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# FROM VACCINES TO UNEQUAL VACCINATIONS – INTERNATIONAL IP LAW PERSPECTIVE ON THE GLOBAL DISTRIBUTION OF COVID-19 VACCINES

Advanced International Law and Technology
Master's thesis

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Abstract page

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Ever since 2020, COVID-19 has influenced our lives in many foundational ways but also has brought with it multiple life-changing inventions, among which was the first-ever mRNA technology-based vaccine. This thesis examines the international intellectual property (IP) law framework from the perspective of COVID-19 vaccines. After determining the relevant international IP framework, the thesis investigates the influence of these policies on the global distribution of COVID-19 vaccines. Finally, the thesis discusses whether current international IP policies are adequate and in what way they should be amended to better prepare for future health crises.

The research method for this thesis begins with legal dogmatics, focusing on the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) and different international organization policies. Furthermore, the thesis uses e.g., interpretivism in examining the tension between IP policies and the unequal global COVID-19 vaccine distribution, which has disproportionately harmed lower-income countries and indirectly, the entire world during the COVID-19 pandemic.

The research finds that international IP law in connection to medical inventions, especially pharmaceutical patents, constitutes a fundamental tension between human rights and economic development and between innovation incentivization and public health. These tensions have been highlighted even more during the pandemic in relation to COVID-19 vaccines. However, international IP norms themselves do not prohibit equal vaccine access but rather argue for interpreting IP norms in ways that promote public health. Regardless, COVID-19 vaccines have not been equally distributed across the world.

Therefore, while international IP regulation has partly negatively affected the global access to COVID-19 vaccines, the distributional inequalities have not merely been a matter of written international IP law or policies, but rather have stemmed from other underlying factors such as economic interests relating to patents and their licensing, and negotiation power of different stakeholders, just like in the past with the HIV/AIDS pandemic. Thus, to better prepare for future crises, concrete action must be taken toward helping developing countries build up their domestic manufacturing capacity and promoting faster and less reluctant IP and technology sharing and global technology transfer.

**Keywords**: intellectual property law, international law, public health, TRIPS Agreement, COVID-19, pharmaceutical policy, transfer of technology, pandemics

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Oikeustieteellinen tiedekunta

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COVID-19 on vaikuttanut vuodesta 2020 asti elämäämme monella eri tavalla, jonka lisäksi sen myötä on syntynyt myös täysin uusia innovaatioita maailmaan. Näistä keskeisempänä ovat ensimmäisenä mRNA-teknologiaa hyödyntävät koronarokotteet. Tämä tutkielma käsitteleekin kansainvälistä immateriaalioikeussääntelyä erityisesti COVID-19-rokotteiden näkökulmasta. Sen jälkeen kun relevantti kansainvälinen sääntelykehikko on ensin määritelty, tutkielmassa keskustellaan sääntelyn vaikutusta COVID-19-rokotteiden maailmanlaajuiseen jakaantumiseen. Lopuksi tutkielma keskittyy tutkimaan nykyisten käytänteiden toimivuutta ja sitä, onko näitä kansainvälisiä immateriaalisäädöksiä tarpeita muuttaa, jotta tuleviin terveyskriiseihin pystyttäisiin valmistautua paremmin.

Tutkielma alkaa oikeusdogmaattisella näkökulmalla tutkien erityisesti Maailmankauppajärjestön TRIPS-sopimusta sekä kansainvälisten järjestöjen käytänteitä. Tämän lisäksi tutkielma käyttää tulkinnallista metodia löytääkseen ja tutkiakseen jännitteitä immateriaalioikeuspolitiikkojen sekä COVID-19-rokotteiden epätasaisen maailmanlaajuisen jakautumisen välillä, joka on vaikuttanut koronapandemian aikana kielteisesti erityisesti vähävaraisempiin maihin ja siten epäsuorasti koko maailmaan.

Tutkielman johtopäätöksenä on, että lääketieteellisiä keksintöjä, erityisesti lääkepatentteja, koskeva kansainvälinen immateriaalioikeussääntely sisältää keskeisiä jännitteitä sekä ihmisoikeuksien ja taloudellisen kehityksen että toisaalta innovaatioihin kannustamisen ja maailmanlaajuisen kansanterveyden välillä. Nämä jännitteet ovat korostuneet entisestään COVID-19-pandemian aikana koronarokotuksiin liittyen. Kansainvälinen immateriaalioikeussääntely ei itsessään kuitenkaan ole esteenä rokotteiden tasa-arvoiselle jakautumiselle, vaan enemminkin vaatii ja kannustaa immateriaalioikeussääntelyn tulkintaan kansainvälistä kansanterveyttä parhaiten tukevalla tavalla. Tästä huolimatta koronarokotteet eivät ole maailmanlaajuisesti jakaantuneet tasaisesti.

Vaikka kansainvälinen immateriaalioikeussääntely onkin siten vaikuttanut osin kielteisesti COVID-19-rokotteiden maailmanlaajuiseen jakaantumiseen, syy ei löydy ainoastaan kirjoitetusta kansainvälisestä immateriaalioikeudesta. Syitä rokotteiden epätasaiseen jakaantumiseen löytyy lisäksi kirjoitetun oikeuden ulkopuolisista tekijöistä, kuten eri tahojen taloudellisista intresseistä liittyen esimerkiksi patentteihin ja niiden lisensointiin sekä neuvotteluvoimasta, kuten on nähty myös aiemmin HIV/AIDS-pandemian aikana. Konkreettisia toimia on tehtävä, jotta tulevaisuuden kriisitilanteisiin voitaisiin varautua paremmin. Tällaisiin toimenpiteisiin voisi kuulua esimerkiksi panostukset kehittyvien maiden tuotantokapasiteetin nostamiseen ja varmistamalla nopeampi ja vähemmän vastahakoisempi relevanttien immateriaalioikeuksien ja teknologioiden jakaminen sekä teknologiasiirrot eri tahojen välillä.

**Avainsanat**: immateriaalioikeus, kansainvälinen oikeus, kansanterveys, TRIPS-sopimus, COVID-19, lääkepolitiikka, teknologian siirto, pandemiat

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**ABBREVIATIONS**

| | |
|---|---|
| ACDC | African Center for Disease Control and Prevention |
| ACT-A | Access to COVID-19 Tools Accelerator |
| AVAT | African Vaccine Acquisition Trust |
| COVAX | One of four ACT-A's pillars that focuses on vaccines |
| DNDi | Drugs for Neglected Diseases initiative |
| Doha Declaration | Declaration on the TRIPS Agreement and Public Health |
| EU | European Union |
| EUL | Emergency Use Listing |
| Gavi | Vaccine Alliance Gavi |
| GSPA-PHI | Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property |
| ICESCR | International Covenant on Economic, Social, and Cultural Rights |
| IHR | International Health Regulations (2005) |
| IP | Intellectual Property |
| LDCs | Least Developed Countries |
| MedsPal | MPP "Medicines, Patents and Licenses" database |
| MPP | Medicines Patent Pool |
| R&D | Research and Development |
| SDGs | Sustainable Development Goals |
| TRIPS | Trade-Related Aspects of Intellectual Property Rights Agreement |
| TRIPS Council | Council for Trade-Related Aspects of Intellectual Property Rights of World Trade Organization |
| UN | United Nations |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| UNICEF | United Nations International Children's Emergency Fund |
| VaxPal | MPP "Vaccines, Patents and Licenses" database |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| WTO | World Trade Organization |
| WTO Agreement | Marrakesh Agreement Establishing the World Trade Organization |

# 1 INTRODUCTION

## *1.1 Background – from Vaccines to Vaccinations*

*"In a pandemic, nobody is safe until everyone is safe."*[1]

Ever since the Spring of 2020 the world has been living in an unprecedented situation of COVID-19, the battle against which is not yet over at the time of writing this thesis. We have adjusted and shifted many parts of our daily lives but also come up with a vast variety of revolutionary inventions, most notably the COVID-19 vaccine, which was the first-ever mRNA technology-based vaccine invented and produced. The invention was created in late 2020, but the global distribution of vaccines is still far from being completed, even though some developed countries are already slowly getting back to their normal pre-COVID-19 life. As of 13 January 2022, 36 World Health Organization ("**WHO**") Members had vaccination rates less than 10 %, and for 88 Members, the number was under 40 %[2]. According to the World Trade Organization ("**WTO**") as of 31 March 2022, only 12 % of the people in low-income and 48.4 % of people in lower-middle-income countries were fully vaccinated, whereas the same number for high-income countries[3] was 73.2 %[4]. The global target is to vaccinate 70 % of the world in 2022[5].

The importance of the topic of vaccine access is rather clear and has been noted in the international arena on multiple occasions throughout the pandemic[6], but has yet remained as an issue that has not been resolved. Moreover, there have been multiple blocks hindering the

[1] Marianne Meijer et al, 'COVID-19 Vaccines a Global Public Good? Moving Past the Rhetoric and Making Work of Sharing Intellectual Property Rights, Know-How and Technology', (2021) 31(5) European Journal of Public Health 925, p. 925 <https://doi.org/10.1093/eurpub/ckab144>, last accessed 4 March 2022.
[2] WHO, 'COVAX Delivers Its 1 Billionth COVID-19 Vaccine Dose' (16 January 2022), <https://www.who.int/news/item/16-01-2022-COVAX-delivers-its-1-billionth-covid-19-vaccine-dose>, last accessed 25 January 2022.
[3] According to the World Bank, country income groups are determined by a gross national income (GNI) per capita ratio, as provided by the World Bank Atlas calculation method. World Bank, 'World Bank Country and Lending Groups', <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>, last accessed 26 April 2022. For more detailed definition, please see Section *1.5 Definitions*.
[4] WTO, 'WTO-IMF COVID-19 Vaccine Trade Tracker', <https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm>, last accessed 29 April 2022.
[5] WTO, 'International Organizations Discuss How to Improve Access to COVID Vaccines, Countermeasures' (22 December 2021), <https://www.wto.org/english/news_e/news21_e/covid_22dec21_e.htm>, last accessed 10 January 2022.
[6] International organizations, especially WTO and its different councils and meetings, have been active platforms for COVID-19-related debates between different countries on a variety of topics. This thesis will refer to many of these debates later in more detail.

process of international transfer and distribution of vaccines[7]. This paper will discuss the boundaries and opportunities in current international intellectual property ("**IP**") regulation, and therefore, will leave out issues such as taxation, supply shortages, and issues in the physical handling of vaccines and vaccinations, all of which were mentioned in a meeting of representatives from International Monetary Fund, World Bank Group, WHO and WTO on 17 December 2021 as additional issues that some of these lower-income countries were having to face, in addition to actually receiving the vaccines[8]. In general, the questions around IP rights and public health issues are especially challenging, as they involve e.g., a plethora of other factors affecting the use and application of the IP system, such as antitrust issues, national medical product and medicine authority authorizations, physical infrastructure[9] and supply chain, to mention a few. The political aspect surrounding the topic is undoubtedly important as well but in the case of this thesis, will be left out to the extent it goes beyond the international law realm. In any case, it is important to note that the issue of vaccine distribution should not only be seen as a regulatory issue, even though that will be what this paper will focus on.

What makes the topic especially important to take a look into is the fact that, as WHO stated itself, "This is not a supply problem; it's an allocation problem."[10] Moreover, even though the COVID-19 pandemic has been in many ways a new phenomenon for the world, the issue of unequal global medical supply distribution and public health debate is not new – during the peaks of the HIV/AIDS pandemic, similar debates were held. Consequently, after the peak years of that pandemic, multiple further discussions regarding medication accessibility issues and IPs have been held on many different occasions in international organizations to find better and more equal solutions. More generally, the debate connects to a wider topic of inequalities between the so-called "Global North" and "Global South" that have a history going much further back than even the 20th century and beyond just public health issues. My mission with this paper is to find out how IP rights affect this allocation perspective during the COVID-19

[7] In a WTO information note from 2021, it was stated that other regulatory obstacles and "bottlenecks" included e.g., national authority approvals, overlapping regulatory standards, and changing local regulations. See WTO, *Information Note: Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measures on Critical Products to Combat COVID-19* (20 July 2021), <https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_report_e.pdf>, last accessed 10 January 2022.
[8] WTO, 'International Organizations Discuss How to Improve Access to COVID Vaccines, Countermeasures' (22 December 2021), <https://www.wto.org/english/news_e/news21_e/covid_22dec21_e.htm>, last accessed 10 January 2022.
[9] Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 199.
[10] WHO, 'Vaccine Equity', <https://www.who.int/campaigns/vaccine-equity>, last accessed 27 January 2022.

pandemic, but also to draw examples and opinions from discussions held before the current pandemic, because I find it important to understand the current situation more thoroughly.

More specifically, in this paper, I will investigate the distribution of vaccines mainly through technology transfer, which means the process of bringing innovations out to the market and the international platform of trade and commercializing these innovations. In an international law context, technology transfer includes trade and movement of rights and products between the developed and developing world. Despite the name, the transfer of proprietary technologies is understood more as a transfer of exclusive rights to the technology in question. Consequently, international IP regulation and (proprietary) technology transfers are closely connected.[11] In other words, this paper will focus on discussing the distribution of the IP rights related to COVID-19 vaccine technology transfers and these IP rights and regulations acting as potential barriers to vaccine access and distribution. With distribution, I do not refer to the physical distribution of the vaccines via e.g., donations from manufacturing countries per se, but more the distribution of relevant COVID-19 vaccine technology, especially related patents necessary to produce the vaccines. As an important mention, in international law, the term "technology transfer" is not a new concept, but one that has not been specified. Concerning public health matters, technology transfers have at times been considered even a question of human rights[12], which is why this aspect will be considered to some extent as well.

In this paper, the piece of regulation in focus is the Trade-Related Aspects of Intellectual Property Rights Agreement ("**TRIPS**")[13], which creates obligations but also rights for countries and other IP holders to protect different types of IP rights. TRIPS Agreement provides the minimum standards that countries must implement into their national legal systems. Concerning COVID-19, TRIPS has been a central piece of regulation in discussing removing IP barriers surrounding COVID-19 vaccine distribution and technology transfer. A few ways that have been suggested as ways of utilizing the TRIPS Agreement in helping IP distribution have been using the flexibilities the agreement provides, including compulsory licensing, or completely waiving certain provisions of the agreement in the name of public health[14]. The issue is complex

[11] Mark Shugurov and Irina Shugurova, 'The International Legal Policy in the Field of Technology Transfer and the Intellectual Property Rights: Some Controversial Issues' (2015) 6(5) Mediterranean Journal of Social Sciences 177, p. 180 <https://www.mcser.org/journal/index.php/mjss/article/viewFile/7551/7233>, last accessed 27 January 2022.
[12] Michael Waibel and William P Alford, 'Technology Transfer', *Max Planck Encyclopedia of Public International Law* (2012), p. 801 <https://ssrn.com/abstract=2507143>, last accessed 27 January 2022.
[13] Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter "TRIPS" or "TRIPS Agreement"], as amended on 23 January 2017.
[14] Already in 2020 when vaccines were only being in the creation process, India and South Africa pledged for a TRIPS waiver stating that patents and other IP rights were possible obstacles to distribution. See TRIPS Council,

and involves intricate balancing between the interests of manufacturers, and developers but also global health and related human rights, such as the right to health and the right to life. As Gavi, the Vaccine Alliance's Board Chair José Manuel Barroso commented in August 2021, IP rights of vaccines create a "moral and legal predicament -- which at first glance appears to place the legal rights of companies to protect their patents in direct conflict with the rights of people to lead healthy lives by ensuring there are enough vaccine doses to go around"[15].

To summarize, this paper focuses on analyzing international IP law provisions through which COVID-19 vaccines are regulated and looking into how the process of vaccine technology distribution has developed, but it also aims to serve a larger purpose – I wish to point out potential inconsistencies, underlying political and economic biases and barriers that IP regulation has created during the COVID-19 pandemic and has the potential to create in later public health crises, and how this regulation could be used more efficiently in combating future pandemics. However, again, my thesis takes on a rather narrow approach, as these types of situations are likely to be unprecedented at least to some degree, and involve many other components that have not and cannot be foreseen by regulation. My goal, however, is to discuss the best or most efficient ways of tackling or interpreting the current regulation now before the pandemic is over and to determine how effective the use of the current IP regulation has been thus far.

### *1.2 Research Question and Theme*

The relevance of the topic for the current but also for future pandemics is a clear starting point for this thesis. However, for this research and this paper to add value to its reader, we need to acknowledge that there are relevant debates and discussions on the topic both in academia and among international legal specialists, but also in other contexts, such as in international organizations such as the WTO. During COVID-19, some have argued for a total waiver of

*Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Communication from India and South Africa,* WTO Doc. IP/C/W/669 (2 October 2020). The pledge was later renewed with even more WTO Members having signed and revised it, see TRIPS Council, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Revised Decision Text, Communication From The African Group, The Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, The LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, The Bolivarian Republic of Venezuela and Zimbabwe,* WTO Doc. IP/C/W/669/Rev.1 (25 May 2021).

[15] Gavi the Vaccine Alliance, 'Intellectual Property and COVID-19 vaccines' (3 August 2021), <https://www.gavi.org/vaccineswork/intellectual-property-and-covid-19-vaccines>, last accessed 11 January 2022.

relevant IP protection provided by TRIPS[16], and others have argued that IP is vital for providing incentives to innovate and the key to success is collaboration[17]. This tension between these two approaches makes this topic firstly, extremely relevant to look into and consider both sides of the argument, and secondly, an intriguing topic as it tries to balance both the economic and health aspects and find the balance between the two.

The larger discussion of the current day and even this paper is not entirely new as we have found, even though the COVID-19 pandemic has brought up a lot of new aspects to consider. In general, however, technology transfers have been a concept of interest in international law for decades and are occasionally largely debated because they cause tension between developed and developing countries, or more specifically between Global North and Global South in the international law realm.[18] Another reason why these types of discussions are not entirely new in connection to public health matters is the already mentioned HIV/AIDS pandemic that began in the 1980s. Sufficient treatments for the disease were found in the mid-90s, but the equal distribution of them had to wait for years. Even currently, thousands of people die from AIDS each year, despite the improvements of the past decades.[19] Moreover, the extinction of other diseases such as tuberculosis has been even slower than that of AIDS', and some have argued that this has been because of the blocks the IP system causes through it being a reward system for medical and other innovations.[20]

In this paper, I want to contribute to this discussion and intervene by bringing a more in-depth analysis, as the connections discussed above are not as well researched yet due to their complex and relatively recent, still changing nature. I want to provide a basis for further discussions in preparation for better future practices. I believe this type of research is important, as it aims at discussing whether, in cases of public health crises, IP rights are the only way to efficiently

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[16] This argument has been and is strongly brought up by low- and lower-middle-income countries especially. The TRIPS Waiver will be later discussed in Sections 2.5 and 4.4. See e.g., TRIPS Council, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Communication from India and South Africa,* WTO Doc. IP/C/W/669 (2 October 2020).

[17] See e.g., WTO, an Informal Coalition of Civil Society Organizations' Publication, 'A Joint Declaration on the Importance of IPRs to COVID Vaccine Manufacturing Scale-Up and Future Pandemic Preparedness' (May 2021), <https://www.wto.org/english/tratop_e/covid19_e/iprs_declaration_e.pdf>, last accessed 11 January 2022.

[18] Michael Waibel and William P Alford, 'Technology Transfer', *Max Planck Encyclopedia of Public International Law* (2012), p. 801 <https://ssrn.com/abstract=2507143>, last accessed 27 January 2022.

[19] In 2020, between 480 000 to 1 million people died from AIDS. Joint United Nations Programme on HIV/AIDS, 'Fact sheet: World AIDS Day 2021' (2021), p. 1 <https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf>, last accessed 27 January 2022. See also, e.g., WHO Commission on Intellectual Property Rights, Innovation and Public Health, *Report on Public Health, Innovation and Intellectual Property Rights* (World Health Organization 2006), p. 97.

[20] Daniel Opoku Acquah, 'Intellectual Property, Developing Countries and the Law and Policy of the European Union: Towards Postcolonial Control of Development' (Doctoral thesis, IPR University Center 2017), p. 34.

respond to innovation needs or on the contrary, if they are the block to reaching the end of crises fast. My goal is to discuss the matter in a way that would ideally be of benefit to legal professionals, but also, to policymakers and pharmaceutical companies. At the very least, I want to provide a compilation and fresh analysis of the current situation, as innovations and opinions have changed even during this pandemic and are likely to change after the publication of this paper.

My aim with this thesis is to discuss the deeper underlying issues and political and economic biases that affect the current international IP system, but perhaps more importantly, its implementation and practice in a way that has caused severe imbalances in especially the distribution of COVID-19 vaccines during the last few years. My aim is not to provide a perfect solution to the issues addressed as that is not possible within the restrictions of this paper and research, but it is my wish to provide a base for recognizing potential flaws in the current systems and decisions that have been made. I hope to provide valuable new considerations to both proponents and opponents of e.g., IP waivers concerning public health matters.

Drawing from all the discussion above, my research question for this thesis is:

**How has international IP regulation affected the inequalities in COVID-19 vaccine distribution between developed and developing countries, i.e., the Global North and the Global South[21]?**

It is supported by the following sub-question:

**Is the international IP system inefficient or harmful in public health crises, and if so, how should IP policies be amended?**

### *1.3 Methodology and Approach*

In order to provide quality research, we must first lay out the theoretical and methodological ideas and the approach before starting the analysis of a topic. Describing one's theoretical and methodical approaches are also important for the reader to better understand the ways the

[21] In this paper, the Global North and Global South are referred to also as developed and developing countries. Even though this at times is a rather rough division and for some countries, the difference is not always clear, my intention is merely to highlight the imbalances between these two overarching worlds, as they are affected by the COVID-19 pandemic and IP rights differently. Most, but for certain not all, medical producers come from developing countries. The same goes for COVID-19 vaccines, as most – not all – major COVID-19 vaccine IP holders are from developed countries, at least initially. For further definitions, see Section *1.5 Definitions*.

researcher tackles a problem and narrows down the routes to interpretation. This is exactly why we will next discuss the theory and methods that establish the backbone of this paper.

Firstly, as highlighted in the first-page quote or even the title of this thesis, I approach this topic seeing a problem. This problem, in my eyes, is that vaccines have not been distributed fairly. However, my intention is not to say that IP rights are the sole cause or even the actual problem that has led to this unequal vaccine distribution, but that IP is purely an area this paper shall investigate for the sake of understanding potential issues in current IP regulation. Nevertheless, I find it important to mention the way I approach this topic, as it may be a potential bias that affects this paper at times, no matter how precise and objective I seek to be. This view forms the base for my hypothesis, which is that current IP regulation has the potential to combat the current health crisis but is rather lacking in its actual application due to underlying issues that make it at times crucially and life-affectingly pro-North or more specifically, pro-innovator. As we can later see from the paper, this hypothesis in my eyes is confirmed.

As for the methods I will use, the natural starting point to my analysis is the traditional legal dogmatics, but that by itself is rather insufficient. To understand the underlying issues and tensions, the motivations of IP regulation and vaccines, public health, and profitability, and the deeply embedded into the North-South division, we need to investigate other disciplines as well. Most importantly, key factors affecting the field can be found in economics and social sciences, such as political science. This interdisciplinary approach is not to undermine the fundamental jurisdictional starting point of this research, but it is to support us in the quest to find underlying issues and biases sometimes invisible to the regulatory eye of a lawyer, and in understanding how the pandemic response, economics, politics, and regulatory interpretations have intertwined. Therefore, I find it crucial to seek support from other sciences, as it is the most comprehensive way of approaching the issue and the possible solutions that follow, as in my eyes the regulatory network – especially the IP system – does not exist in a vacuum free from other influences[22].

In addition to the traditional legal dogmatic, positivism route and the interdisciplinary approach, we need other tools to understand the underlying structures and reasoning of what is written in law. To achieve this and to gain more depth in my analysis, I will make use of the ideologies

[22] The traditional assumption of the sources doctrine has been that international law is not influenced by other matters, like morals or economics, but this idea is nowadays being largely questioned and opinions vary among scholars. See e.g., Matthias Goldman, 'Sources in the Meta-Theory of International Law: Exploring the Hermeneutics, Authority, and Publicness of International Law' in Jean D'Aspremont and Samantha Besson (eds), *The Oxford Handbook on the Sources of International Law* (Oxford University Press 2017), p. 447.

of hermeneutics[23], considering some additional philosophical reasoning behind the legal norms where suitable, meta-theoretical approaches[24] and interpretivism[25]. As an underlying theory, post-colonialism[26] is considered as well as a tool of analysis.

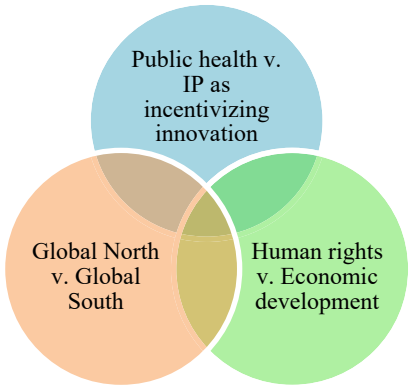
Related to interpretivism especially, the research questions and the discussion in this paper are built on multiple layers of different fundamental challenges that I have identified in the chart below. The circles represent the structural dilemmas of my topic which are not, naturally, evident from e.g., what is said in written law through legal dogmatics. These dilemmas highlight the tricky balancing between different interests and values and are the most foundational tensions that I have identified surrounding my topic. From my research, I have gathered that finding a middle-ground and the "least-worst" solution is about compromising, and in fact, a win-win situation may not even exist. Underneath the graph is highlighted the influence of economic and political biases in all these aspects, in legal policies but most importantly, in interpreting and implementing the law and decision-making.

[23] Kemmerer mentions that often, hermeneutics as a concept is seen as identical to interpretation and used in the same meaning. However, as Kemmerer mentions, this view fails often to include the philosophical and in one sense, more detailed level of hermeneutics, the importance of which has been mentioned by only a few scholars thus far. See Alexandra Kemmerer, 'Sources in the Meta-Theory of International Law: Hermeneutical Conversations' in Jean D'Aspremont and Samantha Besson (eds), The Oxford Handbook on the Sources of International Law (Oxford University Press 2017), pp. 475-476.

[24] Meta-theory looks at and interprets the presumptions that are behind the interpretations and decision-making through international law. See e.g., Matthias Goldman, 'Sources in the Meta-Theory of International Law: Exploring the Hermeneutics, Authority, and Publicness of International Law' in Jean D'Aspremont and Samantha Besson (eds), *The Oxford Handbook on the Sources of International Law* (Oxford University Press 2017), pp. 447-448. And Alexandra Kemmerer, 'Sources in the Meta-Theory of International Law: Hermeneutical Conversations' in Jean D'Aspremont and Samantha Besson (eds), The Oxford Handbook on the Sources of International Law (Oxford University Press 2017), p. 471.

[25] As an example, Kemmerer describes interpretation in this context as "an intellectual praxis raising questions (and sometimes providing answers) as to why we interpret, and with what authority". See Alexandra Kemmerer, 'Sources in the Meta-Theory of International Law: Hermeneutical Conversations' in Jean D'Aspremont and Samantha Besson (eds), The Oxford Handbook on the Sources of International Law (Oxford University Press 2017), p. 475.

[26] Post-colonialism refers to the idea that colonialist measures did not end with the colonialist era but are highlighted even in the society we live in today. As an example, post-colonialism has been argued as an idea that is in the background of the international IP system. See, Daniel Opoku Acquah, 'Intellectual Property, Developing Countries and the Law and Policy of the European Union: Towards Postcolonial Control of Development' (Doctoral thesis, IPR University Center 2017), pp. 54-55.




