyesus, T. A. (2021, March 5). A 'me first' approach to vaccination won't defeat Covid. The Guardian. <https://www.theguardian.com/commentisfree/2021/mar/05/vaccination-covid-vaccines-rich-nations> Accessed on 22 Auguest 2022.

2.2 Defining Right to Health as a Fundamental Right

Defining the term “health” is a more difficile process than it seems in the absence of any universal definition. According to the Oxford dictionary, 'health' is defined as *"the state of being well and a state free from illness in body or mind".*[27] It also connotes the current condition of a person’s body or mind. It is the extent of continuing physical, emotional, mental, and social ability to cope with one's environment. The WHO Constitution of 1946 defines health in both positive and negative way as being *"a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".*[28]

The concept that health is a necessity for everyday living is undeniable. It is that fundamental and continuous energy in our everyday lives that is stimulated on a regular basis by our cultural and social conditions, as well as our economic and physical settings. On the other hand, human rights are those inalienable and inviolable rights of all mankind that are universally inherent in all humans since their birth. As a consequence, the States and the administrative authorities are under obligation to ensure these rights for all the people. According to Morris B. Abram, *“human rights are concerned with the dignity and worth of the individuals and represent minimal moral standards for human society".*[29]

Now the question is, does “right to health” fall within human rights? According to Article 25 of the Universal Declaration of Human Rights of 1948 ("UDHR"), *“everyone has the right to a standard of living adequate for the health and wellbeing of himself and his family including food, clothing, and medical care”*.[30] Though internationally recognized human rights legal frameworks do not specifically state the right to health, the components and principles of health are already prevalent. Health is a fundamental human right to the best achievable standard of living, according to international legal agreements.

The right to health is a fundamental and universal human right recognized by all countries.[31] Access to medications and health-care technologies is a critical component of the right to health.[32] The UN Human Rights Council's Resolution on access to medicine, enacted in June

[27] Health. Oxford Reference. (n.d.). <https://www.oxfordreference.com/view/10.1093/oi/authority.20110803095926577> Accessed on 18 April 2022.
[28] See <https://www.who.int/about/governance/constitution> Accessed on 18 April 2022.
[29] Morris B. Abram, Freedom of Thought, Conscience and Religion, 8 J. INT'L COMM'ONF J URISTs 40 (1967), quoted by Bari.
[30] Article 25 of the Universal Declaration of Human Rights of 1948 ("UDHR").
[31] Muhammad Zaheer Abbas, Treatment of the novel COVID-19: why Costa Rica's proposal for the creation of a global pooling mechanism deserves serious consideration? J Law Biosci (June 2020) 7 (1): 1-10.
[32] Human Rights Council, Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, A/HRC/23/L.10/Rev.1. (2013) paras 5-10.

2011, states that *"access to medicine is one of the key factors in realizing progressively the full fulfillment of everyone's right to enjoy the greatest attainable quality of physical and mental health"*.[33]

Intellectual property rights and regulatory exclusivities granted under patent laws have negative consequences for the availability of important medications, particularly for impoverished patients in low- and middle-income nations.[34] Pharmaceuticals were not patentable under national legislation in over fifty countries prior to the implementation of the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement).[35] As a result of signing the TRIPS Agreement in 1995, intellectual property protection became increasingly intertwined with commerce. This is because becoming a member of the WTO is a requirement for membership in the TRIPS. 20-year duration of patent protection is required under TRIPS for inventions in all disciplines of technology, including pharmaceuticals, and for all types of products.[36]

For the first time at the international level, the TRIPS Agreement established the responsibility to make patents available *"for any invention, whether products or processes, in all domains of technology",*[37] in order to encourage innovation. However, a patent is a legal document that grants the bearer specific exclusive rights. A patent is a public authorisation that prevents others from engaging in the acts of manufacturing, using, offering for sale, selling, or importing a protected product for a period of at least 20 years.[38] Consequently, only the patent holder or those authorized by him or her may manufacture, sell, and import medicines that are protected by patent. Third-party producers or importers are required to get a license from the patent holder before doing business with them. Unauthorized third parties engaged in the manufacturing of identical products run the danger of being sued for patent violations because the use of the patented material is conditional on receiving the patentee's permission before doing so.

[33] Human Right Council, Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development- The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, UN General Assembly 2 (2011).
[34] Walsh, K., Wallace, A., Pavis, M. et al. Intellectual Property Rights and Access in Crisis. IIC 52, 379–416 (2021).
[35] Scherer, F. M., & Watal, J. (2002, December 1). Post-TRIPS options for access to patented medicines in developing nations. Harvard Kennedy School. < https://www.hks.harvard.edu/publications/post-trips-options-access-patented-medicines-developing-nations> Accessed on 25 April 2022.
[36] TRIPS Agreement, Articles 27(1) and 33.
[37] Article 28.1, TRIPS Agreement. Rights of importation, distribution, use and sale of a protected product may only be relied upon until they are "exhausted". Comparable rights are conferred on the holder of a process patent, see Article 28.2, TRIPS Agreement.
[38] Ibid.

As a result, the awarding of pharmaceutical patents may present significant difficulties for generic medicine producers. A patent awarded on a pharmaceutical substance, as opposed to a patent granted on the process of manufacturing or utilizing a drug, is generally considered to be a more substantial barrier for generic producers.

