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I dedicate this thesis to the millions of people who have lost their lives or loved ones to the COVID-19 pandemic.

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Multistakeholder Influence on Intellectual Property:

Vaccine Equity and Access in the COVID-19 Pandemic

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By

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Abstract
On March 11, 2020, the World Health Organization declared the COVID-19 or SARS-CoV-2 outbreak as a global health pandemic. The most developed nations have been able to inoculate significant portions of their populations, but developing countries have faced significant challenges. The disproportion in vaccination efforts has raised questions around vaccine equity and access that can only be addressed with multistakeholder cooperation. A multistakeholder governance structure can be considered a mechanism to foster cooperation between these states, intergovernmental organizations, corporations, nongovernmental organizations, and other civil society actors. With such a diverse set of players involved in the pandemic, it is difficult for all stakeholders to align their interests when their mandates and business activities are not necessarily focused on the same goals. Whereas some stakeholders favor substantial intellectual property rights to foster innovation, others see the benefits that flexible protections could have on vaccine production and deployments efforts. However, to ensure that vaccine equity and universal access remain at the forefront of combatting the COVID-19 pandemic, corporations and their supporters should at least be open to discussions around implementing temporary, flexible intellectual property protections as outlined in the World Trade Organization's TRIPS Agreement. Overall, the COVID-19 pandemic has demonstrated a need for more clearly defined protocols to establish a course of action concerning global public health that does not compromise a global commitment to social justice.

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Introduction

On March 11, 2020, the World Health Organization declared the COVID-19 or SARS-CoV-2 outbreak as a global health pandemic (see Appendix A for an explanation of what a pandemic is). The issue in the ongoing pandemic is multipronged, with countries of different statures facing different problems. In addition, there have been issues with procuring preventative resources such as masks and gloves. Pharmaceutical companies have developed therapies to treat COVID-19 symptoms, but even treatments have been trial and error. Over a year after the onset of the pandemic, vaccines have been developed to bolster immunity, and some countries have seen great success with vaccination efforts. However, Tedros Adhanom Ghebreyesus, the current director-general of the World Health Organization, has expressed deep concern with inequality in vaccine development and deployment efforts (Adhanom Ghebreyesus, 2021). Oxfam's Health Policy Manager, Anna Marriott, notes that pursuits of profit and monopoly power guide the current landscape for vaccine deployment (Dransfield, 2021). The COVID-19 pandemic has imposed several public health concerns on society. While the devastation of the pandemic has been apparent worldwide, low-income countries are disproportionately affected by the pandemic due to the lack of access to vaccines (WHO, 2021c). Despite continued vaccination efforts, stakeholders have struggled to overcome a supply crisis that has only seen three-tenths of 1 percent of vaccines go to low-income countries (Zaitchik, 2021; WHO, 2021b).[1] Further, high-income countries have administered 61 times more doses per inhabitant than low-income, developing countries (WHO, 2021d). The longer vaccine inequity persists, the more the virus will keep circulating and evolving, and the longer the social

[1] On May 14th, 2021, WHO Director-General Tedros Adhanom Ghebreyesus delivered a media briefing, announcing that at the time, 0.3% of vaccine supply was going to low-income countries. This figure may have since changed. Still, it is conceivable that low-income countries continue to be disproportionately allocated vaccines in the COVID-19 pandemic.

and economic disruption will continue. Even though the United States and other governments and coalitions have monetarily supported vaccine production efforts, many vaccine producers in developing countries have limited know-how, and the nations most affected by the pandemic have not been afforded the doses to vaccinate their populations. Countries have proposed an intellectual property patent waiver as a solution to the difficulty of vaccine development and deployment (see Appendix B for an explanation of what an intellectual property waiver is).

The international community, consisting of governments, international organizations, civil society, and non-governmental organizations, has taken on an increasingly collaborative approach to international policymaking, often referred to as multistakeholder governance or multistakeholderism (Scholte, 2020). It builds on multilateral interactions amongst states and intergovernmental organizations. A multistakeholder governance structure can be considered a mechanism to foster cooperation among these actors as well as corporations, nongovernmental organizations, and civil society. This structure is gaining prominence in policymaking and international relations. Multistakeholder governance serves as a point of departure from multilateral negotiations amongst states. A variety of stakeholders are needed in response to the COVID-19 pandemic, but cohesive responses are difficult to achieve when stakeholders have conflicting interests. Some influential stakeholders champion values for creating effective international intellectual property policies. Strong protections may allow for advancement in large multinational corporations primarily based in the United States and other developed nations. However, developing countries in the global economy are disproportionately disadvantaged in their development and public health outcomes. Ultimately, this paper aims to evaluate the multistakeholder influence on intellectual property rights and access as the global response to the patent waiver proposal.