As a caveat, however, due to the limitations of this paper and its rather descriptive nature, I will not be able to use as many of these tools or methodologies to my – or your, the reader's – advantage, even though I acknowledge that these used even more in-depth would add a layer of depth to the writing. Nevertheless, I shall use these tools to the best of my knowledge leaving hopefully room for additional layers of interpretation of both this work and the references I will use.

Moreover, when analyzing international law sources and the *sources doctrine*, our starting point is to look at the list of sources provided in the ICJ Statute Article 38, which refers to 1) international conventions, 2) international custom, 3) general principles, and 4) qualified publications as the sources of international law[27]. However, to say that these sources determined decades ago would be the only relevant sources and the only "right" ones would be too narrow in this instance and would not represent the ongoing debates on the sources doctrine, or in fact, my view on the matter. In this paper, relevant sources also include less formal sources, publications, and in general, *soft law* that can be seen as "a kind of international law that is not yet law, but law in the making"[28]. It includes e.g., international organization documentation, and in connection to COVID-19, especially the documentation by the WTO. However, the list of the "traditional" or "classical" sources of international law in Article 38[29] is not without value but should be used in connection with an expanded ideology and consideration of other sources as well. My idea of international law sources is not necessarily the perfect or "right" one, but simultaneously I argue that there is no such view and views are always dependent on

[27] United Nations, Statute of the International Court of Justice, 26 June 1945, Treaty Series, vol. 993 [hereinafter "ICJ Statute"], Art. 38.
[28] Jean D'Aspremont and Samantha Besson, 'The Sources of International Law: An Introduction' in Jean D'Aspremont and Samantha Besson (eds), *The Oxford Handbook on the Sources of International Law* (Oxford University Press 2017), p. 4.
[29] *Ibid*, p. 4.

whom one asks. There is value, however, in bringing up different views on approaching relevant sources, and the mentioned ideology is my way of navigating the question of the sources doctrine.[30] To summarize, I will use both *hard* and *soft law* sources, which are relevant in the field of public health.[31] In this paper, the main hard law source is the TRIPS Agreement, but a great emphasis on interpretivism and *soft law* sources as well.

In addition to the *sources doctrine*, it must be noted that other doctrines play a relevant role as well and should not be forgotten. It could be useful to consider e.g., the *succession doctrine*, not necessarily in its traditional state succession meaning but more referring to the shift of rights and obligations between different international law subjects during the pandemic. Furthermore, in addition to the *sources* and *succession doctrines,* the *responsibility* and *subjects doctrines* are other key doctrines that will be examined in this paper, but not necessarily to the extent traditionally presented. E.g., the subjects and relevant actors that are related to the topic are touched upon, but more focus is put on the concrete actions by different subjects, rather than just looking for a specific subject responsible for the insufficiencies in IP use during the current pandemic. This once again means that this paper or its analysis is not all-encompassing, but the purpose of it is to start a discussion for further consideration.

Most of the research in this thesis will be conducted via qualitative methods, even though due to its strong economic connection and the commercial aspects of the theme, it is useful to add emphasis to my paper through some, but very limited, use of quantitative methods. The general purpose of using additional data will be to highlight the current regulatory and factual vaccine distribution situation, but also to discuss how the system has failed, whenever relevant. The most important factor, however, is to provide a comprehensive, considerate, interpretative scenario analysis and relevant, useful discussion.

As for the territorial framework and approach of this thesis, I will be discussing mostly international organizations' meeting minutes, papers, and policies, but also provide opinions of individual states within different international organizations to provide a clearer image of the

[30] The variety of sources and doctrines has been and still is a highly debated area among legal professionals, and there are many ways of navigating the lines of sources in international law such as relying on the ICJ statute Article 38 or navigating the doctrine from a domestic source point of view. See e.g., Jean D'Aspremont and Samantha Besson, 'The Sources of International Law: An Introduction' in Jean D'Aspremont and Samantha Besson (eds), *The Oxford Handbook on the Sources of International Law* (Oxford University Press 2017), pp. 2-5.

[31] E.g., an Opinio Juris blog argues that the WHO has preferred to use soft law instruments and they proved effective in fighting against e.g., HIV/AIDS, but that hard law measures are argued to be potentially beneficial too. Giulia Bosi, Opinio Juris, 'Overcoming the "Soft vs Hard Law" Debate in the Development of New Global Health Instruments' (31 November 2021), <https://opiniojuris.org/2021/11/30/overcoming-the-soft-vs-hard-law-debate-in-the-development-of-new-global-health-instruments/>, last accessed 14 March 2022.

different opinions between especially developed and developing countries. Moreover, because the issues in vaccine access, or "vaccine apartheid"[32], currently most affect low- and middle-income countries and least-developed countries, I will discuss the impact of different initiatives on these countries, in addition to their medical product access. Because of this, my paper will have a post-colonial approach in the discussion as well, because it is important in understanding the obstacles these less-resourced countries face when trying to reach these vital COVID-19 vaccines and vaccination targets. Moreover, the perspective of those countries most affected is important because the current issue at hand is about human rights and the right to life as well. In addition to this perspective, I will try to understand the reasons why many developed countries (often with better negotiation power and resources) have been hesitant to help those countries most in need and most affected by the crisis. In my eyes, the ultimate debate surrounding this crisis is about the balancing act between the right to life and health versus economic development, which is explored through the approaches presented above.

However, an important disclaimer regarding the approach of this thesis – as a person from a developed country with access to material mostly written by developed country individuals and states, I am prone to home bias. I am very much aware of this and will try my best to be cautious, but because of the sources, I will use, it is likely that at times, the bias can affect the information in this paper. This is another reason why you, the reader, should approach this paper not necessarily with caution, but with awareness of the ingredients that form this paper and the opinions in it. I have tried my best to highlight differing views from different voices, in addition to my own, but ultimately, the reader should make their conclusions, which are hopefully freer from potential biases.

### *1.4 Structure*

Before an informed and legitimate analysis of the current legislative practice and effect, we will first have to investigate the foundational regulatory norms and principles. Therefore, to lay an effective foundation for this thesis, we will begin by first introducing relevant international IP regulations to the discussion. Only after laying out the foundational regulatory pieces and the past discussions that have been held regarding international IP policies and public health, we

[32] Diane Desierto, EJIL:Talk!, Blog of the European Journal of International Law, 'Overcoming the Global Vaccine and Therapeutics Lag and 'Vaccine Apartheid': Abuse of Rights in the EU's Continued Blocking of the TRIPS Waiver for COVID Vaccines and Related Medicines' (5 January 2022), <https://www.ejiltalk.org/overcoming-the-global-vaccine-and-therapeutics-lag-abuse-of-rights-in-vaccine-apartheid-and-the-eus-continued-blocking-of-the-TRIPS-waiver-for-covid-vaccines-and-related-medicines/>, last accessed 8 March 2022.

can start understanding their current applications to the COVID-19 pandemic. These regulatory principles and norms are, of course, heavily influenced by the political, economic, and social constructions and power dynamics surrounding them, which is exactly why these will be discussed after first introducing them in a more descriptive manner and without emphasizing the underlying power dynamics, which is how naïve realism would suggest the regulatory networks work. With our analysis, however, we will soon determine that this is not the case and that regulatory norms are all but free from outer influences.

Drawing from the above, the first chapter after this introduction will introduce the relevant international IP regulation in connection to COVID-19 vaccines and will primarily focus on relevant TRIPS articles but also other related considerations. The second chapter will consider the different views by different subjects of international law in a general IP and public health crisis context and the power dynamics between these parties. The third chapter will take considerations from both previous chapters and discuss the current situation and the application of the current regulation through different IP initiatives and interpret the current situation to understand the underlying issues and reasons for the inequalities during the pandemic. The fourth chapter will briefly focus on the future, discuss possible IP remedies in both ending this current crisis and in preparation for future ones, and analyze the probabilities of the current system working better in the future or whether we need reforms to perform better crisis response in the future. The final chapter will bring all the previous contributions together in a conclusion.

### *1.5 Definitions*

Some terms that are used throughout this paper should be separately defined in advance to set the basis for our discussion. The first set of terms relates to the central international organizations, to which I will refer on many occasions and indeed, have already referred to. These organizations are central in building the discussion and arguments for my hypothesis and research questions.

Central international organizations for this thesis, and in fact in general, are the World Trade Organization i.e., WTO, the World Health Organization i.e., WHO, and the World Intellectual Property Organization i.e., WIPO. Concerning the COVID-19 pandemic, the first two are more relevant, and WIPO has not been as active in even discussions related to IP and the pandemic. Rather, the forum for IP-related discussions has been WTO, as referred to already above.

Another set of terms that are important to define is the group of terms related to different categorizations of countries into different groups. Firstly, when dividing countries into 1) low-income, 2) lower-middle-income, 3) middle-income, and 4) high-income countries, I refer to the definitions provided by the World Bank calculation method, as briefly mentioned in footnote 3. According to it, country income groups are determined by the gross national income (GNI) per capita ratio, and the income levels for different groups vary according to the calculation annually. In 2022, *low-income countries* in this context refer to those with a GNI per capita ratio under $1,045, *lower-middle-income countries* to those with a ratio between $1 046 and $4 095, *middle-income countries* to those with a ratio between $4 096 and $12 695, and *high-income countries* to those with a ratio that is over $12 695.[33]

Another way of sectioning countries into groups is to divide them between developed and developing countries. WTO has no set way of defining the terms but rather trusts upon countries to announce their status themselves. However, other WTO Members may "challenge the decision of a member to make use of provisions available to developing countries", as the developing country's status may bring some benefits alongside it, like more flexibility and longer transition periods. Furthermore, developing countries are also divided into developing and least-developed countries ("**LDCs**")[34], which are also referred to in this paper. LDCs are determined and listed by the United Nations ("**UN**")[35].

In this paper, these are the definitions that I will refer to when discussing these different types of ways to divide and categorize countries. Moreover, I will use the terms Global North and Global South as another way to refer to the above-mentioned division between developed and developing countries. While this is a rather black-and-white way of sectioning the world and one that does not provide a perfect image of the vast variety of countries, economies, cultures, and areas that exist in the present day, I find it a necessary tool to make the discussion of this paper more efficient. However, it is also one point to add to the potential biases the paper carries as addressed before, which makes it even more important for the reader to read the paper critically.

[33] For a more detailed calculation method, see World Bank, 'World Bank Country and Lending Groups', <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>, last accessed 26 April 2022.
[34] WTO, 'Who Are the Developing Countries in the WTO?', <https://www.wto.org/english/tratop_e/devel_e/d1who_e.htm>, last accessed 29 April 2022.
[35] WTO, 'Least-developed countries', <https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm>, last accessed 29 April 2022.

### *1.6 Limitations*

As already determined, the importance of the topic has brought with it a wave of new proposals, discussions, and initiatives[36] that are often intertwined with each other and have therefore connections to IP matters as well. However, despite the importance of these individual pieces in the larger debate, due to the sheer number of them, some limitations must be made due to the page limitations of this paper. This does not in any way mean that these initiatives are of less importance and worthy of additional research and consideration. This is important to keep in mind when considering this paper and its significance in the bigger picture – IP forms only one part of the discussion, and only a fraction of the larger debate is being brought up in this thesis.

As an example, issues that closely link to equal access to vaccines and medical products as large but also to IP are competition policies and fair pricing.[37] These naturally have an important connection to the issue, but again will not be discussed directly in this paper. Nevertheless, it is important to understand that national competition policies have a great impact on accessibility, with or without IP matters being considered. Moreover, other IP types than just patents play a role too even amidst the current pandemic[38], but will not be examined much further. Our focus will mainly be on patents, which is because in connection to COVID-19 vaccines, patents – in addition to e.g., know-how and related trade secrets – play the most important role.

Moreover, I will not directly be looking into who is responsible for the inequalities and who is not, even though as mentioned above the *subjects doctrine* will inevitably be discussed in some parts of the thesis. Therefore, this consideration is not put aside entirely, but more focus is put on IP and technology, in addition to vaccine access perspectives, because I see them as more important in my effort to answer the research question I have set.

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[36] These new initiatives include e.g., the WTO "Trade and Health Initiative", proposals by WTO members on customs, transparency, discussions around the role of the WTO, and other international organizations in general, just to mention a few. More are likely to arise and to form the most informed picture of the current situation, it will be worthwhile to familiarize oneself with the newest initiatives and developments. See, e.g., WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 15.

[37] As an example, in the Netherlands the pharmaceutical manufacturer Roche and its dominant market position were investigated during the pandemic. Many other competition law examples and policy shifts exist globally, e.g., in South Africa, where its competition and consumer protection regulations were amended to meet the new pandemic introduced challenges. See, *ibid*, p. 6.

[38] Relevant other IP discussions surrounding health and COVID-19 involve e.g., the relationship between copyrights and data mining and medical technology R&D. See e.g., WTO, *Informational Note: The TRIPS Agreement and COVID-19* (15 October 2020), p. 11 <https://www.wto.org/english/tratop_e/covid19_e/TRIPS_report_e.pdf>, last accessed 28 February 2022.

Why am I discussing vaccine access and public health policies, in addition to IP? This is because the two themes are extremely intertwined and cannot – in my eyes – be separated in a way that would provide a good analysis of the current issues. IP policies are intended to provide incentives and rights for their holders, but in connection to public health matters, an extremely relevant question arises – where do we draw the line between IP rights and the health of the public? This is what makes the current COVID-19 vaccine debate extremely interesting, but also sensitive and complex.

Finally, a rather obvious but meaningful limitation to this thesis is the ongoing development of the situation. I have looked at sources both from before the pandemic and also ones that have been published during the pandemic. However, relevant papers and research will for certain continue to be published even after publishing this paper. This means that the current global pandemic and the inequalities in vaccine distribution are subject and very much likely to change after writing the thesis. I hope that this is the case and that inequalities are tackled more efficiently than they have been thus far, but that of course remains to be seen and for the reader to determine. Regardless, I hope and think that there is still value in looking at the situation both currently but also looking at the past development regarding it, because it can provide tools for further analysis, and hopefully, to prepare better for future public health emergencies. Ideally, we will learn from the current and past problems and can be more efficient and equal in future crises.

## 2 VACCINES, DISTRIBUTION AND INTERNATIONAL IP REGULATION

### *2.1 Background on the IP System*

In general, the use and reasoning behind IP rights and regulation is the great societal meaning of the system and its "role as tools of public policy". IP rights play a fundamental role as economic incentives and in larger societal meaning "by stimulating creative work and technological innovation" and in the case of technological research and patents, they give "the incentive and means to finance applied R&D (research and development)". The existence of IP rights does not necessarily mean that no other incentives are required to foster innovation, especially in cases such as pharmaceutical innovation where innovation bears great financial costs. The IP system also acts, at least in theory, as a provider for technology transfers and technological innovation cooperation. Specifically, the nature of patents as disclosable innovations is intended to act as an incentive for further innovations by other operators.[39]

Moreover, intellectual property is connected to the economical aspect related to innovation R&D and related decision making.[40] In general, when considering international economic law[41], it is largely connected to the economic consideration of providing protection and rights to inventors and granting them rights to benefit from their work. What makes it even more interesting and crucial to consider in connection to matters such as COVID-19, is the fact that the IP system has risen out of the Eurocentric colonialist history, which already makes the system biased or at very least heavily prone to biases arising from history. Even though attempts have been made to restructure and reduce the colonialist-derived, neo-liberal ways of the system, including efforts such as the "New International Economic Order", many attempts have left room for improvement, and at times, the historic tensions have even been strengthened.[42] Moreover, while IP does indeed act as a measuring and protection tool for innovation, it can also be argued in the international law realm to serve also as a "mechanism by which to deliver 'civilisation' to the south", possibly even undermining the "legitimacy and indeed morality of intellectual property laws", as they stem from not only economic standpoints but also from

[39] Antony Taubman, Hannu Wager, and Jayashree Watal, 'Introduction to the TRIPS Agreement' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), pp. 2-4.
[40] Johanna Gibson, *Intellectual Property, Medicine and Health: Current Debates* (Ashgate Publishing Limited 2009), p. 81.
[41] International economic law can be regarded of "regimes that regulate international trade, investment, and economic development". Gleider Hernández, *International Law* (Oxford University Press 2019), p. 525.
[42] *Ibid*, pp. 525-527, 549.

colonial history-driven motivations. However, it could also be argued that one's choice of e.g., patenting an invention is not based on the ethical considerations but rather on whether it is commercially reasonable.[43]

On the other hand, intellectual property law is also connected to human rights, as the IP system tries to seek the balance between enabling trade and economic growth, while also respecting fundamental human rights, especially the right to health and life and public health in general. This is one reason that makes investigating international IP norms especially interesting, as discussions have been raised about whether in general e.g., human rights and international trade law conflict with each other.[44] This makes the research complex, as the IP system is filled with internal and structural tensions and potential interest conflicts. One aspect that adds layers to the discussion is the strengthening of the relationship between commercial aspects and pharmaceutical research of the past decades, which has on different occasions caused concerns amongst the public related to matters such as e.g., "access to useful technologies"[45], even before the COVID-19 pandemic.

In terms of providing equitable access to vaccines and other medical products, IP plays a dual role: it promotes innovation, capacity building, and R&D, but also seeks to provide means to provide access to health products. As WHO has declared, the IP system should be used in a way that promotes e.g., patent transparency and pooling of patented medication, and incentives for access to provide affordable medical technologies.[46] In more recent years, it has become a more evident topic of debate, whether the international IP system is imbalanced in favor of innovators.[47] This debate has rather obviously been even more relevant during the COVID-19 pandemic and has caused arguments for and against IP protection related to COVID-19 supplies.

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[43] Johanna Gibson, *Intellectual Property, Medicine and Health: Current Debates* (Ashgate Publishing Limited 2009), pp. 82, 94.
[44] For further discussion on the conflict, see e.g., Prabhash Ranjan, 'International Trade and Human Rights: Conflicting Obligations, Commentary on Frederick M Abbott' in Thomas Cottier, Joost Pauwelyn, and Elisabeth Bürgi (eds), *Human Rights and International Trade* (Oxford University Press 2005).
[45] Timothy Caulfield, 'Biotechnology Patents, Public Trust and Patent pools: The Need for Governance?' in David Castle (ed), *The Role of Intellectual Property Rights in Biotechnology Innovation* (Edward Elgar Publishing 2009), pp. 358, 360-361.
[46] WHO, *Road Map for Access to Medicines, Vaccines and Other Health Products 2019–2023, Comprehensive Support for Access to Medicines, Vaccines and Other Health Products* (World Health Organization 2019), pp. 16-17, 20.
[47] Daniel Opoku Acquah, 'Intellectual Property, Developing Countries and the Law and Policy of the European Union: Towards Postcolonial Control of Development' (Doctoral thesis, IPR University Center 2017), p. 28.

Finally, IP regulation varies a lot from nation to nation. In international law, IP is debated and regulated at a higher level, most importantly through public policies and setting minimum standards. In the current day, the international trade aspect of international economic law is driven most notably by the WTO, which itself does not have "independent policy-making power" and is far from perfect (as will be discussed during this thesis) but creates a platform for Members to gather and negotiate, in addition to providing a platform for dispute resolution[48]. As far as hard law sources go, the TRIPS agreement created through WTO is the most important piece of regulation as mentioned above. Next, I will discuss TRIPS in relation to public health, but also to further regulatory connections, such as human rights.

### *2.2 TRIPS and Public Health*

TRIPS is the guiding international regulatory instrument that sets the minimum standards for the use, protection, scope, and exceptions of IP rights.[49] TRIPS has a central meaning in the global IP scheme, as it "is the only comprehensive multilateral legal framework" for IP enforcement.[50] That is also the case for IP related to medicines, pharmaceutical products, and vaccines as well, especially through TRIPS' patent provisions. TRIPS was created to establish ground measures to either enforce or refuse IP regulation and rights for significant economic and social reasons, one of them being public health.[51] The relationship between TRIPS and public health has also been argued to be in the middle of the larger debate between balancing human rights and international trade law.[52]

The underlying goals and aims of TRIPS are listed in its Preamble, Article 7 and Article 8.[53] What is relevant in connection to the COVID-19 pandemic, is the Preamble statement that acknowledges the special need for least-developed countries to be helped in their technological

[48]Gleider Hernández, *International Law* (Oxford University Press 2019), pp. 525, 539.
[49] Antony Taubman, Hannu Wager, and Jayashree Watal, 'Introduction to the TRIPS Agreement' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), pp. 10-11.
[50] WTO, WHO, and WIPO*, Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2020), p. 90.
[51] Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 199.
[52] Prabhash Ranjan, 'International Trade and Human Rights: Conflicting Obligations, Commentary on Frederick M Abbott' in Thomas Cottier, Joost Pauwelyn, and Elisabeth Bürgi (eds), *Human Rights and International Trade* (Oxford University Press 2005), pp. 1, 3-4.
[53] Antony Taubman, Hannu Wager, and Jayashree Watal, 'Introduction to the TRIPS Agreement' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 13.

progress.[54] Moreover, Article 7 states that IP rights should act as technological innovation incentives and balance the benefits of both "producers and users of technological knowledge and in a manner conducive to social and economic welfare".[55] Finally, Article 8 states that certain necessary measures may be used in the promotion of public health protection.[56] These foundational norms and aims should be used as guiding principles when interpreting other norms.[57] Concerning public health issues, TRIPS plays a crucial role in determining ways for nations to e.g., aid their nationals with adequate access to necessary medicine. TRIPS tries to seek a balance between providing innovation and R&D incentives for medical products and pharmaceutics and making sure these products are accessible.[58]

More broadly, TRIPS acknowledges the importance of technology transfers in Article 7 as mentioned before, but also in e.g., Article 66.2 as follows:

> "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."[59]

These "incentives" have not been described in TRIPS[60], but developed country Members are required to report their incentive activities every three years and provide updates on these in-between reporting years, under a Council for TRIPS ("**TRIPS Council**") decision in 2003[61], to make sure and follow that the Article is implemented. LCDs have later addressed concerns on the lack of implementation of the provision, and that there is a "continued lack of clarity in notifications on the nature of incentives and whether such incentives sufficiently result in technology transfer to LDCs"[62], despite for example the WTO Secretariat's efforts to bring the parties together on this issue and WTO addressing the importance of providing incentives,

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[54] TRIPS Agreement, Preamble.
[55] TRIPS Agreement, Art. 7.
[56] TRIPS Agreement, Art. 8.
[57] Antony Taubman, Hannu Wager, and Jayashree Watal, 'Introduction to the TRIPS Agreement' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 13.
[58] Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 198.
[59] TRIPS Agreement, Art. 66.2.
[60] Antony Taubman, Hannu Wager, and Jayashree Watal, 'Introduction to the TRIPS Agreement' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 25.
[61] TRIPS Council, *Implementation of Article 66.2 of the TRIPS Agreement,* WTO Doc. IP/C/28 (20 February 2003), paras. 1-3.
[62] As an example, in 2018 the LCD Group (Least Developed Countries Group) stated in a communication to the TRIPS Council that "implementation of Article 66.2 continues to fall short of the letter and spirit of TRIPS Agreement mandate". TRIPS Council, *Communication from Cambodia on Behalf of the LCD Group, Proposal on the Implementation of Article 66.2 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement*, WTO Doc. IP/C/W/640 (15 February 2018), para. 1.

especially from a public health perspective[63]. Between 2003 and 2021, only 6 "states" (including the EU as one of these) had succeeded in submitting these reports every year, with more countries having submitted them either on random years or for many countries, not once. In 2021, 15 countries submitted a report about having set up programs to comply with Article 66.2.[64]

Another possibly relevant provision to consider is TRIPS Article 67 on technical cooperation. TRIPS Article 67 requires "technological cooperation" and IP system enforcement on agreed terms and when requested by developed countries in aid for LDCs and developing countries[65]. Like with Article 66.2, developed countries are required to submit reports on their support initiatives regarding Article 67[66]. Article 67 will not be the focus of this thesis, but worthy of additional consideration in the context of COVID-19 and related technology transfer.

Furthermore, based on TRIPS, developed countries must provide help and cooperate with LDCs in aiding them to strengthen their economic and technological development and growth. This duty and idea are reflected in Articles 66 and 67[67], but also in the original TRIPS Council decision to extend the implementation period of TRIPS for LDCs[68], where it was already recognized that LCDs have individual needs for aid and therefore, encouraged them to vocalize their specific needs as well.[69] These needs were vocalized by nine LDCs between 2007 and 2013[70]. Furthermore, if the lack of vocalization of needs was the case before[71], that cannot in

[63] Antony Taubman, Hannu Wager, and Jayashree Watal, 'Current TRIPS Issues' in Taubman Antony, Wager Hannu, and Watal Jayashree (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 236.
[64] These countries included e.g., Finland, the United States, and Japan. TRIPS Council, *Note by the Secretariat: Annual Report on Notifications and Other Information Flows,* WTO Doc. IP/C/W/687/Rev.1 (7 March 2022), pp. 16-17.
[65] TRIPS Agreement, Art. 67.
[66] Antony Taubman, Hannu Wager, and Jayashree Watal, 'Introduction to the TRIPS Agreement' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 26.
[67] TRIPS Agreement, Arts. 66-67.
[68] TRIPS Council, *Extension of the Transition Period Under Article 66.1 for Least-Developed Country Members*, WTO Doc. IP/C/40 (29 November 2005).
[69] *Ibid*, para. 2.
[70] Antony Taubman, Hannu Wager, and Jayashree Watal, 'Current TRIPS Issues' in Taubman Antony, Wager Hannu, and Watal Jayashree (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), pp. 233-234.
[71] See, for example study by the Swedish International Development Co-operation Agency and the WTO conducted in 2013 on LDCs and the technical and financial assistance provided for and in cooperation with them: Saana Consulting, Swedish International Development Cooperation Agency Supplementary Contribution to the WTO Global Trust Fund, 'Factual Overview on Technical & Financial Cooperation for LDCs Related to the TRIPS Agreement, Identifying and Responding to Individual Priority Needs of LDCs' (8 May 2013), pp. 75-76 <https://www.wto.org/english/tratop_e/TRIPS_e/ldc_overview_08.05.2013_full.pdf>, last accessed 20 January 2022.

my view be said to be true in times of COVID-19, as several LDCs have vocalized their need for help and vaccine access.

Nevertheless, TRIPS has provided efforts to harmonize the global IP systems and to aid in economic development. However, it has been argued that in pre-TRIPS times, many developing countries benefited from less IP regulation in the field of public health especially, and because of lighter pre-TRIPS regulation, generic pharmaceutical manufacturers were more able to be active in manufacturing medicines, which consequently lowered the cost of medicines. According to this view, some suggest that TRIPS has had a negative effect on access to medical products in developing countries.[72] Interestingly enough, introducing TRIPS was according to some – at least initially – "seen as a victory for pharmaceutical firms", and that it essentially acted as a barrier to "access to innovation and technology" leading to especially developing countries' added obstacles in accessing pharmaceuticals, which consequently led to the establishment of TRIPS flexibilities negotiations.[73] The challenges added by introducing TRIPS could be seen as the reasons why the implementation of TRIPS was later readdressed and supplemented, which we will look into next.