2.3 Balance and the Limits of Intellectual Property Rights

In recent years, there has been a trend for courts to give exclusive rights to derivatives of existing pharmaceutical chemicals, even when the creativity of the compound is doubtful.[39] In 2002, the Federal Trade Commission of the United States discovered that generic manufacturers had a success rate of about 75% when it came to contesting pharmaceutical patents in the United States of America.[40] Even if not challenged, illegally granted exclusive rights have the potential to create significant barriers to follow-on innovation, particularly in nations where local sectors lack the necessary inventive power. Local producers may be unable to utilize informal technology transfer methods such as reverse engineering, imitation, or adaptation if they have broad exclusive rights (which are frequently held by multinational businesses). Developing country manufacturers' ability to learn from and adapt to new technologies are also dependent on the data, information, resources, and research instruments available in the public domain, as well as on the availability of knowledge and expertise.

Denying foreign investors access to these latter inputs through the use of excessively wide exclusive rights may inhibit or prohibit the development of local knowledge, hence restricting the potential for effective collaboration between international investors and local businesses.

In nations like India or the European Union member states, large pharmaceutical manufacturers may be discouraged from operating in those nations if exclusive rights are given to one party and the public domain is given to the other. In recent years, representatives of the generic industry have expressed an interest to invest their funds in local production sites located in developing countries, particularly in Africa. This is provided that these countries implement, to the greatest extent possible, available TRIPS flexibilities and take advantage of regional collaboration to expand their markets.[41]

[39] Azam, Monirul. Intellectual Property and Public Health in the Developing World. New edition [online]. Cambridge: Open Book Publishers, 2016 (generated 17 April 2022). Available on the Internet: <http://books.openedition.org/obp/3081>. ISBN: 9782821881655.
[40] Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration: An FTC Thesis", Washington, D.C., July 2002, p. 17 [hereinafter United States FTC Thesis]. <http://www.ftc.gov/os/2002/07/genericdrugthesis.pdf>. Accessed on 25 April 2022.
[41] Representative of the Indian Pharmaceutical Alliance, oral communication to UNCTAD staff (September

The significance of patents to pharmaceutical research is known to all. The drugs that efficiently treat serious diseases provide extraordinary value to the consumers. Unlike the developed countries, pharmaceutical intellectual property rights were ill-protected in poor countries. That the deficiency of research into diseases like malaria, AIDS, and drug-resistant tuberculosis being particularly important to these nations are quite apparent to the whole world. So, it is quite visible that the dearth of patent protection may have resulted, from an acute collective action. At the international level, the World Intellectual Property Organization (WIPO) was primarily responsible for the regulation of intellectual property rights. Established in 1970, the WIPO replaced the Union for the Protection of Intellectual Property, an association of states with permanent independent bodies established by the Paris and Bern Conventions.[42] However, WIPO conventions only impose general rules and are not binding upon states which are not signatories to them and have not ratified them.[43]

When foreign entities did nothing to protect the IP rights of the United States, it unilaterally announced that there was an unethical business technique and interpreted that it might be the topic of pre-emptive temporary restraining order under the Trade Act of 1974, Section 301, even though no international treaty had been infringed to protect intellectual property rights.[44] U.S. trade actions were brought against underdeveloped nations for offering "inadequate" intellectual property rights, in accordance with this jurisdiction.[45]

As a consequence, a significant agreement was made with some promises of overcoming a part of this problem. Developing nations subsequently took cooperation in reducing intellectual property protection requirements for pharmaceuticals under the WTO Agreement on TRIPS Agreement.[46] Members of the WTO are required by the TRIPS Agreement to protect intellectual property in accordance with specific requirements. It tries to create a balance between the long-term goal of giving incentives for innovation and the short-term goal of reducing costs. When it comes to short-term goals, making use of current ideas as

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2007); see also Abbott/Reichman, p. 42, footnote 219, citing a statement by a spokesperson of the European Generic Medicines Association, hearing before the European Parliament International Trade Committee, June 5, 2007.

[42] Paris Convention on Intellectual Property of 1883; Bern Convention on Copyright of 1886.

[43] World Health Organization (WHO) Action Programme on Essential Drugs Globalization & Access to Drugs (1999) 15.

[44] 19 USC § 2411(d) (2001); 19 USC § 2242 (2001). The history of these statutory provisions is discussed briefly in John H. Jackson, William J. Davey, and Alan 0. Sykes, Legal Problems of International Economic Relations: Cases, Materials and Text on the National and International Regulation of Transnational Economic Relations 818-20,832-35 (West 3d ed 1995).

[45] Targets of US action included Brazil, Argentina, India, Thailand, the People's Republic of China, and the Republic of China (Taiwan). For a history of these disputes and their outcomes, see Alan O. Sykes, Constructive Unilateral Threats in International Commercial Relations: The Limited Case for Section 301, 23 L & Pol in Ind Bus 263, 318 (1992) (a table of disputes is set out in the Appendix).