Part 1 of this paper will present the theoretical background for intellectual property. The first section will provide an overview of free trade at the intersection of economics and international relations principles, it will also cover industrial organization. The second section will explore development concepts related to the COVID-19 pandemic, providing insight on the developed and developing dichotomy as it relates to the COVI-19 pandemic. The third section will offer policy recommendations for patent-related issues.

Part 2 will broadly cover the multistakeholder governance structure and introduce key corporate players in the pharmaceutical space and nongovernmental and intergovernmental organizations. Notable organizations include the World Health Organization (WHO), the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO). This section will also introduce the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Part 3 will explain the COVID-19 challenge regarding vaccine equity and access. It will offer perspectives from prominent biopharmaceutical groups and provide examples of multistakeholder initiatives related to COVID-19. This section will also offer an overview of the financial prospects of the leading COVID-19 vaccine producers. Finally, this paper will conclude with reflections on how the COVID-19 pandemic has demonstrated a need for more clearly defined protocols for developing a course of action concerning intellectual property that does not compromise the global commitment to preserving global public health.

Part 1. Theoretical Debates on Intellectual Property: Trade, Development, and COVID-19

1.1. Trade and Economic Precursor to Intellectual Property

Discussions to reconcile COVID-19 vaccine equity and access in the international community are rooted in trade history, considering the relationship between trade and intellectual

property. Intellectual property concerns date back to 600 BCE, though more concrete scenarios are traced back to the early renaissance (Abou Naja, 2020). Intellectual property can be thought of as creations of the mind, encompassing everything from art to inventions, computer programs to trademarks, and other commercial signs (World Intellectual Property Organization, 2020: 1). Intangible assets are commonly referenced as forms of intellectual property. Economic development and cultural progression are highly dependent on human capacity to innovate (Anechitoae, 2012). So, while ideas may be plentiful, acting on those ideas has become dependent on whether or not one has the right to do so. Some degree of intellectual property protection is necessary for ensuring that creators can continue to innovate and that they are able to make a fair return on their investment (WIPO, 2020: 2).

The ongoing discourse on free trade is strongly concerned with competing protectionist policies and trade liberalization ideologies that have guided major economies over time. The international community has long grappled with whether or not free trade is an ideal strategy to accomplish essential development objectives. Multilateral cooperation under trade liberalization helps to "protect nations from the unwelcome consequences of openness and therefore, remains crucial as a response to concerns about the fairness and equity of trade" (Gunnella and Quaglietti, 2019). In justifying free trade, an economics scholar may point to limited government intervention in the form of economic or political tariffs, quotas, or subsidies. An international relations scholar may build off these tactics to explain the treaties in place supporting free trade, such as the United States-Mexico-Canada Agreement. Scholars from different schools of thought may struggle with what free trade should look like in the current international arena, with some arguing that we are left with only remnants of free trade. The existence of specific free trade agreements demonstrates that the world operates under a somewhat limited trade liberalization

regime where certain bilateral and multilateral agreements prevail. How has the global economy ended up here, and what has changed over time?

Toward the end of the 19th century, a European depression enticed the rise of protectionism in many nations. Early in the 20th century, following the First World War, the United States gained prominence in the international world and eventually became the largest trading nation. This newfound influence meant that the United States' domestic policies would become increasingly important to the global trading regime, as evidenced by the 1930 Smoot-Hawley tariff and the Reciprocal Trade Agreements Act (RTAA) of 1934 (Winham, 2014). The RTAA served as a point of departure from the protectionist policy enacted by the government at large to the focus on the presidency (Winham, 2014; Paul, 2010). In the grand scheme of the international economy, bilateral negotiations would be the mechanism by which tariffs would be set, ultimately achieving trade liberalization.