### *2.3 Doha Declaration*

To help countries to adapt suitable IP systems for their needs, TRIPS includes some so-called flexibilities, which have been in use for quite some time especially in "mechanisms used in patent systems to maintain a balance of public and private interests". These flexibilities have not directly been defined, but as an example, the "Doha Declaration" given in 2001 which will be discussed below, defined the meaning of these flexibilities, especially in relation to public health. In general, the flexibilities refer to ways in which states can interpret and carry out TRIPS obligations in their national systems, taking into consideration their national needs but also being compliant with TRIPS. In reality, these "TRIPS flexibilities" have been implemented in national IP systems in different ways and approaches.[74]

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[72] Daniel Opoku Acquah, 'Intellectual Property, Developing Countries and the Law and Policy of the European Union: Towards Postcolonial Control of Development' (Doctoral thesis, IPR University Center 2017), pp. 85-86.
[73] Sevil N-Marandi, 'Framing and Reframing Global Patent Policy, Implications on Access to Medicine in Developing Countries' (2009) 1(1) Public Policy & Governance Review 128, p. 129 <https://ppgr.files.wordpress.com/2010/08/1-1-framingrefamingpatentpolicy.pdf>, last accessed 8 February 2022.
[74] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2020), pp. 90, 92.

In 2001, an instrument called the Doha Declaration on the TRIPS Agreement and Public Health ("**Doha Declaration**")[75] was published to aid in the interpretation and application of TRIPS in public health matters, keeping in mind especially the needs of countries most in need of medical aid, i.e., LDCs and many developing countries[76], which also makes the Doha Declaration a central source for discussion in connection to COVID-19 and this paper. The Doha Declaration was initially published to clarify the situation of especially medical patent regulation interpretation and access and the use of TRIPS flexibilities in public health emergencies. In fact, the declaration "led to the amendment of TRIPS" in this respect. Moreover, it highlighted the importance of TRIPS Article 66.2 and developed countries' duty to incentivize technology transfers to LDCs.[77]

When looking at the declaration text itself, we can see that it recognizes that country members are allowed to use TRIPS flexibilities available when necessary for public health matters without other members' permission.[78] However, the TRIPS flexibilities in protecting public health that were specified in the Doha Declaration, cannot necessarily be utilized merely based on having been defined in the declaration, as in addition, they have to be accessible via the country's domestic regulation as well.

Doha Declaration paragraph 5(a) further recognizes that when interpreting TRIPS, the "objectives and principles" of the agreement should be used as a guide.[79] These objectives and principles were mentioned earlier as being included in the TRIPS Preamble, Article 7 and Article 8. In dispute DS435/ DS441/ DS458/ DS46 *Australia – Tobacco Plain Packaging*[80], the Panel highlighted the importance of these objectives and principles in interpreting TRIPS and stated that the Doha Declaration despite its form was a mutual agreement between countries on how to interpret TRIPS in connection to public health matters.[81] In general, the declaration

[75] WTO, Ministerial Declaration of 20 November 2001, WTO Doc. WT/MIN(01)/DEC/2 [hereinafter "Doha Declaration"].
[76] Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), pp. 198, 200.
[77] *Ibid*, pp. 198, 203.
[78] Doha Declaration, para. 3. See Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 200.
[79] Doha Declaration, para. 5(a).
[80] Panel Reports, *Australia–Tobacco Plain Packaging*, WTO Docs. WT/DS435/R, WT/DS441/R, WT/DS458/R, and WT/DS467/R (adopted 28 June 2018) [hereinafter "Panel Reports, *Australia – Tobacco Plain Packaging*"]. The Appellate Body agreed with the Panels argumentation on the interpretational context of TRIPS and its objectives and principles discussed. See, Appellate Panel Reports, *Australia – Tobacco Plain Packaging*, WTO Docs. WT/DS435/AB/R and WT/DS441/AB/R (adopted 9 June 2020), paras. 6.657, 6.658.
[81] Panel Reports, *Australia – Tobacco Plain Packaging,* paras. 7.2407, 7.2408, 7.2410.

communicates that the interpretation of TRIPS should be mindful of countries' "right to protect public health and, in particular, to promote access to medicines for all".[82]

Moreover, in relation to TRIPS flexibilities, the Doha Declaration paragraph 5(b) states that "Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[83] This clarifies TRIPS Article 31(b) and determines that "some form of emergency" is not necessarily required for compulsory licensing to be an eligible measure, even if that of course can be the reason for compulsory licensing. Furthermore, the declaration paragraph 5(c) leaves it up to each country to consider and judge whether an event is a "national emergency", but also states that "public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent such circumstances".[84] This in the case of COVID-19 is not as relevant to consider, as WHO declared the spread of the virus as a pandemic already in 2020[85], but an important note to add to this paper for future considerations.

In addition, the Doha Declaration included two other notes that required action, more specifically paragraphs 6 and 7. Paragraph 7 granted LDCs an implementation period for enforcing pharmaceutical patents[86], which after the publication of the Doha Declaration has been extended, most recently to 2033[87], meaning that LCDs do not have to enforce, e.g., patent protection of medical patents until the end of that period or whenever they are no longer considered an LDC[88].

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[82] Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 200.
[83] Doha Declaration, para. 5(b).
[84] Doha Declaration, para. 5(c). And Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), pp. 201-202.
[85] WHO, 'WHO Director-General's Opening Remarks at the Media Briefing on COVID-19 - 11 March 2020' (11 March 2020), <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>, last accessed 14 March 2022.
[86] Doha Declaration, para. 7.
[87] The original extension was until 2016 (TRIPS Council, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WTO Doc. IP/C/25 (1 July 2002)). The decision was extended in 2015, see, TRIPS Council, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products,* WTO Doc. IP/C/73 (6 November 2015), paras. 1-2.
[88] Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 203.

Paragraph 6 of the Doha Declaration stated that it had to be followed up by "an expeditious solution" to the issue of inefficiencies in compulsory licensing use in countries with little to no "manufacturing capacities in the pharmaceutical sector".[89] This then led to a regime developed in relation to "the export of pharmaceuticals to countries in need". This regime is also known as the Paragraph 6 System[90], and it will be discussed more in-depth in the following chapter. The use of the system has come up in connection to COVID-19 as well, which will be referred to in various parts of the paper.

## *2.4 Doha Declaration Paragraph 6 System on Compulsory Licenses*

### 2.4.1 Use of the Paragraph 6 System

As mentioned above, the Paragraph 6 System or the "Special Compulsory Licensing System"[91] for compulsory licensing arose from worries around certain Members not having adequate national pharmaceutical manufacturing capabilities, but also not being able to gain access to required amounts of imported pharmaceuticals even if import via compulsory licenses was possible, because manufacturers, i.e., the patent holders still had a duty to produce first and foremost to their national market.[92] The system was established by WTO General Council by two different decisions in 2003[93] and 2006[94]. According to the decisions, the "system – should be used in good faith to protect public health"[95]. As another connected and important note, the compulsory licensing system deriving from TRIPS Article 31 only applies to patents, not other types of IP[96], which is another reason why patents are the focus of this paper.

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[89] Doha Declaration, para. 6.
[90] Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 203.
[91] WTO, *Informational Note: The TRIPS Agreement and COVID-19* (15 October 2020), p. 10 <https://www.wto.org/english/tratop_e/covid19_e/TRIPS_report_e.pdf>, last accessed 28 February 2022.
[92] Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 204. See also TRIPS, Art. 31(f).
[93] WTO General Council, *Minutes of Meeting Held in the Centre William Rappard on 25, 26 and 30 August 2003*, WTO Doc. WT/GC/M/82 (13 November 2003), paras. 29-31.
[94] WTO General Council, *Minutes of Meeting Held in the Centre William Rappard on 1, 2 and 6 December 2005*, WTO Doc. WT/GC/M/100 (27 March 2006), paras. 29-32.
[95] WTO General Council, *Minutes of Meeting Held in the Centre William Rappard on 25, 26 and 30 August 2003*, WTO Doc. WT/GC/M/82 (13 November 2003), para. 29. And World Trade Organization General Council, *Minutes of Meeting Held in the Centre William Rappard on 1, 2 and 6 December 2005*, WTO Doc. WT/GC/M/100 (27 March 2006), para. 29.
[96] Diane Desierto, EJIL:Talk!, Blog of the European Journal of International Law, 'Overcoming the Global Vaccine and Therapeutics Lag and 'Vaccine Apartheid': Abuse of Rights in the EU's Continued Blocking of the TRIPS Waiver for COVID Vaccines and Related Medicines' (5 January 2022), <https://www.ejiltalk.org/overcoming-the-global-vaccine-and-therapeutics-lag-abuse-of-rights-in-vaccine-

The Paragraph 6 System's content was defined in the 2003 decision, according to which LDCs and other countries under certain conditions, i.e., "eligible importing Members", could with compulsory licensing waive 1) the TRIPS Article 31(f) obligation of the exporting country to ensure domestic supply of products first before importing pharmaceuticals to these eligible importing Members after completing certain steps beforehand[97], and 2) the TRIPS Article 31(h) obligation of these eligible importing Members to pay the patent holders "adequate remuneration"[98]. The decision further states that it has the objective of "promoting the transfer of technology and capacity building in the pharmaceutical sector", and therefore urges both exporters and importers "to use the system set out in this Decision in a way that would promote this objective", which would also be in line with the TRIPS Article 66.2[99]. If action according to the decision is taken towards a waiver of TRIPS Article 31 provisions, other Member countries may not object[100]. The 2003 decision was a temporary solution to the concern presented in the Doha Declaration Paragraph 6, meaning that it later had to be reconsidered to find a more permanent solution.

Later in 2005, the earlier decision was redefined with a permanent solution to the Doha Declaration Paragraph 6 issue presented earlier and essentially added the 2003 decision and idea into the TRIPS Agreement with some additional clarifications. The 2005 decision, also known as the "2005 Protocol"[101], amended the TRIPS Agreement by introducing an entirely new Article, i.e., Article 31*bis* on compulsory licenses and a related annex. According to the 2005 Protocol, the Paragraph 6 system could be used by eligible importing Members only under certain circumstances, e.g., "only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use"[102]. Like the earlier Decision, with the 2005 Protocol, the duty to ensure most of the production is guided to an exporter's domestic market was waived, making sure that the waiver is only made for "the needed pharmaceutical products under a compulsory license to those countries that do not have sufficient capacity to manufacture them". Another clarification the Protocol presented was that in case both the

apartheid-and-the-eus-continued-blocking-of-the-TRIPS-waiver-for-covid-vaccines-and-related-medicines/>, last accessed 8 March 2022.

[97] This includes e.g., specifying the product needed and estimates of the quantity required. See, WTO General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* WTO Doc. WT/L/540 (30 August 2003), para. 2(a).

[98] *Ibid*, para. 1(b). TRIPS Agreement, Art. 31(f).

[99] *Ibid*, para. 7, TRIPS Agreement, Art. 31(h).

[100] *Ibid*, para. 10.

[101] WTO General Council, *Amendment of the TRIPS Agreement,* WTO Doc. WT/L/641 (6 December 2005).

[102] *Ibid*, Annex to the TRIPS Agreement, para. 1(b).

importing and exporting countries have adequate compulsory licenses, the remuneration is not paid twice, but only to the exporting Member. In addition, Paragraph 3 of Article 31*bis* ensures easier export flows for members of regional trade agreements under certain additional requirements.[103] The Protocol was adopted and enforced on 23 January 2017 in Members who had accepted the Protocol; for other countries, the earlier 2003 Decision remained in force, but both essentially grant the same kinds of obligations and rights[104]. The acceptance of the Protocol is different from being implemented into national regulation as the provided flexibilities are only optional, but many countries have implemented such provisions and the possibility to use the system in their domestic legal systems[105].

The use of the system by either an exporter or importer requires a few different steps, including notifications on the intended use (one-time notification) and later, a more detailed notification on the actual needs or an export. LDCs do not have to announce the one-time notification on the intended use of the system, but they do have to notify each time they want to use it for a specific purpose.[106] The system has not been used much, at least by the time of writing this thesis. It has in fact only been used once in 2007 with HIV/AIDS medication[107], but this attempt between Rwanda and Canada was seen as a failure because of the costs and complex nature of utilizing the TRIPS Article 31*bis* system[108].

More recently in connection to COVID-19, two importers in 2021 gave notification of their initial intention to use the compulsory licensing system, but these notifications have not led to actual technology transfer thus far. These two initial importer notifications given during the COVID-19 pandemic[109] were the first ones to appear after the last use of the system in 2007[110]. One of these notifications submitted by Bolivia was later supplemented by a more detailed notification about the country's COVID-19 pharmaceutical needs, announcing a need for an

[103] Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 206. And TRIPS Agreement, Art. 31bis, paras. 1-3.
[104] *Ibid*, p. 205.
[105] *Ibid*, p. 213.
[106] *Ibid*, pp. 209-210.
[107] This was a notification by Canada in response to Rwanda's earlier notification IP/N/9/RWA/1 on 19 July 2007. See, TRIPS Council, *Notification under Paragraph 2(C) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration,* WTO Doc. IP/N/10/CAN/1 (8 October 2007).
[108] Daniel Opoku Acquah, 'Intellectual Property, Developing Countries and the Law and Policy of the European Union: Towards Postcolonial Control of Development' (Doctoral thesis, IPR University Center 2017), p. 26.
[109] TRIPS Council, *Notification under the Amended TRIPS Agreement, Notification of Intention to Use the Special Compulsory Licensing System as an Importing Member,* WTO Doc. IP/N/8/ATG/1 (17 May 2021) and WTO Doc. IP/N/8/BOL/1 (19 February 2021).
[110] TRIPS Council, *Note by the Secretariat: Annual Report on Notifications and Other Information Flows,* WTO Doc. IP/C/W/687/Rev.1 (7 March 2022), p. 15.

estimate of 15 million vaccines[111]. A Canadian pharmaceutical manufacturer called Biolyse Pharma responded to Bolivia's notification by stating its plan to produce a generic version of the Johnson & Johnson COVID-19 vaccine and made an agreement with Bolivia on the exportation subject to certain administrative approvals, as in Canada it is required for intended exported pharmaceuticals to fulfill the same conditions as products for domestic use for a compulsory license to be possible. However, the question of whether in general COVID-19 vaccines should be allowed through the national "Access to Medicines Regime" under the conditions set for Canadian compulsory licenses remained still in discussion, including that of Biolyse Pharma's generic vaccine after signing the contract with Bolivia[112], which essentially led to a situation where the vaccines could not be delivered. The situation seemed to stay the same at least in late 2021, and Biolyse Pharma was not able to produce and export vaccines to Bolivia, at least according to unofficial news sources[113].

Moreover, according to a Reuters news article, the company had started a similar initiative through the same Canadian "Access to Medicines Regime" approval process in 2006 related an influenza medicine, but at the time the company gained authoritative approval to start the production of the influenza medicine, the company found that the initial demand for the medication was no longer there[114]. News articles, of course, should be read with great caution and many of them regarding this topic have seemed to be rather blunt and opinionated in one way on the topic. Nevertheless, drawing from this example it seems that the compulsory licensing system is not as easy to use as intended, and the same issue surrounding the system dealt in 2006 in Canada, was also encountered in 2021 despite 15 years in between.

Moreover, a country may only force a compulsory license in case the initial "only after price negotiations with the patent holder have failed", which was the case e.g., with HIV/AIDS treatment in 2001 before the Doha Declaration, when South Africa enacted a compulsory license on the basis of TRIPS. The response from pharmaceutical companies to the compulsory

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[111] TRIPS Council, *Notification under the Amended TRIPS Agreement, Notification of Need to Import Pharmaceutical Products under the Special Compulsory Licensing System,* WTO Doc. IP/N/9/BOL/1 (11 May 2021).
[112] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 9.
[113] See, e.g. Global News, 'Canada Lacks 'Political Will' to Waive COVID-19 Vaccine Patents, Bolivian Minister Says' (6 October 2021), <https://globalnews.ca/news/8243635/bolivian-minister-canada-covid-vaccine-waiver/>, last accessed 17 February 2022.
[114] Reuters, 'Bolivia Signs J&J Vaccine Deal With a Twist - It Needs WTO Patent Waiver' (12 May 2021), <https://www.reuters.com/world/americas/bolivia-signs-jj-vaccine-deal-with-twist-someone-else-would-make-it-2021-05-11/>, last accessed 17 February 2022.

license was to file a lawsuit against the South African government for "allegedly infringing on their patent rights" but decided later to "withdraw this lawsuit in the face of immense public pressure". Soon thereafter, the Doha Declaration was published.[115] A similar situation occurred e.g., in Thailand in connection to HIV/AIDS medication in 1997, leading to Thailand backing down from issuing the compulsory license.[116] All in all, the Article 31 system and the TRIPS flexibilities it provides had been used only 144 times between 2001 and 2016[117]. As with the previous Canadian example, these are further pieces of evidence of the lackluster application of the compulsory licensing system in the past, but also from other issues relating to the system beyond the provisions, which will be discussed next.

### 2.4.2 Critique

As evidence suggests, the use of the Paragraph 6 System has been rather modest, even though it "has the potential to serve as a significant procurement tool for access to medicines", as a WTO Staff Working Paper from 2015 suggests. It is important to note that medicines can be imported and exported via other routes as well, sometimes possibly even at better costs if e.g., the system is used to first notify of an importer's medical needs. There have been suggestions to bring the system into broader, *de facto* use, which call for e.g., system simplification, analysis of why the system has not been utilized much, and making the use of the system more appealing. It has also been noted that the role of regional trade agreements in some instances could have had a decreasing effect on the interest of the system, as more recent regional trade agreements seek to ensure the principles set in the Doha Declaration. Moreover, it has been called for adding political encouragement for exporters to use the compulsory licensing system because there has been "political pressure not to use the System in order to explain its limited practical

[115] Richard Gold et al, 'Are Patents Impeding Medical Care and Innovation?' (2010) 7(1) PLoS Medicine, p. 3 <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1000208&type=printable>, last accessed 16 February 2022.
[116] Thailand was intending to issue a compulsory patent that would enable a domestic medicine production, but the intention was prohibited by US authorities representing the Pharmaceutical Research and Manufacturers Association. Sevil N-Marandi, 'Framing and Reframing Global Patent Policy, Implications on Access to Medicine in Developing Countries' (2009) 1(1) Public Policy & Governance Review 128, p. 135 <https://ppgr.files.wordpress.com/2010/08/1-1-framingrefamingpatentpolicy.pdf>, last accessed 8 February 2022.
[117] Nancy S Jecker and Caesar A Atuire, 'What's Yours Is Ours: Waiving Intellectual Property Protections for COVID-19 Vaccines', [2021] 47 Journal of Medical Ethics 595, <https://jme.bmj.com/content/47/9/595>, last accessed 7 March 2022.

relevance".[118] In general, countries have stated that the system is ineffective and too complex, while others have suggested it might still have potential despite its limited usage.[119]

Moreover, in a TRIPS Council meeting in 2017 when discussing the use of the Paragraph 6 System, it was described by India as "complex and cumbersome", but on the contrary, the United States recognized that the system was "only one piece of the puzzle" and that incentivization by taking down trade and IP barriers was important as well. Switzerland noted that even though the system had not been really in use, it did not mean that other "just as, if not more relevant and efficient" ways of accessing pharmaceutical products and distribution were not used and that often many more obstacles to distribution existed, such as insufficient infrastructure. Japan, as an example, stated: "the issue of access to medicines would be more effectively dealt with through a more comprehensive approach, based on the accumulated understanding and recommendations of previous discussions and reports".[120] The debate amidst the COVID-19 pandemic on the use of the system remains similar to these opposing views that have been presented already decades ago.

In WTO, the TRIPS Council has a duty to review the implementation of the Paragraph 6 System on an annual basis. In its latest review on 26 October 2021, the Council had a short discussion on the use of the system during the COVID-19 pandemic, and its relationship with the proposed TRIPS Waiver, which will be discussed below and later in Section 4.4. The Council discussed a Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic that had been submitted by the European Union in response to previous requests to waive TRIPS, which highlighted the potential of the compulsory licensing system during the pandemic.[121] No significant next steps or processes as to how the system would specifically be used in the pandemic were set in place.

Lastly, from a manufacturing perspective, the system has – quite naturally – been criticized as well. As an example, in a TRIPS Council meeting in 2017 when discussing the use of the

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[118] Roger Kampf, World Trade Organization Economic Research and Statistics Division, *WTO Staff Working Paper, Special Compulsory Licences for Export of Medicines: Key Features of WTO Members Implementing Legislation*, WTO Doc. ERSD-2015-07 (31 July 2015), pp.16-18 <https://www.wto.org/english/res_e/reser_e/ersd201507_e.pdf>, last accessed 14 February 2022.
[119] Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), pp. 214-215.
[120] TRIPS Council, *Minutes of Meeting Held in the Centre William Rappard on 19-20 October 2017*, WTO Doc. IP/C/M/87/Add.1 (7 February 2018), paras. 78, 81, 95, 105.
[121] TRIPS Council, *Annual Review of the Special Compulsory Licensing System, Report to the General Council*, WTO Doc. IP/C/90 (26 October 2021), paras. 15-19.

Paragraph 6 System, Switzerland pointed out that "Pharmaceutical companies, whether R&D originators or generic manufacturers, need financial incentives to invest in the manufacturing of relevant medical products, i.e., a fair return on their investment".[122] In another meeting, the same point was raised by the European Union.[123]

### *2.5 TRIPS Waiver*

Another public health aspect of TRIPS especially during the COVID-19 pandemic has been something called a "TRIPS waiver". As TRIPS is a part of the WTO Agreement, its provisions and duties under certain "exceptional circumstances" can be waived.[124] In the case of TRIPS, the first notification for a waiver must be addressed to and by the TRIPS Council after which it may be directed to either the Ministerial Conference or the General Council. The decided waiver will be considered on an annual basis after its approval. By 2011, only two of the total 208 waiver decisions had been related to the TRIPS Agreement. The first one regarded the extension of a waiver of "exclusive marketing rights" in connection to medical products and LDCs. The second one established the "Paragraph 6 System" to help countries with little to no domestic medical product manufacturing capacity[125], as discussed in the previous section.

The TRIPS waiver has been a burning topic of discussion during COVID-19, and it has been presented as one possible solution to more equitable vaccine distribution. In 2020 just after the outburst of COVID-19, India and South Africa presented a TRIPS waiver request to waive all relevant IP rights related to all measures and products connected to COVID-19 such as vaccines and R&D established by TRIPS. The central argument was the out-of-proportion adverse effects the pandemic had had on LDCs and many developing countries, and that fast access to necessary health equipment and medication was necessary. In general, it was argued that to end the pandemic, an IP waiver and international cooperation were required, until a sufficient portion of the global population was vaccinated. Moreover, the proposal stated that "there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients", and that some countries had

[122] TRIPS Council, *Minutes of Meeting Held in the Centre William Rappard on 19-20 October 2017*, WTO Doc. IP/C/M/87/Add.1 (7 February 2018), para. 97.
[123] E.g., *ibid*, para. 439.
[124] Agreement Establishing the World Trade Organization, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994) [hereinafter "WTO Agreement"], Art. IX paras. 3, 4.
[125] Antony Taubman, Hannu Wager, and Jayashree Watal, 'Introduction to the TRIPS Agreement' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), pp. 28-29.

already implemented national IP amendments in response to the pandemic. It further concluded that developing countries especially had had issues in using TRIPS flexibilities themselves in the past and that the Article 31*bis* requirements were of specific concern.[126] Something noteworthy as well is that the waiver request was made even before eligible vaccines had come up to the market.

Later in 2021, the original COVID-19-related TRIPS waiver request was renewed according to comments received to the initial initiative. In addition, many other countries joined in on the request, mainly LDCs and other developing countries. In the renewed request, an additional emphasis was put on the emergence of new virus variants, making the matter even more sensitive timewise.[127] In May 2021 and soon after the renewed waiver request, the US announced its support for a COVID-19-related IP waiver. The US declaration did not specify the support much further but stated that the US will be active in waiver-related WTO discussions to achieve this goal.[128] The statement was declared as an implication of "the wisdom and moral leadership of the United States to work to end this pandemic" by the WHO Director-General[129], but it has been considered by some to be more of a gesture rather than a solution to the situation, because international cooperation still remains a key solution, with or without the IP waiver.[130] US support has not provided much improvement to the TRIPS waiver, as the waiver still as of April 2022 remains on the TRIPS Council's agenda and in discussions in the WTO, with only first the signs of consensus arising among a few WTO Members in April 2022[131].

What would an IP waiver entail in connection to COVID-19? As stated, compulsory licensing of patents specifically is already a possibility in certain cases under TRIPS, but the waiver could expand the compulsory beyond just pharmaceutical patents. The most interesting and perhaps

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[126] The request concerned the following provisions of TRIPS "in relation to prevention, containment or treatment of COVID-19": Sections 1, 4, 5, and 7 of Part II. See TRIPS Council, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Communication from India and South Africa,* WTO Doc. IP/C/W/669 (2 October 2020), paras. 3-13.
[127] *Ibid*, paras. 1-3.
[128] Office of the United States Trade Representative, 'Statement from Ambassador Katherine Tai on the COVID-19 TRIPS Waiver' (5 May 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-TRIPS-waiver>, last accessed 27 January 2022.
[129] WHO, 'WHO Director-General Commends United States Decision to Support Temporary Waiver on Intellectual Property Rights for COVID-19 Vaccines' (5 May 2022), <https://www.who.int/news/item/05-05-2021-who-director-general-commends-united-states-decision-to-support-temporary-waiver-on-intellectual-property-rights-for-covid-19-vaccines>, last accessed 27 January 2022.
[130] Jorge L Contreras, 'US Support for a WTO Waiver of COVID-19 Intellectual Property' (2021) 56(3) Intereconomics 179, p. 180 <https://link.springer.com/content/pdf/10.1007/s10272-021-0976-7.pdf>, last accessed 15 February 2022.
[131] WTO, 'Director-General Okonjo-Iweala hails breakthrough on TRIPS COVID-19 Solution' (16 March 2022), <https://www.wto.org/english/news_e/news22_e/dgno_16mar22_e.htm>, last accessed 26 April 2022.

most powerful implication would be the information that is not patented but that is needed for vaccine development, i.e., most notably know-how and trade secrets related to manufacturing, but also other IP rights like copyrights. In theory with the IP waiver, a compulsory license could make it mandatory for a company to share its trade secrets surrounding the patented invention with another manufacturer, without TRIPS prohibiting this action. This type of "trade secret compulsory licensing" would be a never-before-seen solution to the problem and could prove to be powerful. Regardless, the potential impact of an IP waiver would be determined according to whatever direction the WTO negotiations would take it. Another question remains, how many countries would in the end take advantage of the waiver[132], one reason being that it must be implemented into national legislation.

### *2.6 Human Rights, IP and the Right to Health*

Another fundamental and relevant question related to the pandemic but also to IP rights is whether a virus can undermine human rights. Both the COVID-19 pandemic and the past have shown us that, indeed, the answer is yes.