[46] Ibid.

well as products and other inventions is also a big part of the considerations.[47] Another most important aspect is to promote the public interest in sectors of vital significance to their socio-economic and technological development.[48] Last but not least, taking effective measures to prevent the abuse of intellectual property rights by the holder of patents.[49]

Every branch of technology, including products and processes, is said to be eligible for patent protection. In this case, though, the need is that they be brand new, innovative, and industrially applicable. On a different note, they must be enjoyable without discrimination in case of the place of invention, the field of technology and imported or locally produced products.[50] The monopoly extended to a patent holder is extensive:

> *"1. the following exclusive rights shall be conferred on its owner by a patent:*
>
> *(a) Where the subject matter of a patent is a product, to prevent third parties from making, using, offering for sale, selling, or importing of that product for the mentioned purposes without the owner's consent;*
>
> *(b) Where the subject matter of a patent is a process, to prevent third parties from using, offering for sale, selling, or importing the product for these purposes without having the owner's consent;*
>
> *2. Patent owners shall also have the right to assign the patent or transfer it by succession, and to conclude licensing contracts."* [51]

In order to safeguard human, wildlife, or plants, or to minimize damage to the environment, the agreement allows for a number of exceptions to patent rights. It is shown in the provision titled "Exceptions to Rights Conferred" that the members may grant limited exemptions from patent-granted exclusive rights, so long as those exemptions don't infringe on or otherwise detriment the legitimate interests of a patent's owner or third parties in a way that is unfair or unreasonable.[52]

It is apparent from the provision that the exceptions are subject to certain conditions:

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[47] Cynthia M. Hou., A New World Order for Addressing Patent Rights and Public Health, 82 C Kent Lev. (1469) 1470 (2007).
[48] Art 8(l) of TRIPS Agreement.
[49] Art 8(2) of TRIPS Agreement.
[50] Art 27(1) of TRIPS Agreement.
[51] Art 28 of TRIPS Agreement.
[52] Art 30 of TRIPS Agreement.

1) "They must be limited. The drafters of the agreement certainly did not want to admit an uncontrolled proliferation of exceptions.

2) They must not unreasonably conflict with the normal exercise of the patent or unreasonably affect the patent holder's legitimate interests".[53]

The aim appears to be to strike a balance between the interests of the patent holder and those of third parties. An example of an exception allowed under WTO rules is the United States of America's national legal provision known as the 'Bolar Amendment', as per which prior to the expiration of patents, pharmaceutical firms can initiate preproduction and regulatory requirements so that they can promptly begin marketing their goods upon patent expiration.[54]

With TRIPS firmly in place, it became abundantly clear just how serious the pharmaceutical industry is about respecting the rights of governments to take measures, albeit compliant with TRIPS, to increase access to medications in their countries. The recent action by the Pharmaceutical Manufacturers Association against the government is a case in point. In April 2001, a lawsuit brought against South Africa by foreign pharmaceutical corporations was abandoned after a storm of negative press coverage.[55] Also, the UN Commission on Human Rights mentioned that accessibility to medications should be a basic right, and that TRIPS should be construed widely in order to encourage drug access.[56]

A "national emergency or other event of extraordinary urgency" can be clearly defined as a "public health crisis" as per the Declaration. As previously stated, an "emergency" in this application might refer to a narrow issue or a lengthy one. A claim that perhaps the TRIPS Agreement gives sufficient space for national scale discretion has substantial legal and political consequences. It demonstrates that the incentives to impede the usage of existing flexibilities are at odds with the TRIPS Agreement's intent and objective. Representatives of committees and the Appellate Body are constitutionally required to evaluate the TRIPS Agreement in light of their own country's basic healthcare needs while implementing domestic legal frameworks.[57]

[53] Yousuf A. Vawda, Tripped-up on Trips: The Story of Shrinking Access to Drugs in Developing Countries, 13 Stellenbosch L. Rev. 352 (2002).
[54] The Panos Institute (PANOS) Beyond Our Means? (2000) 37.
[55] International Centre for Trade and Sustainable Development, U.S. Drops TRIPs Dispute Against Brazil's Patent Law.
[56] UNCHR Report.
[57] Carlos M. Correa, TRIPS Agreement and Access to Drugs in Developing Countries, 3 SUR - Int'l J. on Hum Rts. 25 (2005).

As a reminder, ministerial pronouncements in the WTO are not legally enforceable on the participants in the dispute settlement process. As long as there's a disagreement, the treaties' official text will take precedence over any ministerial proclamation to the contrary. Although the Doha Declaration primarily interprets TRIPS responsibilities, that does not seem to pose any objections to any linguistic provisions of the treaty itself. Because of this, it is probable that if there is an immediate disagreement, it would be that authoritative institution in the interpreting of TRIPS that will rule over the subject. As a note, the emerging economies did not get everything on their "priority list" at Doha. Nations that produce patented items under obligatory licensing can now export them to countries that qualify under the Doha Declaration's decision as a "interim waiver." However, the importer must have issued a compulsory license and other requirements must be met. When TRIPS is not changed, the waiver will remain in effect.[58]

This implies that even if a nation has a medical necessity for a certain medication, the patent holder will not be forced to furnish it under the established system. His only option may be to stand by and watch helplessly while the nation in need makes every effort to comply with the Decision's terms while their citizens remain untreated. He may also make things easier by issuing a permit to the prospective exporters on his own initiative. Alternatively, the patent proprietor may leverage the system's complexity and complications to protect his intellectual property rights under the applicable state legislation. In regard to all of these, the method outlined in paragraph 6 can be used in a dispute between a developing nation and a patent-owning nation.