Once rooted almost exclusively in protectionism, the global economy has ultimately trended towards freer trade over the last few decades.[2] Trade used to serve the purposes of specialization, resource procurement, and political and military power, but has evolved to a global development system rooted mainly in free trade, with many countries, international organizations, and other entities championing at least some of the values associated with free trade in an increasingly globalized world (Gunnella and Quaglietti, 2019). Free trade is disputed and often for a good reason, considering, among other vices, its contributions to the exploitation of workers in areas where labor is abundant and restrictions are not very stringent (Fronning,

[2] The European Central Bank published an economic bulletin acknowledging the tension between protectionism and trade liberalization. The United States took on a more protectionist stance on trade under the Trump Administration. Threats from 2017 were followed up tariffs in 2018, carrying significant implications for trade relations; these may include increased costs associated with trade, increased prices for goods, and potential benefits for countries outside of bilateral disputes (Gunnella and Quaglietti, 2019).

2000; Rodrick, 2012). Further, technological advancement that enhances trade has not been uniformly put in place, and in some developing countries, that technology is in the beginning stages (Rodrick, 2012).

1.1.1. Industrial Organization

In order to contextualize stakeholder responses to discussions on COVID-19 patents and potential waivers, it is helpful to start with the basic principles governing how economists evaluate decision-making at the firm level. The COVID-19 pandemic highlights some ways that market failures occur, considering that pharmaceutical companies and governments had not sufficiently prepared for the onslaught of challenges that would come with it (Florio and Gambia, 2021; Firey, 2020). Economic studies of market operations typically assume extreme market conditions under either pure monopoly or perfect competition. A monopoly is characterized as a firm that provides a differentiated product in a market with significant barriers to entry, and the pharmaceutical industry's interaction with intellectual property introduces such conditions (Ilie, 2014). Senator Chris Coons describes the intellectual property as a facilitator of critical, cutting-edge innovation and thus crucial reward innovative efforts (Lopez and Bultman, 2021). Still, it can also limit the spread of technological advances and shift market power, leading to higher prices for consumers (Maxwell and Riker, 2014: 2). In essence, the resulting monopoly is the industry considering the lack of close substitutes.

In economics, the term "competitive market" describes a specific set of characteristics under which all of the following conditions are satisfied in the long run (Waldman and Jensen, 2003; Florio and Gamba, 2021).

1) Perfect competition has many buyers and sellers for the products, each small relative to the total purchases or sales.

2) Homogeneous or identical products, which means that consumers cannot distinguish one firm's product from another's.

3) Perfect information that is freely available and easily accessible to buyers and sellers.

4) A lack of barriers to ensure free entry and exit. Adjustments to changing market conditions require that resources enter or leave the industry. In a perfectly competitive market, these adjustments occur without firms having to incur any special costs.

5) No transaction costs for buyers and sellers, meaning that there are no costs associated with engaging in the market.

Perfect competition is concerned with firms and consumers being price takers and the famed invisible hand regulating the market. In reality, much of what firms encounter falls somewhere on a spectrum between the two, with few markets on either absolute of the spectrum. An alternative to these situations is a state of limited competition with few producers or sellers; this kind of competition is known as an oligopoly. Meanwhile, “monopsony” and “oligopsony” refer to situations where market power shifts so that only one buyer or a small number of buyers exist for a product. Even so, violations of the characteristics above for competitive markets indicate that market failures have occurred, a commonality to the market for intellectual property and thus pharmaceuticals (Florio and Gamba, 2021; Ghauri, 2009).

Market failure can be characterized as any of the following: shifts or unbalances in market power, asymmetric information, and externalities. Negative externalities are linked to common resources, which are rival and non-excludable.[3] Overuse of common resources gives rise to the “tragedy of the commons” scenario, which often refers to environmental resources that

[3] In economics and international relations, goods are categorized by whether or not they are rivalrous and excludable. A good that is rivalrous means that its use by one person will diminish consumption available for others, but a good that is non-rival will not limit others’ consumption. Excludability is determined by whether or not consumers can be denied use of a good based on their ability to pay or meet certain requirements.

are diminished due to over-exploitation because of the community members' greed or desire for security and lack of trust for one another (Zerbe and McCurdy, 1999; Hardin, 1968). Proposed solutions are government intervention or privatization to regulate the use of common resources, though this only addresses the issue at local or national levels, not in the global context (Hardin, 1968). Positive externalities are associated with public goods, which are non-rival and non-excludable. Public goods are susceptible to the free-rider problem in which the maintenance of important public resources is jeopardized by the incentive some single agents have not to contribute; these agents are called free riders because they can still benefit knowing that their lack of effort has very little or even negligible effect on the public good itself (Hardin and Cullity, 2020; Zerbe and McCurdy, 1999; Ledyard, 1987). The application of public goods to specific intellectual property-related issues and distinctions, particularly in COVID-19, remain contested.