Human rights and IP might at first glance seem opposite, but despite the tensions between the two, they stem from similar interests to highlight "the value of the human person through the protection of the fruits of creative endeavour", and indeed, human rights see IP as essential and valuable[133]. The right to health forms one of the cores of human rights for all humans globally, and this notion derives from the Universal Declaration of Human Rights of 1948.[134] Moreover, the access to pharmaceuticals and the right to health and life arise from other human rights norms as well. In 2001, the United Nations Economic and Social Council considered the relationship between TRIPS, IP rights, and human rights in a report[135], which discussed the obligations of countries that arise from the International Covenant on Economic, Social, and Cultural Rights ("**ICESCR**")[136] and TRIPS. The report found that drawing from these two

[132] Jorge L Contreras, 'US Support for a WTO Waiver of COVID-19 Intellectual Property' (2021) 56(3) Intereconomics 179, p. 180 <https://link.springer.com/content/pdf/10.1007/s10272-021-0976-7.pdf>, last accessed 15 February 2022.
[133] Ruth L Okediji, 'The Limits of Development Strategies at the Intersection of Intellectual Property and Human Rights' in Daniel Gervais (ed), *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford University Press 2007), pp. 367-368.
[134] TRIPS Council, *Minutes of Meeting Held in the Centre William Rappard on 19-20 October 2017*, WTO Doc. IP/C/M/87/Add.1 (7 February 2018), para. 465.
[135] UN Commission on Human Rights, Economic and Social Council, Fifty-Second Session, *Economic, Social and Cultural Rights, The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights, Report of the High Commissioner*, UN Doc. E/CN.4/Sub.2/2001/13 (27 June 2001).
[136] UN General Assembly, *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, Treaty Series, vol. 993, p. 3.

instruments, Members should firstly, "balance public and private interests in the design of IP protection" and secondly, keep in mind the protection of public health as well, including e.g., "promotion of research" and "international cooperation to implement the right to health" when considering the balance between innovators and the public, especially regarding pharmaceuticals. In terms of medicines, affordability and accessibility are also important factors to take into consideration.[137] A resolution from 2016 by the UN Human Rights Council further underlined the right to the highest possible mental and physical health – including "access to medicines and vaccines" – and stated that this right is reflected in many other international regulatory instruments as well. It further highlighted the additional burden pandemics and similar have on especially developing countries.[138] In a wider setting, health can be regarded as a public good, which when provided to all will benefit both developed and developing countries.[139]

Moreover, the idea of the right to health has been included in the UN's 2030 Agenda for Sustainable Development Goals ("**SDGs**") released in 2015. Goal number 3 is to "ensure healthy lives and promote well-being for all at all ages", including supporting medication R&D and access to "affordable essential medicines and vaccines", and aiding especially developing countries in their access and control of public health matters. More specifically, target 3.b recognizes the need for medical R&D support for "vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries" and improving related access as stated in the Doha Declaration.[140]

More specifically regarding the COVID-19 pandemic, a UN Human Rights Council resolution in March 2021 highlighted the States' role in carrying out human rights and the right to healthy lives on behalf of the Sustainable Development Goals, and that everyone should have the right to benefit from the COVID-19-related scientific innovations. It noted that ever since vaccines were available for distribution, most of them had gone to developed countries, and argued that

[137] UN Commission on Human Rights, Economic and Social Council, Fifty-Second Session, *Economic, Social and Cultural Rights, The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights, Report of the High Commissioner*, UN Doc. E/CN.4/Sub.2/2001/13 (27 June 2001), paras. 59, 62-63, 66.
[138] UN Human Rights Council, Thirty-Second Session, *Resolution adopted by the Human Rights Council on 1 July 2016, Promoting the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health Through Enhancing Capacity-Building in Public Health,* UN Doc. A/HRC/RES/32/16 (19 July 2016), pp. 1-4.
[139] Johanna Gibson, *Intellectual Property, Medicine and Health: Current Debates* (Ashgate Publishing Limited 2009), p. 81.
[140] UN General Assembly, Seventieth Session, *Transforming Our World: The 2030 Agenda for Sustainable Development*, UN Doc. A/RES/70/1 (21 October 2015), paras. 3.b-3.d.

there was significant concern over this unequal vaccine distribution, as it stood in the way of ending the pandemic but also because it conflicted with the Sustainable Development Goals. The resolution declared a further deep concern "about the negative impact of the COVID-19 pandemic [had] on the enjoyment of human rights around the world", and urged States to e.g., take steps towards ensuring fair and equal vaccine distribution and efficient international collaboration through e.g., sharing relevant knowledge.[141]

Another instrument that highlights one's rights related to public health and that has been created specifically "to prevent, protect against, control and provide a public health response to the international spread of disease", is the International Health Regulations ("**IHR**") from 2005[142]. While this is a binding piece of international law, we will however leave it out of this paper's analysis because of the focus on TRIPS and IP policies. Many other similar resolutions and documents exist, but the central message from these is that the right to health and life, including access to (affordable) medication is a recognized human right. Human rights are not explicitly discussed in much detail in this paper, but they remain an important underlying factor to consider in today's discussion on pharmaceuticals and the current COVID-19 pandemic, and also in past discussions surrounding public health and IP which will be addressed in the next chapter in more detail.

[141] UN Human Rights Council, Forty-Sixth Session, *Ensuring Equitable, Affordable, Timely, and Universal Access for All Countries to Vaccines in Response to the Coronavirus Disease (COVID-19) Pandemic*, UN Doc. A/HRC/46/L.25/Rev.1 (17 March 2021), pp. 1-3, 5.
[142] WHO, *International Health Regulations* (3rd edn, World Health Organization 2005), p. 1.

## 3 VARIED APPROACHES TO IP, PUBLIC HEALTH AND COVID-19

Another important factor in our discussion can be found when we look at the subjects and actors playing in the international arena and how their opinions and discussions have evolved over time. Who is to blame for the inefficiencies and inequalities in vaccine distributions that are affecting the lives of billions of people – is it companies, individual states, or international organizations? Is it the inefficiencies in the current IP regulation? If so, who is responsible for its inefficiency? Or is it the manufacturing corporations' and networks' fault and are they being greedy? Or does the "flaw" lie in government policies? Can history provide any answers? The question is complex, which means that the answer must be complex as well. Let us briefly look into the different views on IP and public health before and during COVID-19 from the standpoint of a few relevant subjects.

### *3.1 Pharmaceutical Companies on IP and Innovations*

Naturally, pharmaceutical companies form a central group of central stakeholders when it comes to IP and public health. One way of making a return on biotechnology R&D and the investments that go into innovating for companies is IP and the economic value it brings to them, especially the value of patents albeit for a limited time. The use of patents in company management and strategy remains optional and for the companies to decide.[143] In general, patents increase the price of companies' R&D because of the burden of checking conflicts and patentability while researching, even though they do *usually* act as incentives to pharmaceutical companies in researching new medical products; however, the evidence is not entirely clear. In some instances, previously patented processes may prohibit conducting further R&D, if permission to use a patented process is not obtained. Some evidence has suggested that the increased costs in new medical product R&D "appear to double every decade". Moreover, in an article written in 2009, it was stated that "investments in the health needs of developing countries remain very low by any standard, and patents continue to get in the way of modifying existing medicines for the needs of those countries" and that especially in these countries, "patents are a factor in inhibiting access to pharmaceutical treatment", but also that patents are not the only aspect causing inequitable access.[144] In addition, the potentially lower profitability

[143] Sharon Oriel, 'Making a Return on R&D: A Business Perspective' in David Castle (ed), *The Role of Intellectual Property Rights in Biotechnology Innovation* (Edward Elgar Publishing 2009), pp. 118-119, 123, 126, 130.
[144] Richard Gold et al, 'Are Patents Impeding Medical Care and Innovation?' (2010) 7(1) PLoS Medicine, pp. 1-3 <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1000208&type=printable>, last accessed 16 February 2022.

of poorer nations' markets might deter companies from entering these markets and in general, even affect the R&D of pharmaceuticals that are yet to be invented.[145] Moreover, the pharmaceutical industry has been highly concentrated in the hands of a hand of a few companies for the last decades[146], which can be another factor in this issue.

One example of the power of IP in pharmaceuticals is HIV/AIDS treatment. The price of the treatment came down "from more than US$15 000 per patient per year in 2001 to less than US$99 in 2007" only due to generic manufacturers, i.e., other manufacturers than the original patent holders, because they started to compete on the market with the original IP holders. Interestingly, in 2009 the so-called neglected diseases, like tuberculosis and malaria which mostly affect developing countries, constituted 21 % of "the global disease burden", but only 0.31 % of public health financing went into R&D focusing on them.[147] Drawing from this, one could argue that financing mostly goes to developed countries or places where companies can make more profit. It is obvious that medical R&D is extremely costly, which is one reason for profit-seeking, but not the whole picture.

In general in connection to public health and the role of IP rights, and beyond just the COVID-19 pandemic, many ways of navigating the complexities and ensuring public health have been presented, including cooperation efforts, licensing, and "tiered-pricing schemes by pharmaceutical companies", in addition to direct donations as ways of easing access to pharmaceuticals. However, the issues surrounding medicine access are a compilation of many factors and actors in the field – on one hand, States discuss, debate, and decide on policies in different international organizations, but the medical industry and national legislators adopt and bring these policies into real-life action. In addition, international bodies such as the WHO assess the legislations and adoptions themselves.[148] Next, we will look at the discussion different countries have contributed to.

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[145] Johanna Gibson, *Intellectual Property, Medicine and Health: Current Debates* (Ashgate Publishing Limited 2009), p. 141.
[146] Margaret Visnji, Revenues & Profits, 'Pharma Industry Merger and Acquisition Analysis 1995 to 2015' (11 February 2019), <https://revenuesandprofits.com/pharma-industry-merger-and-acquisition-analysis-1995-to-2015/>, last accessed 27 January 2022.
[147] Richard Gold et al, 'Are Patents Impeding Medical Care and Innovation?' (2010) 7(1) PLoS Medicine, pp. 1-3 <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1000208&type=printable>, last accessed 16 February 2022.
[148] Antony Taubman, Hannu Wager, and Jayashree Watal, 'Current TRIPS Issues' in Taubman Antony, Wager Hannu, and Watal Jayashree (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), pp. 244-245.

### *3.2 States on IP and Public Health*

> *"We [the European Union], agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health."*[149]

In 2021, the EU announced a communication to the TRIPS Council on a draft declaration on TRIPS and its relationship to the distribution of COVID-19 vaccines and medication. In the draft, the EU countries agree that COVID-19 does indeed fill the meaning of "a national emergency or other circumstances of extreme urgency" within the meaning of TRIPS Article 31(b). In addition, the draft calls for the use of the compulsory licensing system and highlights that the EU's "main objective is to ensure fair and equitable distribution of vaccines and medicines to fight against COVID-19". Finally, the draft states "that the WTO must step up its efforts to ensure that the rules-based global trading system plays its role in response to the COVID-19 crisis".[150] The communication was a response to the proposed TRIPS waiver as discussed above and will be discussed further in Section 4.4.

Furthermore, the TRIPS Council has discussed the relationship between IP and many societal issues and opportunities in its meetings throughout the years and various opinions have been voiced.[151] For example in 2012, in a discussion in the TRIPS Council on innovations and IP policies, the United States declared that in the US, the "private sector was the engine for innovation and that government played an important role in supporting such innovation" and that "IP provided a critical safeguard, particularly in economies that relied heavily on innovation". In addition, it mentioned a program that it had started, called "Patents for Humanity Programme", the idea of which was "to spur increased participation by the patent community in confronting global challenges by rewarding those who applied their patented technology to address humanitarian issues among impoverished peoples around the world, including with respect to medical technology". Finally, it stated that an example of a hindrance on trade, innovation and investments could be "measures to force technology transfer". In the same discussion, Brazil added the following: "Innovation was heavily influenced by factors

[149] TRIPS Council, *Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, Communication from the European Union to the Council for TRIPS*, WTO Doc. IP/C/W/681 (18 June 2021), p. 3.
[150] TRIPS Council, *Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, Communication from the European Union to the Council for TRIPS*, WTO Doc. IP/C/W/681 (18 June 2021), pp. 2-3.
[151] Antony Taubman, Hannu Wager, and Jayashree Watal, 'Current TRIPS Issues' in Taubman Antony, Wager Hannu, and Watal Jayashree (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 239.

other than IP, such as the industrial capacity of a country, the quality of its education, and access to raw materials. Similarly, the level of protection afforded by the IP system was not the only element stimulating technology transfer to developing countries." Chile added that some argued that "IP, especially some elements of the patent regime, would adversely affect the pursuit of sustainable development strategies by raising the price of essential drugs to levels that were too high for the poor to afford", and that only a small number of patents were given to "domestic companies in developing countries" but rather to large corporations from other countries.[152] Continuing, Chile argued the following:

> " -- the IP system, for example in the pharmaceutical industry, failed to fulfil the interests of the society to provide quality drugs, or to develop new drugs to treat the diseases of the poor or to provide access to medicines at an affordable cost, thus defeating the basic purpose of the TRIPS Agreement."[153]

Another debated topic has been compulsory licensing. Regardless of the lack of use of the Paragraph 6 System, countries have in fact granted compulsory licenses for medication via other routes. Moreover, Members may decide the grounds for compulsory licensing themselves based on TRIPS Article 31. As an example, United States' regulation on patents called the Bayh-Dole Act, allows for "federal government "march-in rights"", at least according to India's argument in a TRIPS Council meeting discussion in 2017. On the other hand, this interpretation was stated as misleading by the United States delegation, which stated that "the US Patent and Trademark Office has never issued a compulsory license. In fact, it does not have the authority to do so", and that in general, the Act in question only allows for use of patents without permission in extremely limited cases. In the same meeting, the EU delegation commented that unlike some Members have suggested, the EU does not believe in the IP system and public interest being contradictory and that barriers in access to pharmaceuticals should not be associated with just being an IP issue[154], which is similar to the argumentation presented during COVID-19.

Moreover, the pricing of medication has also been a topic of vast debate among Members. As an example, in a 2019 TRIPS Council meeting, South Africa pointed out that "(t)he marginal production costs of medicines are relatively small compared to their market prices", but on the other hand, the European Union stated that medicines protected with IP rights are in fact a

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[152] TRIPS Council, *Minutes of Meeting Held in the Centre William Rappard on 6-7 November 2012,* WTO Doc. IP/C/M/71 (12 February 2013), paras. 256, 259, 262, 264, 272, 291, 294.
[153] *Ibid*, para. 294.
[154] As examples, compulsory licenses have been granted in Malaysia and Germany for pharmaceuticals based on public interest. See, e.g., TRIPS Council, *Minutes of Meeting Held in the Centre William Rappard on 19-20 October 2017*, WTO Doc. IP/C/M/87/Add.1 (7 February 2018), paras. 470, 476-477, 482-483, 494, 501. And TRIPS, Art. 31.

minority of the pharmaceuticals that developing countries are in fact in need of. In the same connection, the EU stated that "compulsory licenses to pharmaceutical patents as a remedy to excessive pricing would have a negative impact on innovation incentives" and that even though IP rights are largely debated among Members, they, in fact, play a small part of the whole issue and larger debate. China, on the other hand, highlighted that while IP rights are important, strengthening them does not necessarily lead to merely positive impacts in terms of "economic efficiency" and the public interest.[155] Many Members take part in these debates and take one side of the discussion – being either pro or against stronger IP rights[156].

To summarize, the key factor in a Member country's opinion on the issue largely seems to be affected by its financial standpoint, whether it is a developing or a developed country, and whether it has large domestic pharmaceutical manufacturers. In my opinion, if vaccine patent holders, mostly from developed countries, would have wanted to use compulsory licensing, they could have potentially done so already – noting that of course, national regulations vary. This is not as black and white as presented here, because other factors affect the situation as well, and each country has its own nationals' interests in mind. Regardless, many of the comments and opinions have seemed vague and not always connected to the factual use or issues connected to the existing system, such as opinions emphasizing the potential of the Doha Declaration Paragraph 6 System.

### *3.3 International Organizations on IP and Public Health*

Throughout the last few decades, many international organization efforts have been put out to discuss and address the issues between public health and the IP system. As an example, in a Report in 2006, the WHO Commission on Intellectual Property Rights, Innovation and Public Health assessed the relationship between TRIPS, the Doha Declaration, and public health[157], and already then recognized the tension between the IP system's role in innovation incentives, pricing of pharmaceutics and the accessibility of it, especially with countries with less

[155] TRIPS Council, *Minutes of Meeting Held in the Centre William Rappard on 17-18 October 2019*, WTO Doc. IP/C/M/93/Add.1 (9 December 2019), paras. 610, 626, 631, 640, 650.
[156] Other topics have been included in the debate but not explored in this paper, such as competition and anti-trust policies. See, e.g., TRIPS Council, *Minutes of Meeting Held in the Centre William Rappard on 13 February 2019*, WTO Doc. IP/C/M/91/Add.1 (2 April 2019), paras. 412-487.
[157] WHO Commission on Intellectual Property Rights, Innovation and Public Health, *Report on Public Health, Innovation and Intellectual Property Rights* (World Health Organization 2006).

wealth.[158] Moreover, the report found that the role of IP rights is context-dependent and may have different roles in different parts of the "innovation cycle". Regarding the HIV/AIDS pandemic that began in the 1980s but to which medication was discovered in the mid-90s as was already determined above, the report stated that even though the medication was available, deaths in developing countries did not go down in the entirety of the 1990s because of high prices, capacity issues in infrastructure and "political commitment sometimes lacking". Therefore, the newly found medication was inaccessible to many developing countries.[159] This statement feels ominously familiar at the times of COVID-19, even despite efforts to equalize vaccine distribution, which will be discussed in more detail in Chapter 4.

### 3.3.1 GSPA-PHI Strategy

Moreover in 2008, the WHO World Health Assembly introduced the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property ("**GSPA-PHI**"). The strategy was put in place to give specific, concrete steps to use IP and innovation as tools for strengthened public health efforts, equality, and research especially in developing countries that are most affected. The strategy specifies that neither TRIPS nor the Doha Declaration act or should act as a barrier in actions for the benefit of public health and that they should be interpreted in the best interest of public health among Members. Moreover, the strategy states that while IP acts as a tool for innovation incentivization for new pharmaceutics, it is not enough on its own especially when the target market is less well resourced.[160]

Later, a report that commented on the GSPA-PHI in 2017 stated that while some steps had been taken forward in relation to IP and access to medicine as a consequence of the strategy, e.g., the founding of the Medicines Patent Pool ("**MPP**") - that will be discussed in Section 4.3.4 - and helping more people in need access HIV/AIDS medication, much of the development had been rather modest or at points, non-existent and that most countries had not implemented TRIPS flexibilities in their national laws or had done so in very limiting ways. It further stated that

[158] Antony Taubman, Hannu Wager, and Jayashree Watal, 'Current TRIPS Issues' in Taubman Antony, Wager Hannu, and Watal Jayashree (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 245.
[159] As a comparison, the report states that between 1995-1998, the number of deaths per 100 000 went down from 17 % to 5 % in the United States. WHO Commission on Intellectual Property Rights, Innovation and Public Health, *Report on Public Health, Innovation and Intellectual Property Rights* (World Health Organization 2006), p. 97.
[160] The GSPA-PHI was published as a consolidated version in 2011 by the WHO, which combined the texts from a few different decisions together with the Strategy, and briefly discussed the development of the Strategy. WHO, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (consolidated version, World Health Organization 2011), paras. 7-8, 13-14.

access issues exist with or without patents and in all price ranges. The report concluded that in general the efforts of GSPA-PHI were largely hindered by the lack of awareness of the strategy in the first place.[161] Moreover, TRIPS was seen as a possibility to help developing countries' local health innovation and R&D, but this had not been the reality thus far.[162] One example of this type of effort included e.g., open-source (patent) pooling which had been used on a few occasions in the past but had not been the most common choice because of its heavy reliance on outside funding and research grants to incentivize and attract different parties to contribute.[163] Moreover, local manufacturing requires that a manufacturer gains access to the original invention for example by a license, if they have not invented the product themselves.[164] This can be either by a voluntary or a compulsory license. As mentioned earlier, LDCs have an extension to apply to rules of TRIPS only in 2033, meaning that they have more freedom in manufacturing. Despite this, not many LDCs have utilized this right to its full potential.[165]

However, one example of using the LCDs' TRIPS transition period to 2033 is from 2020, when Bangladesh took advantage of the extended TRIPS patent transition period for LDCs by manufacturing a version of the medication *remdesivir* for treatments of COVID-19 via a generic manufacturer. The medication had been patented in many other countries, but the transition period made it possible to utilize the patent without having to enforce the patent.[166] Beyond this example, the flexibility provided by the transition period has not been used during the COVID-19 pandemic, at least at the time of writing this thesis.

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[161] WHO, *Overall Programme Review of the Global Strategy and Plan of Action On Public Health, Innovation and Intellectual Property, Report of the Review Panel* (November 2017), pp. 37-38, 40, 52, 63 <https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/gspa/gspa-phi3011rev.pdf?sfvrsn=c66f768b_5>, last accessed 27 January 2022.

[162] Indeed, R&D does exist in developing countries as well, but the growth of it initiated by TRIPS has been less evident, except for actors such as India, which produces significant amounts of pharmaceutical products and components. GSPA-PHI, p. 48.

[163] The GSPA-PHI report from 2017 mentions as an example of these type of open IP pooling initiatives the case of the "Malaria Box", which was an initiative to bring partly patented material to the public upon request and asking for exchange to get presented with the research findings gained with the material provided by the pool. See, GSPA-PHI, p. 49. A similar initiative regarding COVID-19 called the "COVID Box" was launched by same organization (Medicines for Malaria Venture) in 2020. See, WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2020), p. 12.

[164] WHO, *Overall Programme Review of the Global Strategy and Plan of Action On Public Health, Innovation and Intellectual Property, Report of the Review Panel* (November 2017), p. 53 <https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/gspa/gspa-phi3011rev.pdf?sfvrsn=c66f768b_5>, last accessed 27 January 2022.

[165] *Ibid*.

[166] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2020), p. 8.

Later in 2018, the WHO Director-General in a report review discussed the GSPA-PHI strategy and recommended further actions based on the previous strategy for both Members and the WHO Secretariat, some of which were stated as "high-priority". As an example, it suggested that both parties should put efforts into growing developing country research capabilities and that the WHO Secretariat should investigate and report on how the TRIPS Article 66.2 "could be implemented more effectively in relation to health technology transfer". In addition, the suggestions urged the WHO Secretariat to promote TRIPS flexibilities to be implemented in Members' regulations even further, and that it should support cooperation between countries in relation to health products. Lastly, it suggested that the WHO Secretariat should establish a system for accountability and the monitoring of the implementation of the GSPA-PHI strategy by frequent reporting.[167]

### 3.3.2 International Organizations and COVID-19

The above-mentioned suggestions were later encouraged by the WHO Health Assembly when it also urged the Director-General for a report of the implementation in later World Health Assembly meetings.[168] In a 2021 report on the implementation of the GSPA-PHI strategy, the guiding principles were (re)introduced. As an example, the principles included that "the enjoyment of the highest attainable standard of health" is a right despite one's nationality or status, and that "intellectual property rights do not and should not prevent Member States from taking measures to protect public health." The report further highlighted the importance of "strengthening of the innovative capacity of developing countries" in combating public health issues. Finally, the report stated that while IP plays a great role in incentivizing innovation, it on its own is not enough to meet the need in markets, where the "potential paying market is small or uncertain". It did not directly discuss COVID-19-related strategies, but rather generally brought forward the message that work needed to be done in implementing the strategy.[169]

Furthermore, the pandemic has highlighted the importance of implementing the GSPA-PHI strategy and revealed differences in circumstances for interpretation between both high and low

[167] WHO, Seventy-First World Health Assembly, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, Report by the Director-General,* WHO Doc. A71/13 (15 March 2018), Annex para. 4 (p. 3), Recommendations paras. 8, 14. (p. 5), para. 16 (p. 6), para. 32 (p. 8).
[168] WHO, Seventy-First World Health Assembly, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property: Overall Programme Review,* WHO Doc. WHA71(9) (25 May 2018), para. (4).
[169] WHO Executive board, 148th session, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, Report by the Director-General,* WHO Doc. EB148/10 (11 January 2021), Annex paras. 7.(b), (d), (f), (i).

manufacturing capacity countries and those with either small or large market power. The solution to solve the COVID-19 pandemic includes measures such as "increased manufacturing capacity, voluntary sharing of intellectual property, data and knowledge, and licensing, for example, through C-TAP (COVID-19 Technology Access Pool)", which also are "essential to concretely bring results on [the] implementation of the GSPA-PHI".[170] The plan was later criticized by the South Centre, an intergovernmental organization for developing countries, as not being ambitious enough and relying too much upon the actions of the WHO Secretariat instead of imposing duties on individual Member States. South Centre also stated that more detailed reports and briefings would be necessary to understand the level of implementation.[171]

In the seventy-fourth World Health Assembly held in May/June 2021, e.g., Bangladesh commented that despite previous efforts, the presented new "initiatives have not been effectively operational yet". It further argued that "TRIPS flexibilities should be used to ensure that intellectual property rules do not hamper the development of local production capacity and the building of technological capacities", and further highlighted the importance of Article 66.2 and the implementation of GSPA-PHI. It also urged WHO to make further efforts to boost vaccine manufacturing through, inter alia, either compulsory or voluntary licensing.[172] In a similar vein, Indonesia stated that one reason for the inequalities and insufficiencies in vaccine distribution that affected especially low- and middle-income countries, had been that the world had relied too much on a "handful" of pharmaceutical manufacturers, calling for more support toward domestic manufacturing.[173]

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[170] WHO, *Informal Consultation on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, Summary Report* (3 December 2020), paras. 4, 9, <https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/gspa/summary-report-gspa-phi-informal-consultation-3-december-2020-as-at-12-january-2021.pdf?sfvrsn=62b12074_3&download=true>, last accessed 1 February 2022.

[171] WHO, Seventy-Fourth World Health Assembly, *South Centre Statement for the 74th World Health Assembly Item 13.4: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (Assembly held 24 May - 1 June 2021), p. 1 <https://apps.who.int/gb/statements/WHA74/PDF/South-Centre-13.4.pdf>, last accessed 3 February 2022.

[172] WHO, Seventy-Fourth World Health Assembly, *Statement by Bangladesh, Agenda Item 13.4: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property; and Item 13.7: Standardization of Medical Devices Nomenclature* (Assembly held 24 May - 1 June 2021), pp. 1-2 <https://apps.who.int/gb/statements/WHA74/PDF/Bangladesh-13.4-13.7.pdf>, last accessed 2 February 2022.

[173] WHO, Seventy-Fourth World Health Assembly, *Statement from the Delegation of the Republic Indonesia on Agenda item 13.4, 13.6, and 13.7* (Assembly held 24 May - 1 June 2021), p. 1 <https://apps.who.int/gb/statements/WHA74/PDF/Indonesia-13.4-13.6-13.7.pdf>, last accessed 2 February 2022.

In the same meeting, some Members such as the Philippines[174], Kenya[175], and Tanzania[176] referenced again the need for an IP waiver. Furthermore, the EU delegation highlighted that fast and equal access to e.g., vaccines is crucial, and stated that the EU at the time of giving the statement, was exporting the majority of COVID-19 vaccines globally and noted that further active cooperation was still needed. The delegation noted further that the EU's efforts to help the cooperation and the situation overall included measures such as, creating functioning circumstances "by strengthening regulatory frameworks -- and stimulating the voluntary transfer of technology and know-how", while in addition highlighting the importance of adequate competition on the market "for affordable, high-quality and safe health technologies".[177]

Moreover, another comment was provided in the same meeting by a joint statement from a total of over 40 Member States, including both developed and developing countries, which had previously in May 2020 started the initiative "Solidarity Call to Action: To realize equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data", which had led to the creation of the COVID—19 Technology Access Pool ("**C-TAP**") discussed later in Section 4.3.3. The joint statement argued that the pandemic had made it essential to find new solutions to answer public health concerns now and in the future, and that cooperation between different stakeholders from companies to governments and international organizations was more important than ever. The statement concluded that even despite positive development, the Solidarity Call to Action groups' efforts were still to reach their fullest potential. Thus, the group argued for relevant parties "to join the solidarity call to action, to use the C-TAP platform and ensure that humanity can turn the page and start its way to recovery".[178]

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[174] WHO, Seventy-Fourth World Health Assembly, *Statement from the Republic of the Philippines on Agenda items 13.4, 13.6, and 13.7* (Assembly held 24 May - 1 June 2021), p. 1 <https://apps.who.int/gb/statements/WHA74/PDF/Philippines-13.4-13.6-13.7.pdf>, last accessed 2 February 2022.