The Council for TRIPS shall be notified by exporter nations of the license issued and any limitations associated with it. The approved approach recognizes the option of providing a compulsory license for the importation of a patented medicament, which is entirely consistent with the TRIPS Agreement. As a result, many emerging countries give compulsory permits to produce patented subject matter, but not for the importing of protected subject material. For this idea to work, emerging economies would need to alter their domestic copyright and patent rules. Non-commercial governmental use of copyrighted ideas may be optional if

[58] According to paragraph 11,*"... This Decision, including the waivers granted in it, shall terminate for each member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(O1)/DEC/1)".*

national courts in emerging and low - income countries permit for domestic drug industries or imports.[59]

As indicated in the foregoing discussion, articles 6, 30, and 31 of TRIPS (dealing with exhaustion of intellectual property rights; exceptions and compulsory licensing) contradict the PMA's contentions. In April 2001, the PMA unconditionally withdrew its challenge, thereby opening the way for the introduction of three important measures in the new legislation. These are the generic substitution of off-patent medicinal drugs and drugs imported and produced under compulsory licenses; parallel importation of patented drugs; and a transparent medicine pricing system by the establishment of a pricing committee.[60]

However, just as the obligations of developing nations are starting to take place under TRIPS, a great doubt on the future of patent rights is cast by the Doha Declaration for pharmaceuticals in developing nations. As a consequence, the result may be quite unfortunate for research initiatives, especially those relating to particular diseases of the underdeveloped countries.

2.4 Summary and Concluding Remarks

The duty to make optimum use of all resources available to protect the right to health encompasses both country's resources and assets made available by the foreign community as a result of international collaboration and help. States should consider economic relief measures, fiscal stimulus and social protection packages as necessary to mitigate the social and economic impacts of the pandemic. State commitments to safeguard the right to health are underpinned by the principles of accountability and transparency, which are especially essential when it comes to reasoning, interaction with partners, and the availability of remedies.

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights serves as the worldwide framework for the regulation of intellectual property rights (TRIPS). This agreement includes a number of distinct methods that, in the event of a public health emergency, it will enable member nations to diminish patent rights. Moreover, one of these methods is mandatory licensing, which could only be issued on a nationwide basis, and are

[59] It is to be noted that the Decision only refers to "compulsory licenses" and not to government use for non-commercial purposes. However, the waiver is adopted with regard to Article 31, paragraphs (f) and (h) of the TRIPS Agreement, which equally covers both forms of uses without authorization of the patent holder. Any good faith interpretation of the Decision, therefore, should admit such government uses.

[60] Treatment Action Campaign: An Explanation of the Medicines Act and the Implications of the Court Victory (2001-04-24).

restricted to certain practices and products, and do not permit for a rapid and internationally synchronized response. Presently, legal services are being marketed as a means of pursuing reimbursement depending on investment agreements. Except from that, nations that have adequate manufacturing capability are the only ones that can consider implementing obligatory licensing.

Neo-colonial behaviour can be seen in the on-going obstruction of the TRIPS exemption by developed countries including in their concentration on consensual and charitable alternatives throughout most of the COVID-19 pandemic, such as the COVAX project. Both of these actions are problematic. The developed member states are promoting methods that significantly raise reliance as well as worldwide bureaucratic inefficiencies, rather than providing nations in the Global South with flexibility and independence in tackling the issue.

Chapter 3: Access to Affordable Medicine: Comparative Thesis in the International Context

3.1 Introduction

On a global scale, the COVID-19 epidemic is causing an ever-increasing public health, financial, and social crises. Because of this, it has become a human rights violation issue. Rather than relying on profit-driven global drug industry or a nationalistic "first come, first serve" attitude that solely serves one's own populations, politics of the least developed countries should take a human rights strategy in this circumstance.

Germany's Angela Merkel and France's Emmanuel Macron, just recently referred to prospective COVID-19 vaccines as a "global common good".[61] In spite of this, the governments of many developed countries' recent actions ignored their human rights commitments, which extend beyond their boundaries, notably regarding social human and civil rights. The arrogance of these developed countries can be observed in various ways. More than half of all COVID-19 vaccinations will be available in September 2020 in a tiny group of developed countries, which make up just 13% of the world's population, according to Oxfam, a development aid organization.

A request for temporary waivers of intellectual property rights for COVID-19-related products was made by South Africa and India to the WTO at the beginning of October 2020.[62] COVID-19 drugs should be made available to everyone as quickly as feasible, they said. Pharmaceutical drugs and pharmaceuticals may be produced more quickly and less centrally if drug manufacturers were granted a patent exemption. Pharmaceuticals and vaccines and also emergency services like masks, ventilation systems, and respiratory protection might be produced in nations in the Global South without extensive discussions with patent owners. These commodities could also be exported to nations that lack the

[61] Botenga, M. (2020, June 25). A covid-19 vaccine must have a 'global public good' guarantee. www.euractiv.com. <https://www.euractiv.com/section/health-consumers/opinion/a-covid-19-vaccine-must-have-a-global-public-good-guarantee>/ Accessed on 25 June 2022.

[62] Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of COVID-19, Communication from India and South Africa, Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/W/669, 2 October 2020. <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf> Accessed 25th May 2022.

necessary facilities or ability to produce them themselves. Subsidies from industrialised nations or humanitarian initiatives like the UN COVAX project were rejected by both South Africa and India. There has been a rejection of the TRIPS waiver by Germany and other EU member states and developed countries. All these happened because of the selfish characteristic of the developed nations and to make profit of a global pandemic situation.