Inventions and innovations, the capital needed to produce them, and the body of knowledge required to replicate products and services encompass the crucial aspects of the costly innovation process. Boldrin and Levine (2003) emphasize the importance of know-how in the intellectual property process; this relationship between the ideas embodied in innovation and the people that create them provides significant economic value. To borrow from Ghauri (2009) and Pisano (2006: 9), know-how itself has become a separable asset that is traded, valued, and appropriated. Some debates on COVID-19 intellectual property waivers relate to the importance of know-how. The following scenarios illustrate outcomes regarding intellectual property under three specific conditions.

1) Scenario 1: Society and the patent holder both benefit from intellectual property patent protection. However, society would experience reduced efficiency over the

duration of the patent. Also, due to the patent holder's dominance and a lack of incentive from competitors, there has been a slow rate of technological improvement. Essentially, this scenario supports patents, allowing the holder to develop a monopoly and leaving a little space for other producers to join the industry successfully (Waldman and Jensen, 2007: 494).

2) Scenario 2: The second scenario is one without a patent system at all. An innovator lacking patent protection may face greater competition as others seek to innovate and advance their market share. Interestingly, this scenario leads to an increased rate of technological advance, considering the aggressive innovation (Waldman and Jensen, 2007: 495).
3) Scenario 3: Alternatively, the absence of a patent protection system may result in diminished societal benefits, that is, no innovation at all. Patents offer the security of taking on the expense of research and development to bring a product to market (Waldman and Jensen, 2007: 495). It is significantly more expensive to get a drug to market with no protection, and doing so is not guaranteed.

While there is some variability in the absence of a patent protection system, the economic uncertainty for the resulting situation leaves society better off relying on patent protection. We can conclude that technological advances would continue without the patent system. One key difference would be the reduction of monopoly power.

Intellectual property regimes ultimately aim to foster innovation by allowing innovators to restrict the use of knowledge produced by imposing incentives in exchange for that knowledge and thus offer the possibility of a return on investment (Ilie, 2014). Attention to different types of goods provides valuable insight into the patent system. Knowledge is both non-rival and non-

excludable, so there is no marginal cost associated with consuming knowledge and information (Ilie, 2014). Therefore, intellectual property, that is, the vast breadth of knowledge and ideas, can be considered intangible capital (WIPO, 2017; Bolatto et al., 2020). However, the protection of knowledge is a "deliberate construction to create scarcity and allow individual commercial exploitation of an un-rival source" (West, 2012: 28). Intellectual property protections are a maneuver to transition knowledge from a public good to a monopoly. While there are benefits of an intellectual property protection system, an overprotected system will limit social gains by limiting the dissemination of the innovations, and in the case of public health, stifling the potential for global results.

Nevertheless, a weaker system would reduce innovation due to the lack of an adequate return on investment. Essentially, investors are not willing to take on the costs without provisions that guarantee at least some profit over time. Meanwhile, offering intellectual property protection and the allowance of extended exclusive rights may lead to pricing above marginal cost and a positive return on investment in R&D. The result, however, is the creation of monopoly power, which may indicate, among other things, inequalities regarding consumption and distortions in resource allocation (Ilie 2014). Also implicated in this result is the creation and dissemination of information, which is often asymmetric. Ultimately, monopoly power can cause concern, but it offers some insight into how capitalist societies function. Moreover, research and empirical reality suggest that oligopolies are actually more likely to coincide with rapid technological change (Waldman and Jensen, 2007). The COVID-19 pandemic demonstrates how a few companies have been able to develop vaccines at unprecedented rates.