[175] WHO, Seventy-Fourth World Health Assembly, *Statement from the Republic of Kenya, National Statement on Agenda 13.4: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property; 13.6: Substandard and Falsified Medical Products; and 13.7: Standardization of Medical Devices Nomenclature* (Assembly held 24 May - 1 June 2021), p. 1 <https://apps.who.int/gb/statements/WHA74/PDF/Kenya-13.4-13.6-13.7.pdf>, last accessed 2 February 2022.

[176] WHO, Seventy-Fourth World Health Assembly, *Statement from the United Republic of Tanzania, Agenda Items 13.4, 13.6, and 13.7* (Assembly held 24 May - 1 June 2021), p. 1 <https://apps.who.int/gb/statements/WHA74/PDF/Tanzania-13.4-13.6-13.7.pdf>, last accessed 3 February 2022.

[177] WHO, Seventy-Fourth World Health Assembly, *Draft European Union Statement on Agenda items 13.4, 13.6, and 13.7* (Assembly held 24 May - 1 June 2021), p. 3 <https://apps.who.int/gb/statements/WHA74/PDF/UE-13.4-13.6-13.7.pdf>, last accessed 3 February 2022.

[178] WHO, Seventy-Fourth World Health Assembly, *Joint Statement on Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property, Committee A, Agenda Item 13.4* (Assembly held 24 May -

Moreover, other international non-profit organizations have presented initiatives aiming to push for further R&D and to address COVID-19 equality issues. One example is the non-profit called Drugs for Neglected Diseases initiative ("**DNDi**"), which launched a separate initiative called COVID-19 Clinical Research Coalition together with other industry organizations at the start of the pandemic, keeping in mind especially the needs of developing countries. It stated that what it feared at the start of the pandemic, had proven to be true, i.e., that "wealthy countries have access to vaccines, while millions of people in low-and middle-income countries are still waiting for their first shots".[179] However and naturally, many of these organizations focus on R&D and less is discussed about general IP policies in this connection.

Lastly, while not necessarily considered international organizations in the international law sense, civil society organizations are important subjects as well, especially in matters relating to access to medicine and making a sure effort is put in place to make pharmaceutical access a reality. In fact, they have been active during COVID-19. One example would be the Doctors Without Borders organization (Médecins Sans Frontières)[180], which has been active in commenting e.g., the TRIPS waiver as has already and will be discussed in more detail later. In the following Chapter I will discuss these organizations and other subjects' initiatives in more detail.

1 June 2021), pp. 1-3 <https://apps.who.int/gb/statements/WHA74/PDF/Costa_Rica-13.4.pdf>, last accessed 2 February 2022.

[179] COVID-19 Clinical Research Coalition, 'About Us', <https://covid19crc.org/about-us/>, last accessed 25 January 2022.

[180] Johanna Gibson, *Intellectual Property, Medicine and Health: Current Debates* (Ashgate Publishing Limited 2009), pp. 141, 143.

# 4 APPLICATION AND ISSUES IN INTERNATIONAL IP REGULATION DURING COVID-19

A central issue with the COVID-19 pandemic and IP rights has been the search for the optimal solution to fit all needs and wants, and determining whether that would mean e.g., the proposed TRIPS waiver to boost manufacturing and distribution or utilizing the IP system to the advantage of the pandemic, e.g., through TRIPS flexibilities.[181] Regardless of the attempts to equalize vaccine distribution, wealthy countries have gained access to vaccine doses that could cover their entire nations' populations multiple times and have already provided multiple boosters to their populations, while the lack of vaccine access is still prohibiting many other countries from vaccinating their populations.[182] Moreover, vaccine production and IP rights of COVID-19 vaccines lie mostly in the hands of high-income countries and pharmaceutical manufacturers in these countries. A direct impact of this concentration of power has reduced the possibilities to compete and reduced overall pharmaceutical product access.[183] This creates the question of how IP has been implemented and used in efforts to equalize distribution, which is exactly what we will investigate in this chapter.

## *4.1 Current Situation*

> *"The scarcity of COVID-19 vaccine supplies [has] led to a situation in which around 75 countries are able to move ahead with vaccination while 115 countries wait as people die".*[184]

Early in the pandemic in 2020, multiple documents on COVID-19 response were released by international organizations as addressed earlier. Among them, a UN General Assembly resolution on equal access to COVID-19-related pharmaceuticals, including vaccines, was released. The resolution stated that equal access to necessary medical supplements and products

[181] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 15.
[182] COVID-19 Clinical Research Coalition, 'COVID-19 Vaccine Access, Achieving Equitable Access to Quality COVID-19 Vaccines, Using Digital, AI, and GIS Tools' (January 2022), p. 3 <https://covid19crc.org/wp-content/uploads/2022/01/Vaccine-Access-Report_6-January.pdf>, last accessed 3 March 2022.
[183] Marianne Meijer et al, 'COVID-19 Vaccines a Global Public Good? Moving Past the Rhetoric and Making Work of Sharing Intellectual Property Rights, Know-How and Technology', (2021) 31(5) European Journal of Public Health 925, pp. 925-926 <https://doi.org/10.1093/eurpub/ckab144>, last accessed 4 March 2022.
[184] Quote from WTO's Director-General Ngozi Okonjo-Iweala on 9 March 2021 from a speech she gave at the Global C19 Vaccine Supply Chain and Manufacturing Summit pleading for the acceleration of vaccine distribution and manufacturing to developing countries. See WTO, 'DG Calls on COVID-19 Vaccine Manufacturers to Increase Production in Developing Countries' (9 March 2021), <https://www.wto.org/english/news_e/news21_e/dgno_09mar21_e.htm>, last accessed 11 January 2022.

is at the heart of stopping the pandemic, and urged States to prevent "undue stockpiling" that could cause unequal access to relevant medical products.[185] Further, a 2020 World Health Assembly resolution on COVID-19 response early on in the pandemic urged international organizations and other relevant parties to collaborate relating to e.g. COVID-19 medication and vaccine sharing, using measures "including, existing mechanisms for voluntary pooling and licensing of patents in order to facilitate timely, equitable and affordable access", taking into consideration e.g., TRIPS, its flexibilities and the Doha Declaration.[186] More recently, the issue regarding vaccine distribution has changed from the actual number and supply of vaccines to delivery and storage challenges due to infrastructure and medical staff inadequacies, in addition to general caution towards the vaccines.[187]

Global collaboration between different stakeholders has been highlighted as the solution to the pandemic, and a myriad of initiatives have been launched in an effort to capture this collaborative goal.[188] Below, I will discuss the most relevant ones in terms of IP, but it is crucial to note that many other initiatives and efforts exist beyond the ones mentioned here – leaving them out of this paper does not mean that they are of less importance. These initiatives include, among others, the "#Vaccines4All" campaign by the President of the UN General Assembly, and multiple COVID-19 workshops, events, and high-level discussions led by the WTO and the WHO, such as the "Vaccine Supply Chain and Regulatory Transparency Technical Symposium" in 2021, to mention a few.[189]

Furthermore, COVID-19 has introduced many initiatives in relation to vaccine distribution and technology transfers. These include the COVAX initiative, the Access to COVID-19 Accelerator program ("**ACT-A**"), and the already mentioned C-TAP. The pandemic has in addition highlighted the importance of the Doha Declaration.[190] The global need for fast

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[185] UN General Assembly, Seventy-Fourth Session, *Resolution Adopted by the General Assembly on 20 April 2020, International cooperation to ensure global access to medicines, vaccines, and medical equipment to face COVID-19*, UN Doc. A/RES/74/274 (21 April 2020), paras. 2-4.
[186] WHO, Seventy-Third World Health Assembly, *Agenda Item 3, COVID-19 Response*, WHO Doc. WHA73.1 (19 May 2020), para. 8(2).
[187] COVID-19 Clinical Research Coalition, 'COVID-19 Vaccine Access, Achieving Equitable Access to Quality COVID-19 Vaccines, Using Digital, AI, and GIS Tools' (January 2022), p. 22 <https://covid19crc.org/wp-content/uploads/2022/01/Vaccine-Access-Report_6-January.pdf>, last accessed 3 March 2022.
[188] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 13.
[189] See, e.g., *ibid*, p. 13.
[190] WHO, *Informal Consultation on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, Summary Report* (3 December 2020), paras. 4, 8 <https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/gspa/summary-report-gspa-phi-informal-consultation-3-

technology R&D has introduced new levels of national financing needs as well, and in the EU, for example, a temporary exception for granting state aid directly towards COVID-19 was allowed, conditioned to aid receivers committing to the European Economic Area wide non-exclusive licenses.[191] In 2021, Access to COVID-19 Tools Accelerator announced that there is an additional need for COVID-19 R&D funding of $16.7 billion.[192]

Many commentators have brought out that IP barriers in connection to the pandemic should be removed and that IP should not stand in the way of vaccine and other medical supply distribution. However, to my view, IP is referred to generally rather than naming out any specific rules or TRIPS Articles that are hindering the process of technology transfers. Patent rights are referred to as a blocking obstacle as well, but more often, the criticism and discussions that revolve around the IP system seem at times vague due to their non-specific. One possible reason for this lack of specificity might be that it is hard to name purely one IP right or provision that would be the sole reason for a multitude of problems in connection to COVID-19. Regardless, this has made it questionable whether IP can be seen as a genuine concrete block in the way of equal vaccine access.

Moreover, in a trilateral WIPO-WHO-WTO report introduced in 2020 which talked about then vaccine candidate developed at Oxford University, it was stated that at the time of publication, the vaccine was "licensed to an originator pharmaceutical company for manufacture", but that the "originator company has committed to supplying the vaccine globally on a no-profit basis and has signed an agreement with an Indian-based manufacturer allowing for the latter to supply low- and middle-income countries".[193] More specifically, the manufacturer stated that the agreement was one of their commitments towards "broad and equitable global access to the University of Oxford's COVID-19 vaccine".[194] This originator company was in fact AstraZeneca, which later became one of the major manufacturers of COVID-19 vaccines. As

december-2020-as-at-12-january-2021.pdf?sfvrsn=62b12074_3&download=true>, last accessed 1 February 2022.

[191] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 12.

[192] *Ibid*, p. 12.

[193] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2020), p. 10.

[194] AstraZeneca, 'AstraZeneca Takes Next Steps Towards Broad and Equitable Access to Oxford University's COVID-19 Vaccine' (4 June 2020), <https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-covid-19-vaccine.html>, last accessed 14 February 2022.

an important note, however, a lot had and has happened in terms of the spread of COVID-19 after the initial publication of both the trilateral publication and the news article by the manufacturer stating the collaboration with the Indian manufacturer, meaning that later circumstances have inevitably affected the original commitments as defined in mid-2020.

As of 28 March 2022, a total of 13.3 billion COVID-19 vaccine doses had been distributed globally, and around 1.4 billion of these were via the COVAX facility and 1.1 billion had been donated. By that date, vaccine manufacturers had agreed to 527 supply agreements globally. The African continent has been overly dependent on importations, and only 11 agreements between vaccine developers and producers from African countries are in place. However, as an example, the creation of the South African COVID-19 vaccine mRNA Technology Transfer Hub is expected to increase this number, in addition to added local manufacturing hubs.[195] The COVAX facility and the Technology Transfer Hub will be discussed later in Sections 4.3.1 and 4.3.5.

Furthermore, at an event initiated by the Independent Panel on Pandemic Preparedness and Response in 2021, it was concluded that the current pandemic's response has not been able to shift the global vaccine distribution to an equal direction, due to hurdles caused by e.g., profit-seeking and "vaccine nationalism", leaving the risk that the same could happen in future pandemics. This also left a need for a global pandemic response agreement to create clearer structures for the future.[196] These factors will be considered in this and the next Chapter as well.

Finally, to highlight the inequalities in vaccine distributions, I have introduced the graph below. From the graph, one can see the distribution of vaccines per country income group and as a comparison, the total population of that specific country income group (as of 31 January 2022):

[195] UNICEF, 'COVID-19 Vaccine Market Dashboard' (28 March 2022), <https://mailchi.mp/unicef/unicef-covid-19-vaccine-market-dashboard-update-15927078?e=7ea6d8cc0d>, last accessed 26 April 2022.
[196] Rohit Ramchandani et al, 'Vaccines, Therapeutics, and Diagnostics for COVID-19: Redesigning Systems to Improve Pandemic Response' [2021] 375 BMJ, p. 3 <https://www.bmj.com/content/bmj/375/bmj-2021-067488.full.pdf> last accessed 7 February 2022.

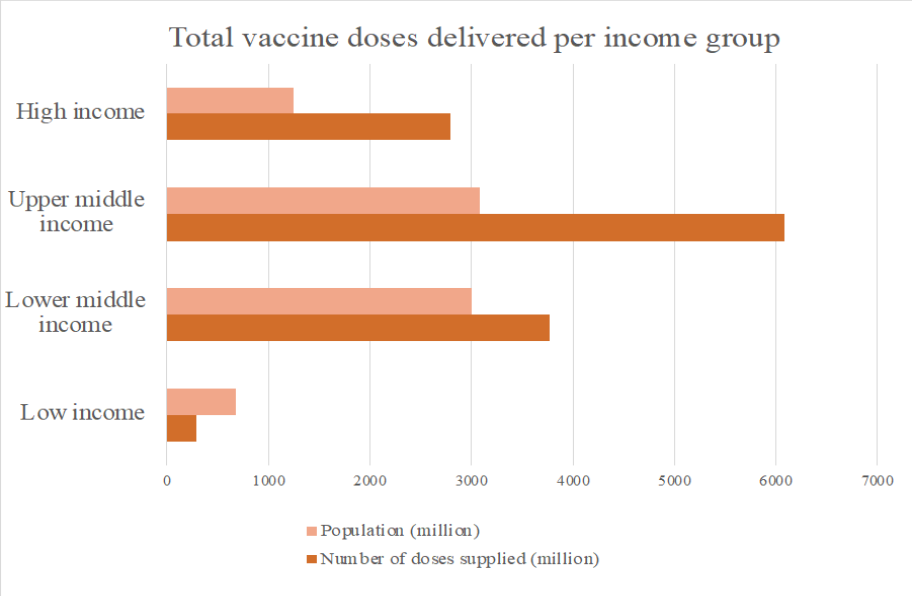


*Chart 1: Total vaccine doses delivered per income group as of 31 January 2022*[197]

We can gather from the above graph that while high-income countries have received over twice the amount of vaccine doses in comparison to their population, low-income countries have received less than half of the number of doses compared to the size of their population. This is a meaningful consideration to keep in mind, especially since the total population of low-income countries in comparison to higher-income ones is much smaller, but the delivered dose number is a fraction of the globally delivered vaccine doses.

Next, we will discuss the relationship between TRIPS and COVID-19 and the TRIPS waiver that was briefly discussed earlier as well, after which we will look into different IP-related vaccine and pharmaceutical initiatives during the pandemic.

### *4.2 TRIPS and COVID-19*

TRIPS has never had the meaning to "cause the suffering and death of innocent people", as was argued already during the HIV/AIDS pandemic. Opponents of introducing the agreement argued that TRIPS has exactly had this effect. Moreover, one argument that has been presented in connection to insufficiencies caused by TRIPS, has been the idea that TRIPS flexibilities were not used by developing countries during the HIV/AIDS crisis because of the fear of

[197] Chart data adopted from WTO, 'WTO-IMF COVID-19 Vaccine Trade Tracker', <https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm>, last accessed 14 March 2022.

political backlash.[198] This is rather contradictory in comparison to what the flexibilities were meant for, which was to help especially lower-income countries and in situations of e.g., public health crises. Moreover, some studies have suggested that by introducing common global IP rules through TRIPS, innovation, in general, has improved but access to medicine has not.[199]

In October 2020, WTO published an information note on the relationship between TRIPS and COVID-19. In it, the use of the IP system is referred to as being a useful tool for supporting cooperation activities between different stakeholders, and in connection to TRIPS, many possibilities for different policies are still available during COVID-19, referring to especially compulsory and government-use licensing. It also acknowledges that "appropriate measures" can be taken based on e.g., TRIPS Article 8.2 to respond to actions that "adversely affect the international transfer of technology", but also that countries have room for individual approaches regarding e.g., granting patents at a faster pace or prioritizing IP applications related to public health and COVID-19 innovations.[200]

Moreover, the above note further refers to TRIPS Article 30 which gives countries the possibility to grant limited exceptions to the rights incurring from a patent.[201] An exception like this may not "unreasonably conflict with a normal exploitation of the patent" and does not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".[202] Possible exceptions to be implemented into national legal systems relevant to the pandemic include 1) "research and experimental use exception" which allows the use of a patent for research is allowed, and 2) "regulatory review exception", also known as the "Bolar" exception, which enables other manufacturers to use a patent to get marketing approval for a generic version of the patented product before the patent period has come to an end. For COVID-19, the latter was determined as potentially relevant for situations where a patent period of a medication or treatment is coming near its end.[203]

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[198] Sevil N-Marandi, 'Framing and Reframing Global Patent Policy, Implications on Access to Medicine in Developing Countries' (2009) 1(1) Public Policy & Governance Review 128, pp. 136-138 <https://ppgr.files.wordpress.com/2010/08/1-1-framingrefamingpatentpolicy.pdf>, last accessed 8 February 2022.
[199] *Ibid*, pp. 138-139.
[200] WTO, *Informational Note: The TRIPS Agreement and COVID-19* (15 October 2020), pp. 1-3, 6, 8 <https://www.wto.org/english/tratop_e/covid19_e/TRIPS_report_e.pdf>, last accessed 28 February 2022.
[201] *Ibid*, pp. 1-3, 6, 8.
[202] TRIPS Agreement, Art. 30.
[203] WTO, *Informational Note: The TRIPS Agreement and COVID-19* (15 October 2020), p. 8 <https://www.wto.org/english/tratop_e/covid19_e/TRIPS_report_e.pdf>, last accessed 28 February 2022.

As an important note, the above note was written before the mass roll-out of vaccines, meaning that things have shifted since its publishing, which is probably why the text remains somewhat vague in its suggestions and views on the relationship between COVID-19 and TRIPS. Much of the note's content has been covered elsewhere in this paper, including e.g., the discussion on TRIPS Article 31 and compulsory licenses. Regarding compulsory licensing, the note mentions that it does carry the potential to be useful in COVID-19 treatment and vaccine access, especially for countries that would not afford treatments otherwise. TRIPS does not specify the specific requirements for a country to issue a compulsory license, leaving room for their interpretation of necessary qualifications. The note also referred to the potential provided by the "Special Compulsory Licensing System" or the Paragraph 6 System which was discussed above, as it gives countries with little local manufacturing capability the chance to import via compulsory licenses from another manufacturing country that could produce a generic version of the originally patented, but now compulsorily licensed product. The note further commented that "the system serves as a reminder that patent rights are not absolute and that public interest considerations can prevail".[204] The evidence shows that the potential of the system discussed in 2020 before the vaccine roll-out has not been as great as presented, and the system has lacked both effectiveness and interest by Members.

### *4.3 COVID-19-related IP Regimes*

International IP policies have been used on many occasions and ways in efforts to innovate and deliver COVID-19 vaccine doses globally. Some private manufacturers have incorporated measures to promote open-source information access, such as using "non-exclusive and royalty-free licensing", "sharing knowledge to enable others to manufacture and use such technologies", and some have voluntarily issued "non-enforcement declarations of patent rights in some or all jurisdictions". Moreover, an initiative called the "Open COVID Pledge" has been implemented by manufacturers, companies, and universities to share patents and further COVID-19-related information without commission.[205] The Open COVID Pledge was initially launched by efforts from a collaboration of academics, scientists, researchers, and lawyers.[206]

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[204] WTO, *Informational Note: The TRIPS Agreement and COVID-19* (15 October 2020), p. 9 <https://www.wto.org/english/tratop_e/covid19_e/TRIPS_report_e.pdf>, last accessed 28 February 2022.
[205] World Trade Organization, World Health Organization, and World Intellectual Property Organization, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2020), p. 10.
[206] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to*

The Open COVID Pledge includes companies such as Intel, Microsoft, and IBM. Regarding vaccines, Moderna has stated in 2020 that it will not enforce its COVID-19-related vaccine patent rights during the COVID-19 pandemic against other vaccine manufacturers[207] and that after the pandemic, it is open to continuing licensing these COVID-19-related IP rights, however acknowledging that it makes no explicit promises of such.[208] However, as of at least November 2021, no parties had declared that they had taken advantage of Moderna's COVID-19-related IP – other than what has been claimed in relation to the mRNA Technology Transfer Hub initiative which will be discussed in Section 4.3.5 – leaving the question of how effective this pledge has been in tackling the lack of vaccine technologies.[209] As an important note as well, companies do not *in general* usually try to go out of their way to seek IP protection in countries with low expected profits, because the profitability versus the cost ratio does not match. Some companies had also in connection to e.g., HIV/AIDS medication announced that they would not seek to enforce the IP rights in certain less wealthy countries, and a few granted voluntary licenses.[210]

Of the plethora of initiatives, some have proven more successful than others, but much work remains ahead of the global community to reach all vaccination targets. In the following Sections, we will investigate the most central pieces of IP-related vaccine initiatives and finally, evaluate their effectiveness.

### 4.3.1 COVID-19 Tools Accelerator and COVAX

The Access to COVID-19 Tools Accelerator, i.e., ACT-A was established as a global tool to increase COVID-19-related R&D and equality, and bring together different stakeholders from governments, companies, and public health organizations. Even though its efforts and its global platform for cooperation, it has been criticized for the lack of all-encompassing cooperation and

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*Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), pp. 11-12.

[207] WIPO, 'COVID-19 IP Policy Tracker, Voluntary Actions', <https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/voluntary-actions-text>, last accessed 23 February 2022.

[208] Moderna, 'Statement by Moderna on Intellectual Property Matters During the COVID-19 Pandemic' (8 October 2020), <https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic-10-08-2020/default.aspx>, last accessed 23 February 2022.

[209] Nancy S Jecker and Caesar A Atuire, 'What's Yours Is Ours: Waiving Intellectual Property Protections for COVID-19 Vaccines', [2021] 47 Journal of Medical Ethics 595, <https://jme.bmj.com/content/47/9/595>, last accessed 7 March 2022.

[210] The Report states that, at least at the time of the Report, e.g., Roche had stated that "it will not file patents for any of its medicines" in LDCs. WHO Commission on Intellectual Property Rights, Innovation and Public Health, *Report on Public Health, Innovation and Intellectual Property Rights* (World Health Organization 2006), p. 120.

being too focused on product supply instead of focusing on "inclusivity and transparency". One of its four pillars that focuses on vaccines, called COVAX, had by October 2021 delivered only "less than 6 % of the 6.82 billion COVID-19 vaccines" that had in total been globally delivered.[211] COVAX is co-led by three organizations, the Coalition for Epidemic Preparedness Innovations ("**CEPI**")[212], Gavi the Vaccine Alliance ("**Gavi**"), and WHO, with the support of the United Nations International Children's Emergency Fund ("**UNICEF**").[213]

The COVAX facility was established especially keeping in mind the needs and access to vaccines of developing countries. In 2021, COVAX was awarded the "North-South Prize of the Council of Europe" for its efforts toward equitable vaccine access globally.[214] COVAX is donor-funded by 98 higher-income countries that can afford vaccines themselves and supplies free vaccines to 92 lower-income countries.[215] By 4 February 2022, 500 million doses had been donated by 31 countries and vaccine producers, such as Pfizer and AstraZeneca to COVAX, which in total had delivered 1.1 billion doses to 144 countries. However, a funding gap exists prohibiting COVAX to meet the targets that have been set.[216] Moreover, the donations have at times been with very short notice times and short shelf lives, making vaccination planning difficult.[217]

In this connection, human rights and the "right to life and health" play a central role in the COVAX facility's response to the crisis. Accordingly, it has added a "humanitarian buffer" to its offering for use in cases where all other supply options are not possible, e.g., in areas of

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[211] Rohit Ramchandani et al, 'Vaccines, Therapeutics, and Diagnostics for COVID-19: Redesigning Systems to Improve Pandemic Response' [2021] 375 BMJ, p. 1 <https://www.bmj.com/content/bmj/375/bmj-2021-067488.full.pdf> last accessed 7 February 2022.

[212] CEPI is an organization that finances companies in their R&D efforts. CEPI requires the companies it finances to ensure equal access of all vaccines the company produces and requires these companies to use IP in a way that promotes equal access. See, WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 12. And Gavi the Vaccine Alliance, 'Protecting Human Rights in the COVAX Roll-Out' (last update 8 April 2021), <https://www.gavi.org/COVAX-facility/protecting-human-rights>, last accessed 28 February 2022.

[213] WHO, 'COVAX, Working for Global Equitable Access to COVID-19 Vaccines', <https://www.who.int/initiatives/act-accelerator/COVAX>, last accessed 18 February 2022.

[214] Gavi the Vaccine Alliance, 'COVAX Awarded 2021 North-South Prize for Enhancing Global Equitable Access to COVID-19 Vaccines' (21 December 2021), <https://www.gavi.org/news/media-room/COVAX-awarded-2021-north-south-prize-enhancing-global-equitable-access-covid-19>, last accessed 28 February 2022.

[215] Gavi the Vaccine Alliance, 'Protecting Human Rights in the COVAX Roll-Out' (last update 8 April 2021), <https://www.gavi.org/COVAX-facility/protecting-human-rights>, last accessed 28 February 2022.

[216] Gavi the Vaccine Alliance, 'COVAX Crosses Milestone of 500 Million Donated Doses Shipped to 105 Countries' (4 February 2022), <https://www.gavi.org/news/media-room/COVAX-crosses-milestone-500-million-donated-doses-shipped-105-countries>, last accessed 28 February 2022.