3.2 Access to Affordable Medicine

3.2.1 Introduction

There are many areas in which IP laws and policies can be improved, because they're much far from being perfect, particularly when it comes to dealing with global health crises including the COVID-19 epidemic, which requires a more comprehensive approach. COVID-19's pandemic has been hindered by IP and administrative exclusivities, which have stifled the availability of key medications and vaccinations to tackle it. In order to provide universal accessibility to COVID-19 vaccinations and medicines, a variety of policy tools can be used in conjunction to lessen or eradicate these obstacles.

Is the fundamental right to health more important than the enforcement of intellectual property rights in a legal sense? This right is recognized in Article 12 of the UN Covenant on Economic, Social and Cultural Rights, which states that "everyone has the right to the best achievable quality of physical and mental health." Vaccines and critical medicines are also included in this category. As a result, the signatory governments must act to stop and cure disease outbreaks.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights governs intellectual property worldwide (TRIPS). For instance, member countries can use methods like patent system, that can only be issued at the state level and are confined to specific items and processes, to diminish patent claims in situations of health emergency, but these methods do not allow for a speedy or worldwide solution. Many governments are afraid of being held liable for health care costs incurred as a result of the coronavirus epidemic. As a result of investment treaties, legal firms are already promoting claims for compensation. For countries with greater manufacturing capacity, compulsory licenses are not a solution.

3.2.2 Policies in EU and USA

Exclusivity rights are typically granted by WTO members for a defined amount of time ranging from five to eight years, but they can be stretched in certain circumstances.[63] Five years of data privilege for drug candidates are among the many regulation exclusivities available in the United States (NCEs).[64] A 12-year data exclusivity period and a 4-year market exclusivity period are provided for new biological entities (NBEs), such as immunoglobulin drugs, under the Biologics Price Competition and Innovation Act. It is really important to keep in mind that a generic drug item cannot be finalized until four years have passed since the effective date of the reference product, and it cannot be authorised until twelve years have passed since that date if it depends heavily on testing data from the reference standard. US orphan drug exclusivity is also provided in an attempt to motivate pharmaceutical firms to expand treatments for serious illnesses (i.e. ailments that impact less than 200,000 individuals in the United States). Gilead became embroiled in the debate after submitting an application to the US FDA for orphan drug designation in March 2020 and receiving it. Additionally, orphan drug provides an advanced a seven-year market exclusivity as well as tax and other incentive schemes, under the US Orphan Drugs Act. To combat the COVID-19 pandemic, Gilead was chastised for requesting such a classification "despite pleas for cooperation."[65] Gilead announced it has withdrawn its orphan medicine designation after receiving a barrage of criticism.[66]

The EU, on the other hand, employs an exclusive scheme known as the "8+2+1" method.[67] A ten-year marketing exclusivity period, beginning with the date of marketing clearance, is provided under the EU system for original pharmaceuticals.[68] An anticipated standardized contender can only be approved for sale after the ten-year branding safeguard duration, which can be extended to an additional 11-year period, if expired. A growth in income can be expected as a result of supervisory exclusivities, such as data credentials. So in theory, technological innovation is encouraged while generic drug access is delayed.

[63] Thomas, J. R. (2014), The Role of Patents and Regulatory Exclusivities in Pharmaceutical Innovation Washington, DC: Congressional Research Service.
[64] Thomas, J. R. (2015), Pharmaceutical Patent Law, 3rd Edition, Arlington (VA): Bloomberg BNA.
[65] DP Mancini, Gilead Criticised Over 'Orphan Status' for Potential Virus Treatment, Financial Times, 24 March 2020, <https://www.ft.com/content/9fea4f1c-6dba-11ea-89df-41bea055720b>.
[66] Gilead Sciences, Press release, Mar 24, 2020, https://www.gilead.com/-/media/gileadcorporate/files/pdfs/company-statements/remdesivir-orphan-drugdesignation.pdf?la=en&hash=ED14BC7B26E2FEAA2E31E7741A8C9692.
[67] WHA, Resolution WHA65.19: Substandard/spurious/falselylabelled/falsified/counterfeit medical products, <https://www.who.int/medicines/regulation/ssffc/mechanism/WHA65.19_English.pdf?ua=1>.
[68] WHA, WHO member state mechanism on substandard, medical products, <https://www.who.int/medicines/regulation/ssffc/mechanism/A70_23-en33-36.pdf?ua=1> Accessed 25 May 2022.

Drug manufacturing industries frequently use intellectual property rights renewal as a patent protection strategy in an effort to secure new conglomerates or extend their marketing authorization. Supplementary patents deduced from parent patents should be subject to more stringent patent law requirements in order to avoid enabling "patent evergreening" in all countries. However, nations can schedule extra stringent patent protection standards and expectations to meet the consumer's demand for public wellbeing and economy, even though the TRIPS Agreement no longer permits the exclusion of a whole area of technology (e.g. drugs, food). Providing supplementary and fresh patent rights will be curtailed in this way, preventing the practice known as "patent ever greening." The power to accept or deny a supplementary patent in the current IP systems depends on its virtues. It is necessary to ascertain whether the supplementary patent is patentable on its own. Just because an invention is iterative doesn't mean that an ancillary patent claim should be denied because of it.

In reality, the majority of new ideas are merely dynamic in nature. Supplementary patents must only be conferred if the personified continuous improvement offers enough medicinal value to justify the increased set of criteria of efficacy of treatment, according to some researchers and policymakers. Some nations have updated their intellectual property laws in an effort to reduce patent ever greening. Both Section 26.2 and Section 3(d) of the Philippines' Intellectual Property Code have a narrow view of patentability requirements.[69] In other countries, the methods are very different. As a case thesis, patent assessment rules for medicinal innovations have been created by various patent offices, including Argentina, Brazil, China, Germany, the UK, the US, and the EPO.[70] Argentina's examination rules for filing a patent application are based on Section 3(d) of India's Patents Act 1970, which was also adopted by Argentina.[71] It is so possible to prohibit patent ever greening at both legal and executive levels.