1.2. Aligning Development Concepts With COVID-19 Debates

The debates around COVID-19 and intellectual property involve all developmental and economic categorizations of countries. Under the umbrella of trade relations, as previously discussed, governments dictate policy regarding intellectual property. Rodrick (2012) alludes to the idea that intellectual property rights can hinder technological and economic growth in some developing economies. The majority of patent applications come from developed countries, whose corporations have the capital and manufacturing capacity to innovate (Kitch, 1994; Kmietowicz, 2002).[4] While the United States and a few countries in the European Union are influential leaders in economic development, there are others that are gaining regional and global traction. Brazil, Russia, India, China, and South Africa have formed a bloc of emerging countries that have been gaining traction as influential countries. Each of them has managed to shift intellectual property, and they collectively hold around 25% of the global biotechnology patents (Streltsova and Linton, 2018).

Some developing countries do not have the resources, know-how, or infrastructure necessary to facilitate research. The disparity between what developing countries are able to do and what they are not able to do has been exacerbated during the COVID-19 pandemic. Countries hit hardest have been reliant on aid from international organizations and developed countries with the vital resources to develop vaccines quickly. A trend toward globalization means that countries are often reliant on one another to carry out production. Globalization alters inequality both within and across countries, sometimes for the better, sometimes for the worse. So, while free trade and globalization work in tandem, there are downsides that produce losers in certain situations.

[4] Development is dynamic. China was once undoubtedly regarded as a developing economy but has gained significant traction in developing technologies and is now a leader in filing patents (Nebehay, 2020).

Though there are no universal criteria for justifying country classification based on their level of development, countries are generally referenced as either developed or developing. Within this dichotomy, there is much variation (Gbadamosi, (n.d.); Nielsen, 2011). Hansen (2013) presents the following categories for dividing the countries engaged in the international economic system: net sellers exporters, transitioning countries, and net user importers. Of these categorizations, the net seller exporters refer to developed countries that seek strong intellectual property protection worldwide, primarily the United States and other highly developed countries. Hansen (2013) describes transitioning countries as developed European countries seeking increased domestic protection to give more incentives to their industries to create and compete domestically and abroad. The net user importers are mainly developing and newly industrialized nations, who seek to limit protection globally, but at least within their borders (Hansen, 2013; Dittrich and Bringezu, 2010).

Different measures such as economic performance or composite indicators like the Human Development Index will classify countries based on different criteria. Developing countries can be categorized as low or middle-income, and developed countries are typically high-income countries. The United Nations releases an annual World Economic Situation and Prospects (WESP) report, classifying countries based on the economic conditions, whereby countries with less than $1,036 gross national income (GNI) per capita are classified as low-income countries, those with between $1,036 and $4,045 GNI per capita as lower-middle-income countries, those with between $4,046 and $12,535 GNI per capita as upper-middle-income countries, and those with incomes of more than $12,535 GNI per capita as high-income countries (Bodsky, 2021). [5]

[5] These figures were estimated based on the World Bank Atlas. The classifications can be seen in the 2021 WESP Report (Brodsky, 2021).

Many scholars have used empirical tests to characterize the relationships between intellectual property and development. It is important to note that empirical modeling can be complicated considering the fact that data can be limited, and policies for implementing intellectual property rights are not always transparent. Lai and Qui (2003) explore the developed world's intellectual property rights standard for the developing countries, noting different economic implications. They consider negotiations under which the developing countries strengthen protections, and as a result, the advanced developed countries lower their tariff rates. Grossman and Lai (2004) also consider the incentives and motives of developed and developing nations. They demonstrate that there is a level of patent protection that maximizes global economic welfare, and that can be achieved with different combinations of country-level patent protection. Ultimately, there would need to be some level of compensation or at least some action taken by the advanced technology companies in order for the developing world to be willing to strengthen intellectual property rights.

Chen and Puttitanum (2005) consider how a developing country's capacity for innovation contributes to the intellectual property regime it adopts. Their model aims to predict how a country will choose its level of intellectual property protection in order to maximize domestic social surplus, that is, the combined consumer and producer surplus within a country. According to their model, poor or low-income countries will actually provide strong protection for intellectual property in order to secure access to foreign technologies. This study appears to assume that technologically advanced countries are willing to share their technology and know-how, despite strong protection. Advanced or high-income countries would continue to implement and enforce strong protection to benefit domestic innovators and the national economy. Under

the same model, middle-income countries would opt for weak protection in order to allow for domestic imitation of foreign technologies.