[217] Gavi the Vaccine Alliance, 'Joint Statement on Dose Donations of COVID-19 Vaccines to African Countries' (28 February 2022), <https://www.gavi.org/news/media-room/joint-statement-dose-donations-covid-19-vaccines-african-countries>, last accessed 28 February 2022.

conflict.[218] COVAX is not the only organization for vaccine access acceleration, and its mandate is complemented by e.g. that of the African Vaccine Acquisition Trust ("**AVAT**"), which has the target to vaccinate 70 % of the African continent's population.[219] As of 31 January, the African continent has been provided 761.7 million vaccine doses, of which 67,5 % were supplied via COVAX either by donation or agreement and 9,9 % via AVAT; domestic supply was only 1,6 % of the total number. As an example, the total dose number supplied to the European continent was 1 557.5 million doses.[220]

How efficient has COVAX been in its efforts to deliver vaccines? By January 2022, the threshold of the billionth dose of COVID-19 vaccine delivered through COVAX was met. By that point, COVAX had delivered vaccines to 144 countries. COVAX's journey to equalize vaccination distribution has at times been challenged through developed countries' "hoarding/stockpiling", in addition to patent holder companies' "lack of sharing of licenses, technology and know how [and therefore,] manufacturing capacity [has gone] unused", as stated by the WHO.[221] COVAX has also noted that "the lack of political will in several settings" should be addressed and changed because it continues to be a block in vaccine distribution equality.[222]

Moreover, according to Moderna, it delivered 807 million doses of its COVID-19 vaccine globally in 2021. It claims that circa 25 % of these deliveries were to low- and middle-income countries.[223] In late 2021, Moderna made an agreement with Gavi to deliver via it up to 650 million COVID-19 vaccines covering 92 low- and middle-income countries[224], and has also

[218] Gavi the Vaccine Alliance, 'Protecting Human Rights in the COVAX Roll-Out' (last update 8 April 2021), <https://www.gavi.org/COVAX-facility/protecting-human-rights>, last accessed 28 February 2022.
[219] Gavi the Vaccine Alliance, 'Joint Statement on Dose Donations of COVID-19 Vaccines to African Countries' (28 February 2022), <https://www.gavi.org/news/media-room/joint-statement-dose-donations-covid-19-vaccines-african-countries>, last accessed 28 February 2022.
[220] WTO, 'WTO-IMF COVID-19 Vaccine Trade Tracker', <https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm>, last accessed 14 March 2022.
[221] WHO, 'COVAX Delivers Its 1 Billionth COVID-19 Vaccine Dose' (16 January 2022), <https://www.who.int/news/item/16-01-2022-COVAX-delivers-its-1-billionth-covid-19-vaccine-dose>, last accessed 25 January 2022.
[222] WHO, 'What Needs to Change to Enhance COVID-19 Vaccine Access*'* (24 September 2021), <https://www.who.int/news/item/24-09-2021-what-needs-to-change-to-enhance-covid-19-vaccine-access>, last accessed 27 January 2022.
[223] See, e.g., Moderna*,* 'Moderna Receives Full U.S. FDA Approval for COVID-19 Vaccine Spikevax' (31 January 2022), <https://investors.modernatx.com/news/news-details/2022/Moderna-Receives-Full-U.S.-FDA-Approval-for-COVID-19-Vaccine-Spikevax-01-31-2022/default.aspx>, last accessed 24 February 2022.
[224] Moderna, 'Moderna Announces Additional 20 Million Doses of COVID-19 Vaccine to COVAX for Supply in 2021 and New Additional Supply Agreement for 2022' (10 December 2021), <https://investors.modernatx.com/news/news-details/2021/Moderna-Announces-Additional-20-Million-Doses-of-COVID-19-Vaccine-to-COVAX-for-Supply-in-2021-and-New-Additional-Supply-Agreement-for-2022-12-10-2021/default.aspx>, last accessed 28 February 2022.

made a long-term supply agreement with UNICEF and COVAX[225], and a supply agreement with Botswana, as an example, which according to themselves "reflects Moderna's commitment to mak[ing] its vaccine available in Africa"[226]. As a comparison, by 16 June 2021, the US government had ordered a total of 500 million COVID-19 vaccine doses from Moderna[227].

Despite its efforts and achievements, COVAX has been criticized for its focus to develop and distribute the vaccines (and other medical products) as fast as possible, leaving out creating a specific strategy with clear steps and specific considerations of low- and middle-income countries, such as those related to the supply chain issues. The need for speedy delivery led to utilizing the "usual market based approach", which relies on R&D for higher-income countries and thereafter, their donations and efforts to distribute products in question forward to other countries, instead of creating a system of collective cooperation e.g., by sharing relevant technologies across all countries.[228] COVAX has stated itself that its focus is not on IP rights, because regarding patents, the sheer availability of them is not enough – making use of them requires specific know-how and includes "high start-up costs". In 2021, it commented that the key constraint is supply issues, not IP.[229]

Why COVAX remains very much relevant to the topic of this thesis, despite its non-IP attachment, is because in my view this non-IP approach highlights the core issues even more. It seems clear that without an organization like COVAX, the vaccination rate in lower-income countries would be even lower than what it currently is, and that the system works only because of the heavy donations by developed countries, as not sharing relevant IP, and thus empowering developing and lower-income countries prevents them from producing the vaccines themselves. COVAX has been a great achievement, but it ignores the greater possibilities in using IP for

[225] Moderna, 'UNICEF and Moderna Announce Long Term Agreement to Supply Vaccine on Behalf of the COVAX Facility' (2 June 2021), <https://investors.modernatx.com/news/news-details/2021/UNICEF-and-Moderna-Announce-Long-Term-Agreement-to-Supply-Vaccine-on-Behalf-of-the-COVAX-Facility-06-02-2021/default.aspx>, last accessed 28 February 2022.
[226] Moderna, 'Moderna Announces Agreement to Supply the Republic of Botswana With Its COVID-19 Vaccine' (3 June 2021), <https://investors.modernatx.com/news/news-details/2021/Moderna-Announces-Agreement-to-Supply-the-Republic-of-Botswana-with-its-COVID-19-Vaccine-06-03-2021/default.aspx>, last accessed 28 February 2022.
[227] Moderna, 'U.S. Government Purchases Additional 200 Million Doses of Moderna's COVID-19 Vaccine' (16 June 2021), <https://investors.modernatx.com/news/news-details/2021/U.S.-Government-Purchases-Additional-200-Million-Doses-of-Modernas-COVID-19-Vaccine-06-16-2021/default.aspx>, last accessed 28 February 2022.
[228] Rohit Ramchandani et al, 'Vaccines, Therapeutics, and Diagnostics for COVID-19: Redesigning Systems to Improve Pandemic Response' [2021] 375 BMJ, pp. 1-2 <https://www.bmj.com/content/bmj/375/bmj-2021-067488.full.pdf> last accessed 7 February 2022.
[229] Gavi the Vaccine Alliance, 'Protecting Human Rights in the COVAX Roll-Out' (last update 8 April 2021), <https://www.gavi.org/COVAX-facility/protecting-human-rights>, last accessed 28 February 2022.

good and e.g., sharing relevant knowledge with developing countries. In my view, a donor-heavy system is a very risky system to rely on, as during this pandemic it has seemed to start gaining momentum only after enough doses have been secured by high-income countries. An important notion is, however, that other initiatives, especially the Medicines Patent Pool and the mRNA Technology Transfer Hub have been put in place to cover some of the issues I have mentioned here, which will be discussed shortly below.

### 4.3.2 PATENTSCOPE

Another initiative has been launched by the World Intellectual Property Organization, which is a specific "COVID-19 search facility" within its already existing database called PATENTSCOPE. In addition to this, individual states and coalitions, such as the EU, China, and a coalition between Argentina, Brazil, Chile, Colombia, Ecuador, Peru, and Uruguay have launched similar platforms to share COVID-19-related technology patents, related information, and analysis. The US has launched a "COVID-19 Prioritized Examination Pilot Program" to ease the analysis of COVID-19-related patent applications. Overall, the availability of patent information is said to help in further COVID-19-related R&D, including research patentability exceptions that many countries offer in their national IP systems.[230] In my research, little information was found on the use of the PATENSCOPE system, or the other systems mentioned here, and therefore this initiative is mentioned only briefly.

### 4.3.3 COVID-19 Technology Access Pool

Another central initiative called the COVID-19 Technology Access Pool ("**C-TAP**") was launched by WHO in May 2020 after a proposal from Costa Rica, together with the previously mentioned initiative "Solidarity Call to Action".[231] The Call to Action's mission was and is "To realize equitable global access to COVID-19 health technologies through the pooling of knowledge, intellectual property and data." In terms of IP, it urged governments and R&D financers to promote equal access and open sharing of IP, global accessibility of publicly funded COVID-19 R&D, and non-restricted licensing of R&D innovations. It urged IP holders to e.g., grant voluntary licenses to the Medicines Patent Pool or other related systems, share necessary

[230] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2020), p. 9.
[231] *Ibid*, p. 11.

data, IP and knowledge and refrain from IP enforcement. Further, it urged researchers to share research data as well. Finally, it urged all stakeholders to e.g., utilize the C-TAP in information, IP, technology, and knowledge sharing to allow for "effective technology transfer".[232]

Consequently, the Call was later signed by 39 more States, both from developed and developing countries, but mostly from the latter.[233] As an example, the US or the EU did not – at least at the time of publication – sign the initiative. However, in March 2022, the Biden administration declared that the United States National Institutes of Health will share COVID-19-related technologies, including vaccines, to C-TAP on a voluntary and non-exclusive basis, which could enable their licensing through the Medicines Patent Pool.[234] However, the types of technologies that will or would be offered to C-TAP were not shared, meaning that the actual effect of this declaration will remain to be seen.

Furthermore, patent pooling as a solution to issues in access to medicine is not a new phenomenon. Similar proposals have been seen e.g., by UNITAID which had earlier suggested pooling of HIV/AIDS-related medical patents to increase access to needed medication.[235] Patent pools in general have been proposed by many as one solution to removing access barriers to relevant IP. A patent pool would collect patent holders' patents into a system, where others could use them in either direct manufacturing or further R&D. In exchange, the patent holder would be compensated in royalties, the amount and the logistics of which would be decided between the patent holder and the pool.[236] However, in creating COVID-19 vaccines, IP rights have affected the process of manufacturing especially, as technology transfers and licensing have been limited and geographically concentrated, and platforms such as C-TAP have not been utilized in their full capacity.[237] Moreover in general, in order for patent pools to work, enough licensed patents are needed, the terms of which must also be enticing for companies to make

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[232] WHO, 'Solidarity Call to Action, Making the Response to COVID-19 a Public Common Good' (29 May 2020), <https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action>, last accessed 15 February 2022.
[233] WHO, 'Solidarity Call to Action, Making the Response to COVID-19 a Public Common Good' (29 May 2020), <https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action>, last accessed 15 February 2022.
[234] WHO, 'WHO and MPP Welcome NIH's Offer of COVID-19 Health Technologies to C-TAP' (3 March 2022), <https://www.who.int/news/item/03-03-2022-who-and-mpp-welcome-nih-s-offer-of-covid-19-health-technologies-to-c-tap>, last accessed 8 March 2022.
[235] Cynthia M. Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (Oxford University Press 2011), p. 359.
[236] Richard Gold et al, 'Are Patents Impeding Medical Care and Innovation?' (2010) 7(1) PLoS Medicine, p. 4 <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1000208&type=printable>, last accessed 16 February 2022.
[237] Rohit Ramchandani et al, 'Vaccines, Therapeutics, and Diagnostics for COVID-19: Redesigning Systems to Improve Pandemic Response' [2021] 375 BMJ, p. 3 <https://www.bmj.com/content/bmj/375/bmj-2021-067488.full.pdf> last accessed 7 February 2022.

use of the pool. A key question is the willingness of companies to license to the pool, leaving a lot of responsibility again on voluntary actions.[238]

### 4.3.4 Medicines Patent Pool

Perhaps one of the most commented instruments in IP-related policy reforms in an effort to speed up COVID-19 R&D is the Medicines Patent Pool ("**MPP**"). MPP launched its database called "Medicines, Patents and Licenses" ("**MedsPaL**") in response to the GSPA-PHI strategy that has been discussed before in Section 3.3.1 even before the pandemic. Later during the COVID-19 pandemic, MPP widened its scope to include information on different COVID-19 medications as well.[239] More recently, a similar database for vaccines was launched ("**VaxPal**"), which compiles COVID-19 patent information into one database.[240] However, as the database acknowledges, the information compiled might not include all current information, and the use of VaxPal does not imply that the patented information can be used directly, or as it states itself, "VaxPal is not a freedom to operate analysis" platform, but rather a collection of available data from multiple sources in one place.[241]

Furthermore, MPP has launched various other initiatives as well. In late 2020, eighteen generic pharmaceutical manufacturers announced a collaboration with the Medicines Patent Pool to aid in equal COVID-19-related medical product distribution. The collaboration was at the time described as "a breakthrough" in MPP's work on ensuring equal treatment access.[242] However, the announcement was made rather early on in the timeline of the vaccine rollout, and the efforts, in reality, have not met the great initial expectations set beforehand.

Regarding medication, MPP agreed with pharmaceutical manufacturers Merck and Pfizer on releasing COVID-19-related voluntary "non-exclusive sub-licenses" on the companies' potential antiviral medications (i.e., not vaccines). These agreements were the first use of MPP

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[238] Cynthia M. Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (Oxford University Press 2011), pp. 361-362

[239] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2020), p. 9.

[240] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 8.

[241] MPP, 'VaxPal', <https://medicinespatentpool.org/what-we-do/vaxpal>, last accessed 16 February 2022.

[242] MPP, 'Leading Generic Drug Makers Unite to Pledge Capacity for Developing and Delivering Affordable COVID-19 Interventions as Pandemic Intensifies' (12 November 2020), <https://medicinespatentpool.org/news-publications-post/covid-19-generic-pledge-press-release>, last accessed 16 February 2022.

during this pandemic and were seen as a step forward but were also criticized for leaving out some relevant countries from the jurisdiction in which generic producers could challenge patents and thus, start manufacturing the medication.[243] Regarding the agreement between Merck and MPP, Merck and other IP holders are not entitled to royalties from the particular agreements during the COVID-19 pandemic[244], and the same goes with the agreement between Pfizer and MPP; Pfizer will not receive royalties in low-income countries in general, and will not receive royalties elsewhere either during the pandemic. The agreement was claimed to be in line with Pfizer's goal "to work toward equitable access to COVID-19 vaccines and treatments for all people, particularly those living in the poorest parts of the world".[245]

Later in January 2022 progress was made, as 27 generic pharmaceutical producers in Asia and Africa entered into non-exclusive sub-licensing agreements with the MPP to start the production of COVID-19 oral medication *molnupiravir*, to provide for low- and middle-income countries. These sub-licenses were created out of the licensing agreement between Merck and the MPP in late 2021.[246] As of April 2022, MPP does not include IP related to COVID-19 vaccines. In other words, MPP has not been as central in vaccine development as has been presented in advance, but rather has been somewhat used in connection to e.g., oral COVID-19 medication.

### 4.3.5 mRNA Technology Transfer Hub

In 2021, WHO announced it was planning to establish an "mRNA Technology Transfer Hub" in collaboration with a South African consortium leading the hub. The hub's goal was to promote accessibility in low- and middle-income countries by supporting national

[243] The Independent Panel for Pandemic Preparedness & Response, 'Losing Time: End This Pandemic and Secure the Future, Progress Six Months After the Report of the Independent Panel for Pandemic Preparedness and Response' (22 November 2021), p. 21 <https://theindependentpanel.org/wp-content/uploads/2021/11/COVID-19-Losing-Time_Final.pdf>, last accessed 4 February 2022.
[244] MPP, 'The Medicines Patent Pool (MPP) and MSD Enter into License Agreement for *Molnupiravir*, an Investigational Oral Antiviral COVID-19 Medicine, to Increase Broad Access in Low- and Middle-Income Countries' (27 October 2021), <https://medicinespatentpool.org/news-publications-post/mpp-msd-new-license-announcement-molnupiravir>, last accessed 22 February 2022.
[245] MPP, 'Pfizer, and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries' (16 November 2021), <https://medicinespatentpool.org/news-publications-post/pfizer-and-the-medicines-patent-pool-mpp-sign-licensing-agreement-for-covid-19-oral-antiviral-treatment-candidate-to-expand-access-in-low-and-middle-income-countries>, last accessed 22 February 2022.
[246] MPP, '27 Generic Manufacturers Sign Agreements with MPP to Produce Low-Cost Versions of COVID-19 Antiviral Medication *Molnupiravir* for Supply in 105 Low- and Middle-Income Countries' (20 January 2022), <https://medicinespatentpool.org/news-publications-post/27-generic-manufacturers-sign-agreements-with-mpp-to-produce-molnupiravir>, last accessed 22 February 2022.

manufacturers to start domestic COVID-19 vaccine production, by providing the required technology and know-how. The hub carries the potential to expand to other health products as well, giving countries more freedom to operate on a domestic need basis, and is part of a larger goal of strengthening low- and middle-income countries' manufacturing capacity and helping them respond more efficiently to their public health needs. The initiative is also supported by e.g., the MPP, ACT-A, and COVAX. Since its establishment, the hub has initiated "mRNA vaccine production at laboratory scale and is currently scaling up", with the aim to create commercially produced vaccines. On 18 February 2022, the first 6 recipients – Egypt, Kenya, Nigeria, Senegal, South Africa, and Tunisia – were chosen as the first ones to receive the necessary mRNA technology transfers to start the production of COVID-19 vaccines. These countries were set to begin their training in March 2022.[247] Since its creation, the hub has succeeded in recreating Moderna's COVID-19 vaccine on its own.[248]

In addition to sharing the technology, the hub will help the technology recipient countries e.g., with know-how, IP, formulas, and training where necessary in one place. The hub produces vaccines based on available vaccine information for clinical trials and replicates the technology from a patent holder company (who has not been disclosed), who has stated that it will not enforce its patents in the COVID-19 pandemic. IP rights of developed vaccines go to investors but can be freely used by the beneficiary countries of the hub. Moreover, MPP will provide IP-related consultation and help with e.g., contract negotiations. The first approved vaccine after clinical trials could "potentially be in 2024".[249]

Why was the hub established? An argument for the establishment of a Technology Transfer Hub, in general, is that when the demand and supply do not meet, and in cases where there is "limited interest in bilateral agreements", initiatives such as the hub are necessary. Reasons for the establishment of the mRNA COVID-19 Technology Transfer Hub included also e.g., "vaccine hoarding by wealthy countries and companies prioritizing sales to governments that could pay the highest price".[250] Also, only 1 % of all vaccines used in the African continent, in

[247] WHO, 'WHO Announces First Technology Recipients of mRNA Vaccine Hub With Strong Support From African and European Partners' (18 February 2022), <https://www.who.int/news/item/18-02-2022-who-announces-first-technology-recipients-of-mrna-vaccine-hub-with-strong-support-from-african-and-european-partners>, last accessed 21 February 2022.
[248] UNICEF, 'COVID-19 Vaccine Market Dashboard' (23 February 2022), <https://us20.campaign-archive.com/?u=40658b1a132cdc263e35b5b97&id=59cc9c8a5e>, last accessed 28 February 2022.
[249] WHO, 'FAQ - The mRNA Vaccine Technology Transfer Hub', <https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub/faq>, last accessed 22 February 2022.
[250] *Ibid*.

general, are currently locally produced[251] and mainly imported by UNICEF and not the African countries themselves[252], meaning that for preparing for future pandemics and local needs, a hub carries the most potential to support local vaccine demand. By January 2022, there were a total of 12 COVID-19 vaccine manufacturing facilities put up or in progress, but challenges remain before these facilities can produce COVID-19 vaccines on their own, and these include IP and know-how transfer related challenges with which the hub intends to help. A few facilities have announced that they will be able to start COVID-19 vaccine production in 2022.[253] Moreover, another mRNA R&D hub has been initiated in Argentina by WHO in 2021.[254]

Moreover, at the EU – African Union Summit in 2022 where the first beneficiaries of the hub were announced, the WHO Director-General, Dr. Tedros Adhanom Ghebreyesus, commented as follows related to the launch of the hub:

> ”No other event like the COVID-19 pandemic has shown that reliance on a few companies to supply global public goods is limiting, and dangerous. In the mid- to long-term, the best way to address health emergencies and reach universal health coverage is to significantly increase the capacity of all regions to manufacture the health products they need, with equitable access as their primary endpoint.”[255]

Moreover, WHO has been helping in building vaccine development centers in e.g., South Africa and Brazil. Moreover, e.g., vaccine producers BioNTech and Moderna both had initiatives to start production of COVID-19 vaccines in the African continent.[256] Compared to these initiatives, the previously discussed mRNA Technology Transfer Hub offers a more “global approach”.[257]

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[251] Statistic from the video *South Africa mRNA Vaccines Technology Transfer Hub* (published 11 February 2022) on the MPP website regarding the hub. See MPP, ‘Technology Transfer Hub’, <https://medicinespatentpool.org/covid-19/technology-transfer-hub>, last accessed 22 February 2022.
[252] COVID-19 Clinical Research Coalition, ‘COVID-19 Vaccine Access, Achieving Equitable Access to Quality COVID-19 Vaccines, Using Digital, AI, and GIS Tools’ (January 2022), p. 19 <https://covid19crc.org/wp-content/uploads/2022/01/Vaccine-Access-Report_6-January.pdf>, last accessed 3 March 2022.
[253] COVID-19 Clinical Research Coalition, ‘COVID-19 Vaccine Access, Achieving Equitable Access to Quality COVID-19 Vaccines, Using Digital, AI, and GIS Tools’ (January 2022), p. 19 <https://covid19crc.org/wp-content/uploads/2022/01/Vaccine-Access-Report_6-January.pdf>, last accessed 3 March 2022.
[254] *Ibid*.
[255] Quote from the WHO Director-General, Dr Tedros Adhanom Ghebreyesus during the European Union - African Union summit on 18 February 2022. See, WHO, ‘WHO Announces First Technology Recipients of mRNA Vaccine Hub With Strong Support From African and European Partners’ (18 February 2022), <https://www.who.int/news/item/18-02-2022-who-announces-first-technology-recipients-of-mrna-vaccine-hub-with-strong-support-from-african-and-european-partners>, last accessed 21 February 2022.
[256] The Independent Panel for Pandemic Preparedness & Response, ‘Losing Time: End This Pandemic and Secure the Future, Progress Six Months After the Report of the Independent Panel for Pandemic Preparedness and Response’ (22 November 2021), p. 21 <https://theindependentpanel.org/wp-content/uploads/2021/11/COVID-19-Losing-Time_Final.pdf>, last accessed 4 February 2022.
[257] WHO, ‘FAQ - The mRNA Vaccine Technology Transfer Hub’, <https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub/faq>, last accessed 22 February 2022.

Finally, beyond just COVID-19, the African Center for Disease Control and Prevention ("**ACDC**")[258] has a target to increase local African vaccine production from 1 % to 60 % by 2040. However, during the current pandemic, the efforts of COVAX and the African Union at their current speed are not able to meet the COVID-19 vaccination targets for 2022 and 2023, which are to vaccinate at first 20 % of the population and later, 60 % against COVID-19. However, in a January 2022 report by the COVID-19 Clinical Research Coalition, it was stated that drawing from the amount and capacities of the current African facilities, the inequalities in vaccine distribution, and the challenges imposed by the COVID-19 pandemic, "accelerating the manufacturing of vaccines in Africa is not likely to be a solution" for the current pandemic. But more importantly, upping local manufacturing efforts is "an important step in the right direction to protect Africans from future pandemics and to help prevent future gross inequities in access to vaccines".[259]

### *4.4 Progress of the TRIPS Waiver*

As mentioned already, the TRIPS waiver has been in discussion almost for as long as the COVID-19 pandemic has lasted as a potential tool for boosting vaccine production and distribution, with both strong opposition and strong proposition, which will both be discussed next. The TRIPS waiver was supposed to be discussed at the 12th WTO Ministerial Conference in Geneva in November/December 2021 after having originally been postponed from 2020, but the Conference was postponed again indefinitely and at the time of the writing, has still not been held. As of April 2022, the Conference is set to be held in June 2022.[260]

A trilateral WTO-WHO-WIPO paper described the problem surrounding the debate rather well as follows:

> "A key question has been whether a solution to access problems in developing countries can be found by operating within the IP system, including by making full use of the flexibilities in the TRIPS Agreement, or whether such a solution would require waiving certain obligations under

[258] Operating in the African Union, ACDC is the Union's public health agency, which was founded in 2016 with the aim to aid in "disease control and prevention within the continent". See, COVID-19 Clinical Research Coalition, 'COVID-19 Vaccine Access, Achieving Equitable Access to Quality COVID-19 Vaccines, Using Digital, AI, and GIS Tools' (January 2022), p. 33 <https://covid19crc.org/wp-content/uploads/2022/01/Vaccine-Access-Report_6-January.pdf>, last accessed 3 March 2022.
[259] COVID-19 Clinical Research Coalition, 'COVID-19 Vaccine Access, Achieving Equitable Access to Quality COVID-19 Vaccines, Using Digital, AI, and GIS Tools' (January 2022), pp. 19-20 <https://covid19crc.org/wp-content/uploads/2022/01/Vaccine-Access-Report_6-January.pdf>, last accessed 3 March 2022.
[260]. WTO, 'General Council Decides to Postpone MC12 Indefinitely' (26 November 2021), <https://www.wto.org/english/news_e/news21_e/mc12_26nov21_e.htm>, last accessed 9 February 2022. And WTO, 'Dates fixed for 12th Ministerial Conference in June' (25 April 2022), <https://www.wto.org/english/news_e/news22_e/mc12_25apr22_e.htm>, last accessed 26 April 2022.

> the TRIPS Agreement during the pandemic in order to allow for a rapid scaling up of manufacturing capacities".[261]

### 4.4.1 Proposition

In a report of the Independent Panel for Pandemic Preparedness & Response, an initiative formed in 2020 by WHO, the Panel stated that WTO and WHO should urge central vaccine manufacturers and related countries to agree on COVID-19 technology transfers and voluntary licenses, including utilizing MPP, and if after three months the actions were lacking, the TRIPS waiver should put in use. The report notes that knowledge sharing and cooperation in licensing have been slow in going forward, even though C-TAP was established already in 2020. The report makes a rather direct statement and says that although C-TAP was "Supported in principle by 41 high- middle- and low-income countries, it has received no contributions so far." Furthermore, it states that the IP waiver proposal by India and South Africa "continues to run into opposition", leaving India, "potentially among the world's largest vaccine-makers" struggling itself with producing enough vaccines and delivering them to its own population.[262]

Later in May 2021, the same Panel argued the following:

> "For the Panel it is clear that the combination of poor strategic choices, unwillingness to tackle inequalities, and an uncoordinated system created a toxic cocktail which allowed the pandemic to turn into a catastrophic human crisis."[263]

As evident, the Panel's wish for a solution within three months or alternatively, announcing the TRIPS waiver, did not become a reality and still, in 2022, has not come true. In the progress report announced six months later by the Panel, it was stated that ACT-A's effect was limited due to national interest conflicts and funding, and – quite bluntly – that "global health cannot be left hostage to a pharmaceutical industry which buys up patents -- and develops them in the interest of making profits". The report stated that "an overwhelming majority of countries" were in favor of an IP waiver but that total agreement between parties on the issue was still in progress. In addition, the report called for faster technology transfers and making the authoritative power of WHO stronger to act more efficiently. One further recommendation of

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[261] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 15.
[262] The Independent Panel for Pandemic Preparedness & Response, 'COVID-19: Make It the Last Pandemic' (May 2021), pp. 14, 43 <https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf>, last accessed 3 February 2022.
[263] *Ibid,* p. 43.

the report was the establishment of a "Pandemic Framework Convention", as the further development of the efficiency of ACT-A and MPP was unclear.[264]

Furthermore, the TRIPS waiver has been supported by other organizations as well, such as Doctors Without Borders, which has argued that despite MPP was able to secure the first voluntary license with pharmaceutical company Merck for oral COVID-19 medicine, it still was not enough as the license included several limitations, including limiting out some manufacturing countries out of the license, including countries such as China and Brazil. Moreover, the medication in question called *molnupiravir*, had originally been developed at Emory University with the support of funding by the United States government, but the rights to which eventually ended up in the hands of pharmaceutical manufacturers Merck and Ridgeback. Leaning on this, the organization's senior legal and policy advisor argued that a need for a TRIPS waiver was still there.[265]

In November 2021 Doctors Without Border further issued a more detailed statement on why the TRIPS waiver should be enforced. It highlighted the waiver as a central possibility to aid in combating the issues brought up by the pandemic and to aid in manufacturing and distributing relevant medical tools, which is why it underlined that the waiver should go beyond just vaccines, including medical technology, manufacturing knowledge, and components. Moreover, it stated that the pandemic has brought up other IP issues and obstacles than those only related to patents. The statement claimed current TRIPS provisions are not enabling efficient ways of removing IP-related barriers in a pandemic, including challenges imposed by provisions such as Article 39 on "undisclosed information", or trade secrets[266]. Further, it stated that the waiver would remove the barrier of litigation risks connected to IP rights enforcement, and in general, would bring clarity to the current situation.[267]

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[264] The Independent Panel for Pandemic Preparedness & Response, 'Losing Time: End This Pandemic and Secure the Future, Progress Six Months After the Report of the Independent Panel for Pandemic Preparedness and Response' (22 November 2021), pp. 20-21, 23, 30, 33, <https://theindependentpanel.org/wp-content/uploads/2021/11/COVID-19-Losing-Time_Final.pdf>, last accessed 4 February 2022.
[265] Doctors Without Borders (Médecins Sans Frontières), 'MSF: Merck and Medicines Patent Pool license for new COVID-19 Drug Molnupiravir Doesn't Go Far Enough' (27 October 2021), <https://www.doctorswithoutborders.org/what-we-do/news-stories/news/msf-merck-and-medicines-patent-pool-license-new-covid-19-drug>, last accessed 4 February 2022.
[266] TRIPS Agreement, Art. 39.
[267] Doctors Without Borders (Médecins Sans Frontières), 'MSF Position on the Scope and Duration of the TRIPS Waiver for COVID-19' (11 November 2021), <https://msfaccess.org/msf-position-scope-and-duration-TRIPS-waiver-covid-19>, last accessed 7 February 2022.