Up cycled medications and therapeutic approaches may be eligible for getting a second use patents in various countries, including the United States.[72] SARS, MERS, HIV/AIDS and malaria-related antivirals have been studied as potential COVID-19 therapies, and some of

[69] WTO/WHO/WIPO, Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade (second edition), July 2020.
[70] WIPO document SCP/30/4, Further Thesis on Inventive Step (Part III), <https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_4.pdf>. Accessed 25 April 2022.
[71] Joint Resolution 118/2012, 546/2012 and 107/2012 (Ministry of Industry, Ministry of Health and National Industrial Property Institute) of 5 May 2012, published in Official Gazette of 8 May 2012.
[72] Li G, De Clercq E. Therapeutic options for the 2019 novel coronavirus (2019-nCoV). Nature Reviews. Drug Discovery. 19 (3): 149–150 (2020). doi:10.1038/d41573-020-00016-0.

these are currently being examined in clinical studies.[73] The United Kingdom (UK) launched the world's largest COVID-19 clinical thesis to assess remanufactured pharmaceuticals, for instance.[74]

Exception clauses in the TRIPS Agreement stem from an idea borrowed from the trade law instrument GATT.[75] Due to its focus on business, it frankly does not mention human rights. To close this loophole, exception provisions could be used to spell out if a nation can take extraordinary compliance steps to guarantee the interest of the public in the event of a pandemic without having to worry about harming pharmaceutical companies' best interest. Allows for greater flexibility in dealing with threats to Human Rights, such as those involving the right to "access to medicine." Despite this, exception clauses are not widely used.

Canada and the United States, two countries outside of the EU, entail explicit exception provisions in their investment negotiations concepts. When it comes to protecting "human, or plants and animals or health," nothing else in the Contract shall be interpreted as preventing a group from making efforts "required". To strike the right balance among medicines companies' self-interest and the public good, this sort of exception provision is employed.

Patients in the United States, the European Union, and other nations face inflated prices compared to their incomes, which is the root of the problem. In the event of a pandemic, administering the vaccine to every sick person at once may take more time and money than budget cuts permit. The pandemic tragedy can be slowed if massive regulatory expenditures and strong legal protections to safeguard medicinal corporate entity preferences and patients' lives are put in place during the Research and development stage of pharmaceutical companies (approximately 5-10 years with hundreds and thousands of Euros/USD spending).

Although it was not a simple process to tackle this marketing problem, particularly throughout pandemics, it can be done. That's why I propose provisions requiring governments to make investments in drug manufacturers during pandemics like the Coronavirus outbreak. As a result, it will no longer be an option; rather, it will be required by the new legislation. An international effort is also needed to help create or phrase provisions

[73] Sanders JM, Monogue ML, Jodlowski TZ, Cutrell JB. Pharmacologic Treatments for Coronavirus Disease 2019 (COVID-19): A Review. JAMA. 323 (18): 1824–1836 (2020).
[74] Biggest COVID-19 trial tests repurposed drugs first. Nat Biotechnol 38, 510 (2020). https://doi.org/10.1038/s41587-020-0528-x.
[75] General Agreement on Tariffs and Trade (1994) (‘GATT’).

regarding for the COVID-19 disease outbreak as well as for any upcoming ones that may arise.

COVID-19 is still most deadly to the elderly, those with preexisting chronic illnesses, and those who are malnourished. In comparison to other nations, the United States seems to have a higher than normal percentage of persons aged 65 and over who have one or more chronic diseases such as diabetes, cholesterol, lung infections, or cardiovascular disease.

Healthcare institutions and organizations worldwide are struggling to meet the growing demands for health care workers and hospital wards to test for and treat new cases and those already infected. There are fewer doctors and inadequate hospital beds available in the United States than in many of the other nations according to online data. As a result, the United States' goods and services will be pushed to a higher level than in many other nations. An investigation by the Commonwealth Fund shows that governments differ greatly in their flexibility to act.

As a result of a reduced occupancy rate in acute hospital beds, the United States is better equipped to deal with public health crises. A bigger number of intensive care units and greater access to radiography (CT) scans for suspected COVID-19 patients are two additional advantages that the United States appears to have.

Response to a global pandemic necessitates understanding from other nations. For the first time in far more than a generation, the United States and several European countries are dealing with a pandemic of this magnitude. In response to COVID-19, European countries have built a joint resource to monitor the health system's response. COVID-19 has been contained in Asian countries including Taiwan and South Korea thanks to insights learnt from the 2003 SARS pandemic. In order to better respond to present and future pandemics, health care authorities must take into consideration the experiences of other countries.