Furthermore, in December 2021, a group of 120 civil society organizations from all over the world addressed the TRIPS Council in an open letter, demanding the waiver be implemented and that in fact the obstacle in the way of the waiver has been reluctance – the letter mentions that the US and EU have publicly supported the idea of the waiver but continued resistance exists, which has led to prolonged inaction with discussions surrounding the waiver.[268] Another proposing argument presented has been that developing countries and LCDs, in particular, have faced obstacles in implementing TRIPS flexibilities to their full potential over time. These obstacles have included "political and economic pressure from some industrialized countries, the complexity of practical implementation, insufficient institutional capacity and lack of coordination between patent offices, ministries of health and trade, and drug regulatory authorities".[269]

Lastly, if successful, the TRIPS waiver could be beneficial and would no doubt bring more competition to the COVID-19 vaccine market, and possibly lower the price of the vaccines, but the waiver by itself would probably not be enough – developing successful competing vaccines requires know-how and specific raw ingredients too, but also understanding the "complex web" of relevant IPs. Furthermore, as a European Journal of International Law blog post suggested in January 2022 that while the TRIPS Waiver could be a potential tool to reach the ultimate goal of ending the pandemic, it would not be a perfect solution because it would essentially have to be implemented on national levels. In general, the blog post argues that the most important aspect is that the stand-still situation is resolved in one way or another and that the biggest hindrance has been the reluctance of the EU which has been called a "protectionist or vaccine nationalist block"[270], but also having "misplaced and myopic faith in the multilateral trading system to organically produce the desired global cooperation and coordination to overcome the global vaccine and therapeutics lag". The blog post argues that "expecting altruistic behavior -- is plainly unrealistic" and finds that the EU's objection against the waiver is a direct violation of international norms, such as the spirit of Article 7 of TRIPS and

[268] Doctors Without Borders (Médecins Sans Frontières), 'CSO Open Letter to the Chair of the WTO TRIPS Council' (8 December 2021), <https://msfaccess.org/cso-open-letter-chair-wto-TRIPS-council>, last accessed 8 March 2022.
[269] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2020), p. 91.
[270] Diane Desierto, EJIL:Talk!, Blog of the European Journal of International Law, 'International Economic Law in a Time of Global Perils: Omicron and Other COVID Variants, Climate Change, Human Rights, and Development' (29 November 2021), <https://www.ejiltalk.org/international-economic-law-in-a-time-of-global-perils-omicron-and-other-covid-variants-climate-change-human-rights-and-development/>, last accessed 14 March 2022.

respecting human rights, but also against what the EU declares as its values.[271] Another blog post suggests an estimate that states that due to the inefficient actions of providing equal vaccine access and unwillingness to put international human rights norms in front of economic IP considerations, some countries are estimated to reach full access to COVID—19 vaccines only from 2023 onwards.[272]

### 4.4.2 Opposition

Opponents of the TRIPS have also been vocal during the pandemic. As a counter-proposal to the original TRIPS waiver proposal, the EU submitted a draft of a General Council Declaration in June 2021. The proposal has since been discussed on multiple occasions in TRIPS Council meetings.[273] The EU proposal aims to focus on ”fair and equitable distribution of vaccines and medicines”, while providing “appropriate incentives” for COVID-19-related R&D, by making sure that the IP system is in support of vaccine and medication manufacturing and distribution, and states that TRIPS “does not and should not prevent Members from taking measures to protect public health” but should be interpreted in access promoting and supportive way. It also notes that in general, pandemics most affect LDCs and developing countries, calling e.g., multilevel collaboration, voluntary and compulsory licensing, and using TRIPS flexibilities where necessary. It also suggests compensating vaccine manufacturers even in cases of compulsory licensing, “in order to support manufacturers ready to produce pharmaceutical products -- at affordable prices for low- and middle-income countries”.[274] TRIPS Article 31*bis* makes it mandatory to compensate the IP right holder with an ”adequate” amount in the case of

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[271] As a word of caution, the blog post mentions that by the time of writing the paper, no pharmaceutical company had agreed on not enforcing its IP rights related to COVID-19, but I consider this not true – as discussed already in this paper, Moderna had made the pledge of non-enforcement of COVID-19-related IP already in 2020. See the blog post: Diane Desierto, EJIL:Talk!, Blog of the European Journal of International Law, ‘Overcoming the Global Vaccine and Therapeutics Lag and ‘Vaccine Apartheid’: Abuse of Rights in the EU’s Continued Blocking of the TRIPS Waiver for COVID Vaccines and Related Medicines’ (5 January 2022), <https://www.ejiltalk.org/overcoming-the-global-vaccine-and-therapeutics-lag-abuse-of-rights-in-vaccine-apartheid-and-the-eus-continued-blocking-of-the-TRIPS-waiver-for-covid-vaccines-and-related-medicines/>, last accessed 8 March 2022.

[272] Diane Desierto, EJIL:Talk!, Blog of the European Journal of International Law, ‘International Economic Law in a Time of Global Perils: Omicron and Other COVID Variants, Climate Change, Human Rights, and Development’ (29 November 2021), <https://www.ejiltalk.org/international-economic-law-in-a-time-of-global-perils-omicron-and-other-covid-variants-climate-change-human-rights-and-development/>, last accessed 14 March 2022.

[273] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 15.

[274] TRIPS Council, *Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, Communication from the European Union to the Council for TRIPS*, WTO Doc. IP/C/W/681 (18 June 2021), pp. 2-3.

a compulsory license.[275] However, because the TRIPS implementation period for LCDs is still up, LCDs are not obligated to do this; a TRIPS waiver would extend this to other countries as well.

Moreover, the EU proposal calls for further notifications of the need or willingness to use the compulsory licensing system either as an exporter or importer.[276] These notifications were discussed earlier in this paper through the example of Bolivia and Canada which did not prove to be without obstacles either. However, it was indeed acknowledged that they had not been in wide use during the COVID-19 pandemic.[277] Therefore, I find this statement in the EU proposal rather interesting and slightly contradictory, as it would seem through the previous examples of trying to use the compulsory licensing system, the system is probably not the most efficient way to help global public health fast, or at least that parties are not as interested in using the system as has been proposed by the EU. Another question is whether there would be interested exporters to answer the calls of importers in need of vaccines even if more notifications of need were made. This statement was not explained in the EU proposal further, but it remains to be seen whether wider use of the notification system would spark technology and vaccine transfers, but I remain skeptical.

Moreover, the EU proposal was argued as ineffective by Doctors Without Borders, which argued that the proposal was too fixed on measures that already existed but had proven to be insufficient, such as compulsory licensing. It also critiqued the EU proposal of being too reliant on the voluntary willingness of pharmaceutical manufacturers which had already proven lackluster. It was also criticized for only focusing on vaccines and not all medical products. Doctors Without Borders further argued that already in June 2021, the TRIPS Waiver proposal was supported by over 100 countries.[278]

Moreover, opponents of the waiver have referred to the need for incentives to innovate and that the IP that follows, is a reward for the innovations.[279] Arguments have also included mentions

[275] TRIPS Agreement, Art. 31*bis* para. 2.
[276] TRIPS Council, *Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, Communication from the European Union to the Council for TRIPS*, WTO Doc. IP/C/W/681 (18 June 2021), p. 3.
[277] See section 2.4 *Doha Declaration Paragraph 6 System on Compulsory Licenses*.
[278] Doctors Without Borders (Médecins Sans Frontières), '3 Reasons Why the EU's TRIPS Waiver Counter-Proposal Is an Insufficient Solution in a Pandemic' (18 June 2021), <https://msfaccess.org/3-reasons-why-eus-TRIPS-waiver-counter-proposal-insufficient-solution-pandemic>, last accessed 8 March 2022.
[279] Diane Desierto, EJIL:Talk!, Blog of the European Journal of International Law, 'Overcoming the Global Vaccine and Therapeutics Lag and 'Vaccine Apartheid': Abuse of Rights in the EU's Continued Blocking of the TRIPS Waiver for COVID Vaccines and Related Medicines' (5 January 2022),

of the proposed waiver issues, including the potential risk of abusing the system, the difficulty of mRNA technology vaccine production, transparency, and quality issues, but also the fact that countries would need to implement the waiver to their national legislation. Moreover, some opponents have found that the original idea of the waiver proposal was to activate debate on the topic and activate manufacturers' willingness to cooperate and license, rather than completing the actual waiver.[280]

Another interesting, and in my eyes rather provocative argument, has been that "the [original TRIPS waiver] proposal perhaps reveals India's and South Africa's true intent to use the COVID-19 pandemic as an excuse to roll-back IPRs rather than a good-faith effort to rapidly increase access to lifesaving vaccines and treatments around the world" because the TRIPS waiver, according to the argument, is not a fast way to responded to the crisis.[281] While a waiver is most certainly not the fastest way, the argument presented here I do not agree with, because in my mind, it fails to take into consideration the genuine hardships many of the (developing) countries that have signed the waiver proposal have encountered during the pandemic and in trying to reach lifesaving medicines and vaccines. Furthermore, it ignores the Doha Declaration and TRIPS' spirit regarding public health.

In addition to the aspects discussed before, proponents of the waiver have also pointed out that in contrast to the claims of opposing countries and large pharmaceutical companies, developing countries do carry much potential for medical product production, including vaccines.[282] More specifically, by December 2021, a Doctors Without Borders analysis had identified over 100 potential manufacturers in Asia, Africa, and Latin America that would have the capacity to produce the new type of COVID-19 mRNA vaccines.[283] As also discussed in other parts of this paper, proponents of the waiver have referred to the previous examples that highlight the

<https://www.ejiltalk.org/overcoming-the-global-vaccine-and-therapeutics-lag-abuse-of-rights-in-vaccine-apartheid-and-the-eus-continued-blocking-of-the-TRIPS-waiver-for-covid-vaccines-and-related-medicines/>, last accessed 8 March 2022.

[280] See e.g., Bryan Mercurio, 'The IP Waiver for COVID-19: Bad Policy, Bad Precedent', (2021) 52(8) IIC - International Review of Industrial Property and Copyright Law 983, <https://doi.org/10.1007/s40319-021-01083-5>, last accessed 5 March 2022.

[281] Bryan Mercurio, 'The IP Waiver for COVID-19: Bad Policy, Bad Precedent', (2021) 52(8) IIC - International Review of Industrial Property and Copyright Law 983, <https://doi.org/10.1007/s40319-021-01083-5>, last accessed 5 March 2022.

[282] Melody Okereke and Yasir Essar, 'Time to Boost COVID-19 Vaccine Manufacturing: The Need for Intellectual Property Waiver by Big Pharma', [2021] 19 Ethics Med Public Health, <https://doi.org/10.1016/j.jemep.2021.100710>, last accessed 5 March 2022.

[283] Doctors Without Borders (Médecins Sans Frontières), 'Pharmaceutical Firms Across Asia, Africa and Latin America With Potential to Manufacture mRNA Vaccines' (16 December 2021), <https://msfaccess.org/pharmaceutical-firms-across-asia-africa-and-latin-america-potential-manufacture-mrna-vaccines>, last accessed 8 March 2022.

potential in developing country generic manufacturers – as an example, without the generic production of HIV/AIDS antiretroviral therapies in low- and middle-income countries, the global HIV/AIDS situation would not be where it currently is.[284]

Moreover, even during the peak of the HIV/AIDS pandemic, the parties that were against generic manufacturing claimed that the quality of the medication produced in low- and middle-income countries would not be up to standards. However, this claim has been shown insufficient – generic manufacturers have been able to produce HIV/AIDS medication that is up to quality and safety standards. Regardless of the proof of success, the same debate is had with COVID-19 vaccines. Although the mRNA vaccine technology is harder to produce than e.g., oral medicines, the capacity still exists. As an example, UNICEF among others has used many vaccines from manufacturers in developing countries, e.g., India, which is the biggest vaccine producer globally.[285] Moreover, the Human Rights Watch acknowledges that while the TRIPS waiver would not be an instant solution, it would make further sharing and dissemination of knowledge and technology transfers possible. Also, it finds that the waiver would not affect other medical R&D and innovation that is not related to COVID-19 and should also be supported because of the large public funding that the COVID-19 vaccine patents have had.[286]

All in all, the waiver could offer another tool to tackle the issue of access inequality, and in my eyes, could be efficient especially if supplemented with other measures. On the other hand, it could bring with it difficult questions related to what extent an IP right's COVID-19-relatedness has to go to be waived. Nevertheless, I do not feel that as much emphasis should be put on whether the waiver is achieved or not – the discussion, in my view, has been too fixed on the waiver discussion and not on many other important initiatives, such as the new mRNA technology hub. As was pointed out above, the most important thing would be to move forward and come up with *a* solution, rather than stopping at a stand-still for two years, as we have seen with the TRIPS waiver proposal.

[284] Human Rights Watch, 'Seven Reasons the EU is Wrong to Oppose the TRIPS Waiver' (3 June 2021), <https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-TRIPS-waiver#>, last accessed 14 March 2022.
[285] Melody Okereke and Yasir Essar, 'Time to Boost COVID-19 Vaccine Manufacturing: The Need for Intellectual Property Waiver by Big Pharma', [2021] 19 Ethics Med Public Health, <https://doi.org/10.1016/j.jemep.2021.100710>, last accessed 5 March 2022.
[286] Human Rights Watch, 'Seven Reasons the EU is Wrong to Oppose the TRIPS Waiver' (3 June 2021), <https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-TRIPS-waiver#>, last accessed 14 March 2022.

### *4.5 Trilateral Cooperation Between WTO, WHO and WIPO*

The cooperation between WTO, WHO, and WIPO has naturally been active throughout the pandemic. The three organizations published a joint statement in June 2021, highlighting their efforts to provide equal access to e.g., COVID-19 vaccines, and offered to initiate a series of workshops on relevant topics to share knowledge of IP implications in real life and create an information-sharing platform.[287] Later, the chairs of each met on 1 February 2022 to discuss the pandemic and cooperation and highlighted the importance of collaboration. The meeting affirmed the "impending launch of a trilateral technical assistance platform", providing countries with assistance related to e.g., implementation of all different IP-related proposals currently in process in the TRIPS Council.[288]

Earlier in 2020, the three organizations published a joint publication called "Promoting Access to Medical Technologies and Innovation", which was an updated version of the original version of the publication from 2012. The publication included a short additional section for COVID-19-related considerations. Regarding related IP, the publication argued that IP systems in use should consider all parties' interests, "such as start-ups, R&D institutions, both public and private, universities and corporations, as well as the interests of funders, whether public or private and of the public at large, including patients, who ultimately benefit from innovation that meets their needs". Moreover, it highlighted that countries should consider their own circumstances and adapt their national IP systems to fit their needs, "including through TRIPS flexibilities".[289]

The publication was later in 2021 supplemented by a separate informational note on COVID-19. It states that inequalities in global vaccine distribution and "vaccine nationalism" have in fact influenced firstly, the continuing spread of the virus, but also have contributed to new virus variants emerging [290]. Moreover, the pandemic has been a time of strong economic growth for

[287] WTO, 'WHO, WIPO, WTO Map Out Further Collaboration to Tackle COVID-19 Pandemic' (24 June 2021), <https://www.wto.org/english/news_e/news21_e/igo_23jun21_e.htm>, last accessed 7 February 2022.
[288] WTO, 'WHO, WIPO, WTO Heads Chart Future Cooperation on Pandemic Response' (1 February 2022), <https://www.wto.org/english/news_e/news22_e/igo_01feb22_e.htm>, last accessed 7 February 2022.
[289] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2020), pp. 90-91.
[290] At the time of publications, the paper referred to the variants Alpha, Beta, Gamma, and Delta, but naturally, new variants have emerged after August 2021, but most likely the point made in the publication has remained the same thus far. See, WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 4.

developed countries, leaving developing countries behind with piling amounts of debt, especially in developing markets. Moreover, a UN Coordination of Statistical Activities Committee analysis presents the possibility of 71 to 100 million people could be "pushed into extreme poverty" due to COVID-19. The situation was commented by the International Monetary Fund Chief as a "danger for the coherence of growth and it is also a danger for global stability and security".[291]

More specifically regarding IP, the COVID-19 informational note adds to the previous publication by discussing, e.g., the use of the Paragraph 6 System on compulsory licenses. It noted that while it is hard to predict the meaning of the system in the pandemic, it might still be useful regardless of whether it is used, as it can nevertheless aid countries to announce their needs for medical technology related to COVID-19.[292] However, I find this statement slightly problematic. The problem in my eyes boils down to the core reasons why unequal access has been prominent during the pandemic – even though a need would be detected or even announced, it does not mean that other countries will jump into action to fulfill the needs of other countries, at least initially. Even during the current pandemic, lower-income countries have voiced their needs but correspondence with them has not always been as active, as we have discussed already in this paper.

Moreover, the COVID-19 information note finds that some patents possibly relevant for COVID-19 medication R&D have been opposed by civil society organizations, whereas before, such oppositions were made most frequently by the patent holder's competitors, not such organizations.[293] However, despite the presented critique, some private companies have made efforts to improve the accessibility of COVID-19 medications and related technology, through either non-exclusive or royalty-free licensing or by committing to not enforcing their patent rights either at all or in certain jurisdictions, as an example. As a caveat, however, the note states that additional needs for increased voluntary licensing and wider technology transfers and know-how transfers have been called for, especially from e.g., central vaccine IP right holders. Lastly, the note finds that all different IP policy options should be looked at simultaneously, as there are challenges to each one of them.[294] Much of this discussion is not

[291] *Ibid*, pp. 4-5.
[292] *Ibid*, p. 9.
[293] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 9.
[294] *Ibid*, pp. 9-10.

new and is more or less identical to many other comments we have seen from other discussions on medical product access years before the pandemic. However, again, concrete suggestions are not evident, which has been an issue for many other policy papers and suggestions during the pandemic. However, in the next Chapter, I will assess these policies and initiatives collectively and assess ways to learn from the issues that have been encountered during the pandemic.

# 5 ASSESSING COVID-19 IP POLICIES AND PREPARING FOR THE FUTURE

## *5.1 Insufficiencies in International IP Policies During COVID-19*

Have international IP rights, especially patents, stood in the way of equal vaccine distribution, and how? The answer, as already provided in the introductory chapter, is that yes indeed, IP has played a role in the unequal distribution issue. Another question is, just how large of an issue IP truly has been. In my opinion, from various previously quoted sources and the spirit of the Doha Declaration and TRIPS itself, it is by no means the idea or purpose of TRIPS or IP in general to worsen public health crises. Quite the opposite, as the entire purpose for publishing the Doha Declaration, was to address the concerns of utilizing the compulsory licensing system in ensuring equitable medication access. It was created to highlight that in times of public health emergencies, IP should not stand in the way and that "public interest considerations can prevail".[295] To me, it seems that a lot of the potential that there is, at least on paper, is not being used. The reason for this is multifold but includes a web of different political, financial, lack of knowledge, transparency, bias, and power dynamic related issues, which go beyond the COVID-19 pandemic. One central factor in all of this has been the underlying North-South division which is by no means a new phenomenon. As an example, the COVID-19 pandemic, in my eyes, shows just how ineffective the TRIPS 66.2 efforts to promote incentives and technology transfers between the Global North and Global South have been. Moreover, the sheer multitude of different systems and new initiatives are likely to add to the confusion and instead of providing helpful solutions, are doing the opposite.

However, despite my critical assessment, it would be incorrect to state that nothing useful or beneficial has been done in the field of IP and COVID-19. Almost on the contrary, the number of initiatives, statements, discussions, and opinions feel at times overwhelming. Why is it then that despite the numerous efforts, progress seems slow even in the third year of the pandemic? IP does play a part in this issue, and a search for a common consensus on an IP response that would satisfy all interests has been sought after, but the efforts remain without success, especially regarding the TRIPS waiver and whether it is "the appropriate and most effective way to address the shortage and inequitable distribution"[296]. However, in my opinion, IP does

[295] WTO, *Informational Note: The TRIPS Agreement and COVID-19* (15 October 2020), p. 10 <https://www.wto.org/english/tratop_e/covid19_e/TRIPS_report_e.pdf>, last accessed 28 February 2022.
[296] World Trade Organization, 'Members to Continue Discussion on a Common COVID-19 IP Response up Until MC12' (18 November 2022), <https://www.wto.org/english/news_e/news21_e/trip_18nov21_e.htm>, last accessed 7 March 2022.

not play a part in the unequal vaccine distribution issue to the extent it has been argued on many occasions, and at times, seems to be more of an additional excuse for countries not to act swiftly.

As established, IP grants its right holders the opportunity to regulate the number of doses it sells and distributes. As far as R&D goes, IP may prohibit the opportunities for other manufacturers and researchers to develop their own vaccines and other products, in cases where they infringe upon IP rights. However, as has been discussed above, this is a multidimensional topic, because at least on the international IP level, technology transfer connected to health and other measures that help in public health situations, is encouraged and IP is not intended to block the fundamental right to life and health. The other question has been, whether it has been in reality as easy to circumvent the IP rights standing in the way of further vaccine R&D, as the topic is greatly political, and interests between the Global North and Global South are not in reality aligned, despite numerous discussions and attempts to encourage sharing IP, technology, and know-how. In my eyes, these attempts have been tools to encourage countries to work according to the TRIPS Article 66.2 which encourages developed countries to establish incentives to encourage technology transfer to least-developed countries[297]. As the progress has been slow and political reluctance has been prevailing, one could argue that the Global North has not and still is not following either the TRIPS Article 66.2 or the Doha Declaration.

More specifically related to the COVID-19 pandemic, I have identified four specific key issues, in addition to the underlying influences, such as the North-South division and all other influences identified above. These four COVID-19-related problem areas in my opinion are the following: 1) Past arguments are being reused, 2) suggestions and discussions often lack concrete actions, 3) the TRIPS waiver has been overemphasized, and 4) dependency on voluntary actions and donations. Next, I will discuss each issue in more detail and argue why I consider it central in contributing to the issues that have arisen during the COVID-19 pandemic.

1. Past arguments are being reused

The discussions around IP and COVID-19 vaccines have been important and valid, but somewhat repetitive over the years, and many have referred to the same measures and their potential over again often with little concrete proof. Many have mentioned the potential of compulsory licensing, using TRIPS flexibilities, or the need to waive the entire TRIPS. Many similarities in the current debates have been evident pre-pandemic even for decades with

[297] TRIPS Agreement, Art. 66.2.

moderate improvements. Granted, the type of the pandemic is different, and it has spread in a different way than before, but the overarching themes and obstacles remain the same. In general, the same type of discussions calling for solidarity, cooperation, and transparency are very much like those had already in connection to the HIV/AIDS pandemic and e.g., when planning out the GSPA-PHI strategy years before the COVID-19 pandemic.

As an example, as we have gathered in various parts of this thesis, compulsory licenses have been largely debated and discussed throughout the pandemic, but also during the HIV/AIDS pandemic. Compulsory licenses have been highlighted as a potential solution to the pandemic on multiple occasions, but as we have seen, their use has not been much more active during the COVID-19 pandemic than it was before. Doctors Without Borders has argued that one issue with compulsory licensing is the additional requirements that need to be fulfilled when intending to issue compulsory licenses that include e.g., packaging requirements, which makes the process demanding and slow.[298]

However, some exceptions exist. According to the WIPO COVID-19 IP Policy Tracker, e.g., Israel has granted compulsory licenses for certain patented COVID-19 medications, but not vaccines.[299] Moreover, e.g., Hungary granted compulsory licenses for the medication *remdesivir* in 2020. In general, some countries have adopted new national compulsory license and government-use license regulations to enable the use of such related to COVID-19-related medical products.[300] However, like in the example of Bolivia and Canada, their attempt to issue a compulsory license encountered blocks that hindered the process despite the parties having signed an agreement.

All in all, the system was not functional during the HIV/AIDS pandemic and still is not perfectly functional today, which makes referring to measures like this seem rather lackluster and oblivious of the past. A more efficient response would concentrate on what should be amended, rather than pointing to ineffective systems that already exist, as it has not proven efficient.

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[298] Doctors Without Borders (Médecins Sans Frontières), '3 Reasons Why the EU's TRIPS Waiver Counter-Proposal Is an Insufficient Solution in a Pandemic' (18 June 2021), <https://msfaccess.org/3-reasons-why-eus-TRIPS-waiver-counter-proposal-insufficient-solution-pandemic>, last accessed 8 March 2022.
[299] WIPO, 'COVID-19 IP Policy Tracker, Legislative and regulatory measures, Israel', <https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access>, last accessed 15 February 2022.
[300] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 8.

2. Suggestions and discussions often lack concrete actions

In my eyes, many of the new systems and initiatives that have been launched, are crafted in a way to circumvent the IP consideration altogether, by depending on donations and voluntary actions. Further, many proposals lack concrete steps to remove the argued IP barriers, even though in my eyes, IP is not a barrier per se – the question has more been about the willingness to put words into action in the spirit of e.g., the Doha Declaration. Many have argued that mRNA technology vaccine production is too hard for generic manufacturers to produce, and that special know-how is needed. I do agree, but the point where I struggle to see the connection is when this argument leads to the conclusion that COVID-19-related technology transfer should not thus be encouraged. How can generic manufacturers learn to use the new technology, if they are not even given the chance? Compensation for IP holders should, naturally, be provided, but I argue that if concrete steps towards finding mutual agreement between countries and manufacturers, we could (have) found a solution that could be agreeable to both. Win-win situations hardly exist, but the question is more about balancing the needs and wants of different stakeholders, keeping in mind basic human rights.

Despite the obvious issues in the current system both in times of COVID-19 but also before during the previous public health crises that have hit the world, some initiatives are very exciting in terms of the potential for a more equal future. In my eyes despite my critical view, the mRNA Technology Transfer Hub carries the most potential for preparing for future pandemics but also to provide for smaller domestic needs of different medical products, by bringing IP, skill, and training in one place and building a genuine sustainable technological and know-how database, alongside providing the actual skill needed to make use of IP, which during COVID-19 has been in many occasion been referred as the reason why sharing IP and vaccine technology is not an efficient solution. This, in my opinion, is a great concrete step forward that is in fact in line with TRIPS Article 66.2, Article 67, and the Doha Declaration and provides a forward-looking solution rather than just looking at the issues that exist in e.g., lower-income countries' manufacturing capacities. Many other great attempts have been made toward equalizing vaccine access, but a lot remains still to be done.

3. The TRIPS waiver has been overemphasized

*"Initiatives such as the proposed Intellectual Property TRIPS waiver are a distraction to the real challenges of getting shots in arms"*[301]

Related to the point above, the TRIPS waiver has been a central topic of discussion between companies, organizations, and e.g., meetings in the WTO. However, to my view, at times too much emphasis has been put on whether to waive or not to waive the TRIPS agreement. We have seen that this discussion has not led to many actionable results, as the waiver proposal is still waiting for its final decision almost two years later, despite some slight recent signs of progress in April 2022[302]. While the initiative was important, it would not be a perfect solution to the pandemic either. The arguments surrounding the waiver have been quite opinionated one way or another, and rarely a mid-way ground has been discussed. Therefore, as presented in the above discussions as well, the waiver could serve a purpose in the toolbox in improving COVID-19-related medical products and vaccine access, but it should not solely be relied upon. At the end of the day, it would be unprecedented, and no one knows for certain what the effects of the waiver would be, or if it would have much effect on the situation at all. As I argued already, in my opinion, it would be more important to focus on initiatives that carry actionable solutions and results, rather than spending too much energy on initiatives that stay standstill for years.

4. Dependency on voluntary actions and donations

Another issue that is also something we have encountered before in the past, is the emphasis on voluntary actions by pharmaceutical companies and States to act and share relevant IP and knowledge. This has eventually led to a situation of overdependence on vaccine donations, e.g., through COVAX. In general, companies have conducted donation programs in connection to medications in the past in aid of developing countries, which naturally is important for these countries and a positive aspect in general. The motives to help have included naturally the want to help these countries, but also further branding and tax advantage considerations, keeping also in mind the longer-term business implications and possibilities.[303] This is in no way to say that donations are made from greed or that they would not be important even if vaccines were more

[301] Quote by Komal Kalha from the International Federation of Pharmaceutical Manufacturers and Associations from October 2021. See, Rachel Arthur, BioPharma-Reporter, 'COVID-19 Vaccines and IP Waiver Proposals: One Year on, Where Are We Now?' (25 October 2021), https://www.biopharma-reporter.com/Article/2021/10/25/COVID-19-vaccines-and-the-IP-TRIPS-waiver-One-year-on, last accessed 21 March 2022.
[302] WTO, 'Director-General Okonjo-Iweala Hails Breakthrough on TRIPS COVID-19 Solution' (16 March 2022), <https://www.wto.org/english/news_e/news22_e/dgno_16mar22_e.htm>, last accessed 26 April 2022.
[303] WHO Commission on Intellectual Property Rights, Innovation and Public Health, *Report on Public Health, Innovation and Intellectual Property Rights* (World Health Organization 2006), pp. 113-114.

globally available, but just another consideration in applying the current pandemic into the framework of different political and economic biases.

Furthermore, we have seen that voluntary licensing of IP has not been much used, especially in connection to COVID-19 vaccines. Pooling of relevant patents and knowledge through initiatives such as MPP, C-TAP, and VaxPal have been great initiatives, but have not yet been as successful as thought, one reason possibly being their dependency on voluntary licensing and information sharing, in comparison to the mRNA Technology Transfer Hub, which has a more overarching and long-termed approach to the situation, even though it not perhaps the quickest solution to the current pandemic.

### *5.2 Learning from the Past*

> *"The manifest failures of the COVID-19 response to date should motivate all stakeholders to make serious reforms and minimise the impact of future disease threats."*[304]

Has the world learned something from the COVID-19 pandemic response, or does it have the ability to do so? The High-Level Meeting on AIDS meeting which gathered in June 2021 stated that "The world was unprepared in 2020, just as it was unprepared and unable to mount an effective response to HIV in the 1980s and 1990." Among others, relevant medical technology availability and utilization of TRIPS flexibilities remain still areas to improve upon in the future.[305] In the same meeting, the former co-chair of the Independent Panel for Pandemic Preparedness and Response Helen Clark, also the former Prime Minister of New Zealand, claimed on behalf of the Panel that now with COVID-19 that "the same old battles are having to be fought [as with HIV/AIDS previously]". More specifically, she pointed out similarities such as "the battles for a TRIPS waiver" and for equal distribution of vaccines, which have appeared in the discussions surrounding both two pandemics. In addition, Clark argued that as with HIV/AID (that still has not disappeared from the world), the current "pandemic has

[304] The Independent Panel for Pandemic Preparedness & Response, 'Losing Time: End This Pandemic and Secure the Future, Progress Six Months After the Report of the Independent Panel for Pandemic Preparedness and Response' (22 November 2021), p. 5 <https://theindependentpanel.org/wp-content/uploads/2021/11/COVID-19-Losing-Time_Final.pdf>, last accessed 4 February 2022.
[305] High-Level Meeting on AIDS, 'Global Commitments, Local Action, After 40 Years of AIDS, Charting a Course to End the Pandemic' (3 June 2021), p. 39 <https://www.unaids.org/sites/default/files/media_asset/global-commitments-local-action_en.pdf>, last accessed 4 February 2022.

exacerbated pre-existing inequalities".[306] Many issues from the past had been carried to the COVID-19 response, and much work remains to be made to achieve better results in the future.

One of the main challenges in the COVID-19 pandemic has been transparency, and as the WHO Director-General argued, the "lack of transparency is the main disadvantage or bilateral technology transfer through voluntary licensing", and the call for transparency within the health product market has been demanded long before the COVID-19 pandemic. One transparency tool added during the pandemic has been the "WIPO COVID-19 IP Policy Tracker", which is a database that compiles information on regulatory measures and adaptations relating to IP policies during the pandemic. However, the information for the database is given by IP offices themselves[307], and the information does not cover all measures and is not always up to date. Transparency has remained an issue even though it was already in 2020 acknowledged as a central area that needed to be focused on during the COVID-19 pandemic.[308]

Moreover, a research paper by BMJ, a peer-reviewed medical journal, commissioned by the Independent Panel for Pandemic Preparedness and Response and funded by the WHO and Singapore National Medical Research Council, investigated different factors in making some countries more and some countries less successful in their COVID-19 response. Based on the research, the paper suggested a few key factors in making country policies successful or a failure. A common nominator for the most successful[309] countries was their great number of partnerships and cooperation between different actors and sectors. For the less successful countries with higher death tolls, a common factor was e.g., the inefficiency in putting plans in action due to delays and denial, or ineffective infrastructure capacities. Based on these observations, a few measures were suggested to better prepare for future pandemics. Where these measures tie in with IP rights, is the recommendation for countries to establish systems to "allow for, and encourage, the exchange of knowledge, expertise, and innovation".

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[306] The Independent Panel for Pandemic Preparedness & Response, 'Addressing the Impact of the COVID-19 Pandemic on the AIDS Response and Building Back Better for Pandemic Preparedness' (14 June 2021), <https://theindependentpanel.org/addressing-the-impact-of-the-covid-19-pandemic-on-the-aids-response-and-building-back-better-for-pandemic-preparedness/>, last accessed 4 February 2022.

[307] WTO, WHO, and WIPO, *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade. Updated Extract: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 30 August 2021* (2nd edn, World Trade Organization, World Health Organization and World Intellectual Property Organization 2021), p. 14.

[308] WTO, *Informational Note: The TRIPS Agreement and COVID-19* (15 October 2020), p. 1 <https://www.wto.org/english/tratop_e/covid19_e/TRIPS_report_e.pdf>, last accessed 28 February 2022.

[309] "Most successful" in this case was determined as having the lowest fatality rate per capita in November 2020. Victoria Haldane et al, 'From Response to Transformation: How Countries Can Strengthen National Pandemic Preparedness and Response Systems' [2021] 375 BMJ, p. 1 <https://www.bmj.com/content/bmj/375/bmj-2021-067507.full.pdf>, last accessed 7 February 2022.

Furthermore, another presented measure that ties in with this thesis is the recommendation that "requires a serious shift in mindsets to engage with and create policies that reflect the broader social, economic, environmental, and political factors in society" to answer to equality issues, in addition to increasing the level of cooperation between all stakeholders.[310]

Moreover, WTO suggested in an informational note in July 2021 the following ways to provide smoother vaccine (and technology) flow, both during the COVID-19 pandemic but also in preparation for future health crises: mutual recognition, bilateral and multilateral agreements, accepting "restricted emergency use of foreign-produced vaccines" and improving regulatory transparency. The key takeaway, however, is the need for open and earlier communication between all parties and lessening the different regulatory requirements in situations of crisis.[311]

In sum, transparency improvements and strengthening global cooperation remain key areas that need improving to prevent the past, once more, repeating itself in the future. Next, we will take a brief look into the more specific ways and areas to better prepare for the future by using international IP policies more efficiently to the public health's advantage. Not all possible solutions and needs for improvements will be discussed, but below are presented some central points to start a further discussion relating to preparing for the future.

### 5.2.1 More Efficient Voluntary and Compulsory Licensing

Licensing still carries a lot of potential to promote medical technology transfer, even though we should shift our approach to both, to provide genuine incentives for all parties to make use of licensing. As an example, as we have already gathered, the mere existence of a compulsory license is not enough, as the licensee country must have some form of manufacturing capacity in place to make use of the license, which can leave the number of countries gaining advantage from these licenses directly rather limited. However, states with low resources may use compulsory licenses "in an emergency (and in the absence of voluntary arrangements)" to get manufacturers to use the licenses to produce the medication needed for the country in need.[312]

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[310] Victoria Haldane et al, 'From Response to Transformation: How Countries Can Strengthen National Pandemic Preparedness and Response Systems' [2021] 375 BMJ, p. 5 <https://www.bmj.com/content/bmj/375/bmj-2021-067507.full.pdf>, last accessed 7 February 2022.
[311] WTO, *Information Note: Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measures on Critical Products to Combat COVID-19* (20 July 2021), pp. 5-6 <https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_report_e.pdf>, last accessed 10 January 2022.
[312] See, e.g., WHO, *Macroeconomics and Health: Investing in Health for Economic Development, Report of the Commission on Macroeconomics and Health* (World Health Organization 2001), p. 90. Furthermore, to address the issue of manufacturing incapabilities, WHO released a compendium regarding the use of available COVID-

Therefore, even in a time of crisis, like COVID-19, a country's capability to make use of a license – compulsory or not – *should not* be constrained, if the country does not have a domestic medicine production industry already in place.[313]

Despite the theoretical absence of a barrier, we have concluded that several blocks stand in the way of compulsory licensing. Some that have been named in this paper, have included political pressure, excessive demands connected to products manufactured based on compulsory licenses, and the complicated nature of the process. All in all, the international compulsory licensing system arising from TRIPS is currently too stiff for different international subjects to be interested enough in it, which defeats its purpose, at least in my opinion. As we have seen from responses like that of the EU, which promotes using the compulsory licensing system more, many have had a hard time accepting that the system in its current form is not sufficient and changes would have to be made, to make it more incentivizing for different stakeholders. In terms of TRIPS, this could include lightening the notification burden, but also clarifying the use of the system. However, one aspect that adds to the complexity, is the additional layer of domestic regulation, as was seen for example with the mentioned Canadian pharmaceutical manufacturer Biolyse Pharma and Bolivia's attempt to carry out a compulsory license to provide COVID-19 vaccines to Bolivia. Domestic regulation should thus be amended accordingly to make use of the system in the future.

As far as voluntary licensing goes, pharmaceutical companies could in addition grant voluntary licenses to individual countries. Indeed, they have had the same possibility to do so during this pandemic. Voluntary licensing has been highlighted as one of the key areas to improve upon to establish COVID-19 vaccine distribution equality, and WHO and COVAX have been urged to continue efforts to increase the number of voluntary licenses, among other solutions.[314] However, we have seen little interest in voluntary licensing of COVID-19 vaccine technology, even though good examples of voluntary licensing have been evident in the field of oral

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19 health technologies, especially having low-income and low-capacity countries in mind. World Health Organization, *WHO Compendium of Innovative Health Technologies for Low-Resource Settings, COVID-19 and Other Health Priorities* (World Health Organization 2021).

[313] Sevil N-Marandi, 'Framing and Reframing Global Patent Policy, Implications on Access to Medicine in Developing Countries' (2009) 1(1) Public Policy & Governance Review 128, p. 135 <https://ppgr.files.wordpress.com/2010/08/1-1-framingrefamingpatentpolicy.pdf>, last accessed 8 February 2022.

[314] WHO, 'Statement on the Tenth Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic' (19 January 2022), <https://www.who.int/news/item/19-01-2022-statement-on-the-tenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic>, last accessed 27 January 2022.

COVID-19 medication as discussed. In other words, we would need to provide more efficient incentives for companies to surpass the high threshold of granting voluntary licenses of IP, especially licensing of the most valuable IP to the companies, but also of most value to public health.

Utilizing voluntary licensing is not a new suggestion. One article from 2009 suggested that using less compulsory licensing – or abandoning it altogether – and utilizing voluntary licensing more, could help in accelerating developing countries' access to medicine and lower the bar for patent holders to issue licenses for developing country manufacturers. However, this comes with a caveat: relying solely on voluntary licensing could lead to issues in incentivizing pharmaceutical companies and therefore, having the possibility to cause insufficient supply.[315]

Finally, agreements that would be negotiated upfront to prepare for future pandemics have been one solution presented as well to circumvent the issues connected to licensing that have been discussed above. These agreements would be made in agreement with central industry developers and manufacturers, and the agreements would become enforceable through a defined trigger (e.g., a pandemic). These agreements could include explicit agreements on voluntary IP licensing and clauses on technology transfers to other, generic pharmaceutical manufacturers.[316] This could prove potential and could help lessen the weight that has been put into debating different TRIPS provisions as we have seen during the COVID-19 pandemic. Beyond just licensing, WHO Members have also proposed forming a new international agreement or another instrument on preparing better for future pandemics.[317]

### 5.2.2 Further Opportunities

Enhancing local production capabilities has been suggested to improve medical product access in the middle of the pandemic.[318] The same idea is echoed in establishing the mRNA

[315] Sevil N-Marandi, 'Framing and Reframing Global Patent Policy, Implications on Access to Medicine in Developing Countries' (2009) 1(1) Public Policy & Governance Review 128, p. 139 <https://ppgr.files.wordpress.com/2010/08/1-1-framingrefamingpatentpolicy.pdf>, last accessed 8 February 2022.
[316] Rohit Ramchandani et al, 'Vaccines, Therapeutics, and Diagnostics for COVID-19: Redesigning Systems to Improve Pandemic Response' [2021] 375 BMJ, p. 5 <https://www.bmj.com/content/bmj/375/bmj-2021-067488.full.pdf> last accessed 7 February 2022.
[317] WHO, Seventy-Fourth World Health Assembly, *Special Session of the World Health Assembly to Consider Developing a WHO Convention, Agreement or Other International Instrument on Pandemic Preparedness and Response*, WHO Doc. A74/A/CONF./7 (25 May 2021).
[318] WHO, Seventy-Fourth World Health Assembly, *South Centre Statement for the 74th World Health Assembly Item 13.4: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (Assembly

Technology Transfer Hub as well, and as mentioned, the creation of the hub is intended to have a longer-term positive effect on empowering and increasing manufacturing capacities in developing countries.

Furthermore, in May 2021, a draft resolution on strengthening local production of medicines and other health technologies was proposed by several WHO Members, both developing and developed countries, including e.g., EU Member States. The proposal recognizes the connection between access to health, the 2030 Agenda for Sustainable Development's goals, the Doha Declaration, and human rights, and promotes the need to "improve access to quality, safe, effective and affordable medicines and other health technologies, inter alia, through building capacity for local production, especially in low- and middle-income countries, technology transfer on voluntary and mutually agreed terms, cooperation with, support to and development of voluntary patent pools and other voluntary initiatives, such as the WHO COVID-19 Technology Access Pool (C-TAP) and the Medicines Patent Pool".[319] Initiatives such as this give signals of common understanding of the changes that need to be made, especially in terms of promoting local production efforts and other efforts in support of that. Hopefully, in the future, we will see initiatives like this turn into actionable targets and results.

Moreover, a 2006 report from the WHO Commission on Intellectual Property Rights, Innovation and Public Health discussed global purchasing and procurement arrangements and "pooled purchasing" as another possible means to lower prices and thus improve the accessibility of medication in connection to the HIV/AIDS pandemic, and beyond. In addition, the report found that these types of arrangements could help improve (vaccine) production locally.[320] Further possible solutions to improve vaccine access and in general, medical supply access in low- and middle-income countries have also been presented, including the use of

held 24 May - 1 June 2021), <https://apps.who.int/gb/statements/WHA74/PDF/South-Centre-13.4.pdf>, last accessed 3 February 2022.

[319] WHO, Seventy-Fourth World Health Assembly, *Strengthening Local Production of Medicines and Other Health Technologies to Improve Access, Draft Resolution Proposed by Argentina, Australia, Brazil, Canada, China, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, Iceland, Indonesia, Libya, Mexico, Morocco, Norway, Paraguay, Peru, Philippines, Russian Federation, Sudan, Switzerland, Thailand, Turkey, United Kingdom of Great Britain and Northern Ireland, United States of America, Uruguay, Member States of the African Group and Member States of the European Union*, WHO Doc. A74/A/CONF./1 (25 May 2021), pp. 1-2.

[320] WHO Commission on Intellectual Property Rights, Innovation and Public Health, *Report on Public Health, Innovation and Intellectual Property Rights* (World Health Organization 2006), pp. 126-127.

artificial intelligence[321] or creating an entirely new international treaty on pandemics[322]. Moreover, some have argued for a monetary prize-based system to incentivize further medical research, instead of the current IP-centered incentive system, by which exclusive rights are being granted to innovators to foster innovation and R&D[323]. As an example, one proposed way to use the prize-based system which could be useful to consider in the future has been the Health Impact Fund, which "creates markets for less profitable medicines by linking clinical benefit to numeration"[324], in other words, uses prizes to aid in access to medicine-related challenges, but which also has not attracted much interest thus far[325]. All in all, these remain intriguing possibilities and all of them bring out even further regulatory questions but will not be discussed in this paper.

In summary, the optimal solution is probably not a win-win solution for all stakeholders, but what is clearly needed, is to improve and learn from the mistakes and problems we have faced in the current pandemic in connection to the use of the international IP system and the distribution of vaccines. Combining the interests of public health, while providing sufficient IP incentives for companies and other stakeholders to keep innovating, is extremely difficult. Innovating and especially R&D related to medical products is extremely challenging and costly, and competition-related aspects are extremely relevant, and the solution cannot be to ignore these innovation incentives and considerations either. While no one perfect solution is likely to exist, it is important not to waste as much time as we have during COVID-19 in the future, as that has had detrimental effects on public health, and inevitably has caused the loss of too many lives, many of which could probably have been saved with genuine cooperation.

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[321] See for example "Section 3: Case Studies on Digital Solutions for Vaccine Access and Product Safety" from COVID-19 Clinical Research Coalition, 'COVID-19 Vaccine Access, Achieving Equitable Access to Quality COVID-19 Vaccines, Using Digital, AI, and GIS Tools' (January 2022), pp. 19-20 <https://covid19crc.org/wp-content/uploads/2022/01/Vaccine-Access-Report_6-January.pdf>, last accessed 3 March 2022.

[322] Silvia Behrendt, EJIL:Talk!, Blog of the European Journal of International Law, 'Why the Rush? A Call for Critical Reflection on the Legal and Human Rights Implications of a Potential New International Treaty on Pandemics' (29 July 2022), <https://www.ejiltalk.org/why-the-rush-a-call-for-critical-reflection-on-the-legal-and-human-rights-implications-of-a-potential-new-international-treaty-on-pandemics/>, last accessed 14 March 2022.

[323] See, e.g. James Love and Tim Hubbard, 'The Big Idea: Prizes to Stimulate R&D for New Medicines', (2007) 82(7) Chicago-Kent Law Review 1519, p. 1520 <https://scholarship.kentlaw.iit.edu/cklawreview/vol82/iss3/16>, last accessed 7 March 2022.

[324] Johanna Gibson, *Intellectual Property, Medicine and Health: Current Debates* (Ashgate Publishing Limited 2009), p. 142.

[325] Cynthia M. Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (Oxford University Press 2011), pp. 367, 369.

# 6 CONCLUSION

*"Viruses have no nationality. They are the enemy of human community and no country. Nobody has the privilege to be exempted from their attacks."*[326]

The COVID-19 pandemic has changed the world in many foundational ways. However, unlike what has been presented, the issues and debates surrounding medical treatments, especially vaccines, are not entirely new – many of the battles faced in the past with for example the HIV/AIDS pandemic, have been and are still dealt with, just with a new type of disease. In general, the relationship between public health, access to medicines, and the role of IP have been largely debated in different international organizations for the past decades in an effort to learn from the past, but still, the COVID-19 pandemic has shown how ineffective most of these attempts have been.

Currently, while many high-income countries are slowly returning to normal pre-COVID-19 routines, many countries with less negotiation and financial power are still waiting for even their first doses. In this connection, IP has indeed played a part in the vaccine distribution inequalities faced mostly by the Global South, and consequently, international IP rules, especially TRIPS, have been largely debated in international arenas. The debates have sometimes been there for a reason, but in my view, more often not – the possibilities of e.g., TRIPS rather than the issues of it have often been overlooked, and the economic interests of wealthier nations and indirectly, pharmaceutical companies have prevailed. A cynical (or a realist) mind could argue that the events that have taken place during COVID-19 are not surprising, but rather another strong indicator of the colonialist roots the international economic order and law have deeply embedded into them[327].

To answer my research question of *how has international IP regulation affected the inequalities in COVID-19 vaccine distribution between the Global North and Global South***,** I find that while IP is vital for medical companies and innovators to gain profit and prizes from their groundbreaking innovations, during COVID-19 IP has been used as a tool of economic power, to which only the richest countries have had access to, rather than as a tool to promote human

[326] This quote is from a UN blog post from Xiaolan Fu, the founding director of the Technology and Management Centre for Development (TMCD) of the University of Oxford. See, UN Department of Economic and Social Affairs, 'Blog: G20 Should Be Anchor in COVID-19 Storm' (15 May 2020), <https://sustainabledevelopment.un.org/?page=view&nr=1664&type=230&menu=2059>, last accessed 24 January 2022.
[327] Gleider Hernández, *International Law* (Oxford University Press 2019), p. 525.

rights and everyone's right to health and right to benefit from these marvelous technological inventions. Moreover, I argue that too much energy has been put into debates and narrow initiatives such as the TRIPS waiver, without considering what truly matters, which is promoting public health and respecting human rights.

Moreover, international IP regulation should not even have been considered the core issue in these debates – the IP system does indeed carry the potential to be flexible, especially in connection to public health, which was exactly what the Doha Declaration intended to highlight already in 2001. IP regulation was intended to be interpreted while keeping in mind the "right to protect public health and, in particular, to promote access to medicines for all".[328] Furthermore, the objectives, and principles of TRIPS, which explicitly highlight the importance of public health, should be taken into consideration as well[329], as has been laid out in TRIPS Preamble, Article 7, and Article 8 and decades' worth of WTO negotiations, projects, and discussions. This is, in my eyes, the key area in which we as a global community have failed. In other words, even though the Doha Declaration, as an example, has been referred to on multiple occasions during COVID-19, we – i.e., the global community and especially those with more power to negotiate and make decisions – have failed to act according to it, and in fact, according to the spirit of other TRIPS Articles as well, including Articles 66.2 and 67, or even the spirit of e.g., the 2030 Agenda for Sustainable Development goals. Moreover, even the Doha Declaration Paragraph 6 System "serves as a reminder that patent rights are not absolute and that public interest considerations can prevail".[330] We have not been successful enough in providing incentives for sharing IP and COVID-19 technology and have not been able to respond to the public health crisis in a way that TRIPS and human rights norms would demand us to. We have not sought a balance between IP holders' interests and public health but have created a system of slow discussions and leaning on the interest of the most powerful actors.

Moreover, my sub-research question was as follows: *Is the international IP system inefficient in public health crises, and if so, how should it be amended?* Drawing from what we have learned from the COVID-19 pandemic response, the answer is that yes, the current IP *system* – not *regulation* necessarily - is insufficient. This can be seen also from the similarities between

[328] Antony Taubman, Hannu Wager, and Jayashree Watal, 'TRIPS and Public Health' in Antony Taubman, Hannu Wager, and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2020), p. 200.
[329] Doha Declaration, para. 5(a).
[330] WTO, *Informational Note: The TRIPS Agreement and COVID-19* (15 October 2020), p. 9 <https://www.wto.org/english/tratop_e/covid19_e/TRIPS_report_e.pdf>, last accessed 28 February 2022.

the current and the HIV/AIDS pandemic – despite the decades in between, similar IP-related debates and issues have emerged. However, the question of how the current system should be amended is much more complex. The biggest reason for this is that the failures of the COVID-19 vaccine distribution and response are a compilation of different factors such as competition and financing, but more importantly, lacking political willingness, underlying biases, and tensions, rather than merely about international IP norms and the rule of law.

However, we do have tools to learn from the past and better prepare for future public health crises that come our way. Rather than continuing to discuss regulatory shifts and policy changes, we need to create actionable, concrete solutions and targets. A great starting point is to start empowering developing countries and providing them with tools to become more self-sufficient and move away from donor dependency. Developing countries are not incapable of producing medical products, or even the complex COVID-19 vaccines themselves, but the issue has been more the reluctance to share all needed knowledge, components, and IP to start the manufacturing processes. What is positive, is that there have been genuine efforts towards increasing domestic manufacturing capacity and creating IP sharing platforms that would truly work, not just on paper. These have included initiatives such as the mRNA Technology Transfer Hub, which carries a lot of potential. Another possibility to prepare for the future would be to prepare new forward-looking international treaties or agreements, or multilateral agreements between different stakeholders that would create binding commitments to act in a crisis, but also create provisions to prevent further IP debates from arising. Granted, it is extremely difficult to perfectly prepare in advance for the unknown, but as we have seen, we must, or we will face the same debates in the future that are currently had. One could even ask, whether making a more genuine effort in implementing e.g., the GSPA-PHI strategy before the COVID-19 pandemic could have, quite literally, saved lives. Thus, regardless of the efforts presented during COVID-19 and the past few decades, a long road remains ahead to create a system of efficiency and equality.

In sum, even though in many ways the pandemic has shown just how many improvements need to be made in connecting the goals and interests of public health and IP, I remain hopeful for a better future. As we have seen, some initiatives have the potential to help us prepare better for the future and find better balances between public health and IP by incentivizing innovation, and more broadly, finding a better balance between respecting human rights and economic development. I do believe that there is a compromise between these interests and tensions, but it requires the entire world, especially the part of the world with the greatest power, to be interested in finding it. The COVID-19 pandemic has taught us that while there might not be

one perfect solution to answer all needs, we must do better in the future regardless of which solution we end up choosing. If not, the price of unwillingness to act will be paid with the lives of the most vulnerable once again, as history has proven to us on many occasions.

Finally, a quote from 2009 that has remained relevant: "Towards achieving global health equity, the guards surrounding the institutions of health and intellectual property must be challenged."[331]

[331] Johanna Gibson, *Intellectual Property, Medicine and Health: Current Debates* (Ashgate Publishing Limited 2009), p. 193.