3.3 Is Patent System A Drawback in Access to COVID-19 Vaccines?

We have already discussed in our previous chapter that TRIPS governs the protection of IP rights, i.e., patents and trademarks. According to a report of CDC, the death toll from COVID-19 exceeds 4.3 million people with over 200 million infected.[76] As the invention, manufacturing and rolling out of vaccines are protected under TRIPS, the question of whether or not COVID vaccines should be exempt from TRIPS has been at the centre of this collision

[76] Centers for Disease Control and Prevention. 2022. Estimated COVID-19 Burden. [online] Available at: <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html> Accessed 25 August 2022.

between global public health and international trade agreements. However, Harvey Rubin and Nicholas Saidel states that on the patent waiver issue can be characterized within two schools of thought as follows[77]:

> *"**Pro-patent protection:** The first school that patent protections on COVID-19 vaccines are necessary because pharmaceutical companies will otherwise be disincentivized to innovate and invest in vaccine research and development, and they will unfairly lose market share to competitors and adversarial nations such as China. This theory also that removing IP protections will not serve the intended objective of increasing vaccination rates as the developing world lacks the infrastructure and expertise to roll out effective domestic production. Advocates of patent protection argue that the WTO already allows countries to apply for "compulsory licensing," which waives IP during emergencies such as the COVID-19 pandemic. Proponents of continued patent protection see voluntary commitments from industry, developed world governments, and large NGOs as a more effective means of addressing the problem.*
>
> ***Pro-patent waiver:** Conversely, others removing IP protections is a necessity as companies located in high-income countries hold most, if not all, of the COVID-19 vaccine IP and sell the vaccines to governments mostly in the developed world. According to this view, the price of these vaccines, combined with export restrictions and the inability of LMICs to manufacture their own vaccines at a lower price and without fear of litigation from patent holders, are among the main reason why vaccines are not reaching the world's most vulnerable communities. They further that the compulsory license process is both time consuming and cumbersome and that providing basic medical services for these vulnerable communities should be prioritized over industry profits. Finally, a more diffuse global vaccine manufacturing architecture would be more effective and in line with health as a human right."*[78]

As COVID-19 vaccines and medicines entered the market, the subject of patent waiver picked up steam in response to the striking discrepancy in global health outcomes. Data from May 2021 indicates that "people living in G7 countries were 77 times more likely to be offered a vaccine than those living in the world's poorest countries".[79] Data from the end of June 2021 reflects that "46% of people in high-income countries had received at least one

[77] Harvey Rubin and Nicholas Saidel, 'Innovation Beyond Patent Waivers: Achieving Global Vaccination Goals Through Public-Private Partnerships' (Brookings, 2021) <https://www.brookings.edu/blog/up-front/2021/08/31/innovation-beyond-patent-waivers-achieving-global-vaccination-goals-through-public-private-partnerships/> accessed 19 August 2022.
[78] Ibid.
[79] 'More Than A Million COVID Deaths In 4 Months Since G7 Leaders Failed To Break Vaccine Monopolies | Oxfam International' (Oxfam International, 2022) <https://www.oxfam.org/en/press-releases/more-million-covid-deaths-4-months-g7-leaders-failed-break-vaccine-monopolies> accessed 25 August 2022.

dose of the COVID-19 vaccine compared with 20% in middle-income countries and only 0.9% in low-income countries".[80]

As we know, WTO protections for IP last around 20 years. The current US government is now on board with the waiver, and the EU is open to negotiations.[81] The European Union has suggested its own non-waiver proposal, but certain EU member states, including Germany, continue to reject the idea.[82] It will likely take the WTO months to reach a resolution on this issue, since decisions are typically made unanimously, a TRIPS waiver would technically only require a three-quarters majority to approve.[83] The present WTO talks appear to have reached a stalemate in late July, producing progress before being put on pause for the summer break.[84]

3.4 Summary and Conclusion

Despite the fact that a pandemic is a global situation which requires international collective efforts to mitigate, the COVID-19 situation is probable to cause and propagate this disparity in political influence and power relationships between nations, it has emerged in *"a context of governance fragmentation and acute inequality"*.[85] In addition, there seems to be an imbalance of power in the worldwide system of governance, with some jurisdictions and non-state entities often more accomplished than others, which is resulting in as being an impediment to the unrestricted supply of the COVID 19 vaccines. As a result of this inequity, some countries are better prepared to deal with emergencies than others, having a good grasp in patented medicine rights, leaving the poor countries more defenceless to the economic and health consequences of a disaster as they fall victim to inability to attain patented vaccines.

As it is, both WHO and WTO have a different number of objectives, concepts and priorities, but their interests in access to treatment are aligned because WHO symbolizes the requirement for medications, whereas WTO signifies the source. As a result, each company adheres towards its own set of rules. According to our findings, the WHO's key commitments of widespread access to medical care is hindered by strategy differences in the two

[80] BMJ 2021;374:n1837 <https://www.bmj.com/content/374/bmj.n1837.full> Accessed 25th August 2022
[81] Harvey Rubin and Nicholas Saidel, 'Innovation Beyond Patent Waivers: Achieving Global Vaccination Goals Through Public-Private Partnerships' (Brookings, 2021) <https://www.brookings.edu/blog/up-front/2021/08/31/innovation-beyond-patent-waivers-achieving-global-vaccination-goals-through-public-private-partnerships/> accessed 19 August 2022.
[82] Ibid.
[83] Ibid.
[84] Ibid.
[85] Blanco, M. L., Rosales, A. (2020). Global governance and COVID-19: The implications of fragmentation and inequality. <https://www.e-ir.info/2020/05/06/global-governance-and-covid-19-the-implications-of-fragmentation-and-inequality/> Google Scholar. Accessed 25 April 2022.

organizations. This impedes the WHO's ability to combat diseases such as SARS, MERS, Ebola, and currently COVID-19, which necessitates accessibility to drugs and medical equipment's in mass quantities and on an immediate level to establish WHO's asserted target of universal primary access to essential medicines.

To achieve their goals, the two humanitarian bodies each have a unique set of interested parties and objectives in mind. To ensure equitable access to quality health care, WHO and WTO regulations must first be aligned. Because of this, the WTO's policies for access to treatment must be aligned with those of the WHO. If the WTO's trade and IPR policies for pharmaceuticals and medical devices follow the WHO's strategy on access to essential medicines, this problem can be prevented or minimized. Millions of lives around the world could be saved if this issue can be resolved in an effective manner. In addition to these two organizations, it is about the general framework of international cooperation and the apparent lack of consistency and segmentation of their objectives. There is also a discrepancy between the stated goals of these organizations and the jurisdiction and funds they currently have compared to those they ought to accomplish desired objectives.

However, in order to properly handle the pressing issues facing the globe right now, including the current pandemic, the many loopholes that now exist in global governance must be bridged. According to Weiss, a successful global governance system does not necessitate the development of a certain policy mandate but rather an ideal cooperation among the actors concerned.[86] Constructing an environment where global catastrophes can be addressed in a coordinated manner is the most necessary. Efforts to reform the health policy and trade governance structures to make them more effective at curbing worldwide conflicts can be implemented by utilizing the multidisciplinary learnings from global relations and International Relations Theory.

In order to solve the problem of the unequal distribution of COVID-19 vaccinations around the world, we need to think outside the box and come up with a better solution than just temporarily suspending patents. There must be a way for LMICs to take control of the production and distribution of life-saving vaccines and medicines without the cumbersome red tape of mandatory licensing. One study suggests that access to finance markets via impact bonds can provide a long-term, comprehensive solution to the challenge of meeting global

[86] Weiss, T. G. (2016). Global governance: Why? what? whither? John Wiley & Sons.

immunization targets by supporting public-private partnerships (PPPs) between pharmaceutical corporations and key governmental ministries.[87]

[87] Harvey Rubin and Nicholas Saidel, 'Innovation Beyond Patent Waivers: Achieving Global Vaccination Goals Through Public-Private Partnerships' (Brookings, 2021) <https://www.brookings.edu/blog/up-front/2021/08/31/innovation-beyond-patent-waivers-achieving-global-vaccination-goals-through-public-private-partnerships/> accessed 19 August 2022.

Chapter 4: Summery and Conclusion

One of the most major failures in the international response to the pandemic has been the uneven rollout and distribution of COVID-19 vaccinations. This failure has serious ramifications for the human rights and the realization of the right to development. As stated by the Secretary-General in "The highest aspiration: a call to action for human rights," making the world a better place to live again will necessitate making sure that the values of human rights are considered in the implementation of the 2030 Agenda.[88]

Any effort to recover from the destruction caused by the pandemic must focus on addressing the fundamental roots of the problem.[89] The Secretary-General outlined the threats posed by deepening inequality in the document titled "Our common agenda".[90] These threats, in particular, have been brought to light and are currently being exacerbated by the COVID-19 pandemic.[91] The Secretary-General also called for a new social contract to rebuild public trust between the people and their respective governments.[92]

It is imperative that states take use of this window of opportunity to incorporate human rights, specifically the right to development, into their responses to the pandemic as well as their efforts to recover from it and move toward more comprehensive welfare systems. In order to better safeguard populations all over the world against potential upcoming disasters, this presents a significant chance to restructure social security programs and to achieve universal health care for all people.

4.1 Concluding Remarks

The aim of the thesis was to find out the potential conflict between human rights to health and IPRs protection in order to identify the research questions. It all begins with the motivation described in the first chapter, which is driven by an interest in discovering the reasons for the dispute. Following that, the second chapter of the thesis undertakes an analysis on specific provisions that are directly related to the ‘right to health' in order to deduce the right 'to access to medicine' and answer the first research question. The thesis narrows the scope of the legal analysis to include provisions of legal instruments, such as

[88] Peacebuilding, P. C. (2020). THE HIGHEST ASPIRATION: A CALL TO ACTION FOR HUMAN RIGHTS. United Nations <https://www.un.org/peacebuilding/commission> Accessed on 3 August 2022.
[89] Ibid.
[90] United Nations Publications. (2021). OUR COMMON AGENDA – REPORT OF THE SECRETARY-GENERAL. United Nations <https://www.un.org/en/content/common-agenda-report/> Accessed on 22 August 2022.
[91] Ibid.
[92] Ibid.

TRIPS, ICESCR, ICCPR, and ECHR, amongst others. This necessitates an investigation into the ways in which different laws interact with one another, as well as the identification of certain sections that provide assistance to medical professionals and the judicial system in the process of reaching decisions concerning "access to medication." Because of the variety of different laws that are relevant, there is naturally occurring fragmentation rather than unification of laws. The third chapter of the thesis answered the second research question is partially as a result of this finding, which demonstrates that defragmentation can play a role in bringing about equilibrium. After the entire thesis is complete, the search continues on the final chapter to finding a solution to the question of seeking a balance.

One further suggestion that should be reiterated concerns the utilization of the Medicines Patent Pool (MPP) licenses by pharmaceutical companies. In addition, I insist vehemently on the recommendation for a single and harmonized patent legislation across the EU. This law should include particular clauses that can be used in the event of pandemics to guarantee the right to 'access to medicine.'

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