Branstetter and Saggi (2011) establish an empirical test on how the strengthening of intellectual property in developing countries impacts their growth, ability to attract foreign direct investment, and the location of global production. A key takeaway from this study is that strengthened intellectual property protection in the developing Global South countries actually raises the cost for imitation, catering to the concerns of patent holders in the Global North. The decreased risk of imitation would make these developing countries more attractive candidates for foreign direct investment and production or licensing sites. Ultimately, strengthening intellectual property rights in the Global South benefits firms in the Global North but does come at a cost to companies trying to innovate in already disadvantaged developing areas (Maxwell and Riker, 2014). Political economist Joseph Schumpeter theorized that capital would be concentrated in a few large-scale firms under capitalism. Schumpeter describes capitalism as a dynamic, instead of static, method of economic change, pointing to the dynamic efficiency under which capitalist firms operate (Waldman and Jensen, 2007). A market under this model drives innovation, though, almost to a fault considering the idea that there can never be too much development. This perspective is further met with resistance, considering the global externalities that arise from infectious disease. Individual country economic circumstances, in terms of growth and development, will dictate its stance on intellectual property. The same can be said of their disease concerns, for countries with more public health issues and lower economic status could benefit from patent reforms.

The relationships demonstrated by these empirical tests are not wholly representative of developing countries, considering that there is much variation. They do, however, provide an

overview of the possibilities for economic implications of strengthening intellectual property rights. Of course, there is also a view that their reform and advancement in developing countries have little effect on developed countries (Park 2012). An efficient system of intellectual property protection, though hard to define, could benefit creators and consumers, businesses and their competitors, and high- and low-income countries (WIPO, 2020: 3). However, such a system is difficult to realize considering the varying needs of countries based on their technological capabilities, and in the context of COVID-19, based on their social and humanitarian needs.

1.3. Policy Recommendations

Particular policy possibilities allow for patent protection while limiting market power; these include legal proceedings or imposing price ceilings. Solutions include decreasing the number of years that a patent is valid or requiring compulsory licensing to all reasonable royalties (Waldman and Jansen, 2007; Subhan, 2006). Most patents last 20 years from the date of filing (Boldrin and Levine, 2003; Posner, 2005). During this time, patent holders can enforce their right to restrict other innovators from using and trying to create a generic version of the product (De-Campos Rudinsky, 2021). Other policy recommendations include expanding the scope of patent protection to include new areas, tightening legal requirements to gain patent protection, or speeding up the patent review process (Waldman and Jensen, 2007: 499). Besides these, Subhan (2006) proposes establishing patents on processes, a narrower category than product patents, which would shift the focus toward the manufacturing process.

Ilie (2014) and Subhan (2006) suggest establishing a financial system that rewards creators of intellectual property rights through government subsidies; this way, competition is encouraged. To this effect, prices will be lower than in a monopoly situation, the quantity produced will have more potential to increase. However, government subsidies offer security for

corporations driven by profit (Ilie 2014). Alternatively, governments may consider imposing price ceilings on patents, maintaining rights to garner profits. For the benefit of public health, and in the case of COVID-19, these solutions also protect the rights of citizens to access treatments and medical solutions.

Part 2. The Multistakeholder Approach to International Policymaking

2.1. Current State of International Policy Making-A Multistakeholder Approach

A multistakeholder approach for developing joint strategies for addressing global challenges brings together intergovernmental organizations, non-governmental organizations, corporations, civil society, individual governments, and other actors (Gleckman, 2014). Gleckman (2014) notes that multistakeholder governance is a rather new structure that includes corporations in a global context. Multistakeholder governance is essential for many corporate responsibility initiatives, taking on structures outside the typical multilateral scope (Rasche, 2012). In the face of the COVID-19 pandemic, corporations have needed to become socially committed even in areas not directly related to their business (Scherer and Palazzo, 2007).

Further, a multistakeholder governance structure can be considered a key mechanism for the legitimate involvement of corporations and other actors in regulatory processes. To illustrate this, consider the United Nations and its affiliates. Many non-governmental organizations operate independently of the UN but have been granted observer status. In 2016, the UN bestowed this status upon the International Chamber of Commerce, an unprecedented act for an organization of its kind (Wilson and Huneke, 2016). The International Chamber of Commerce is a business organization with millions of member corporations across several countries. It includes some of the largest companies and several smaller ones across every sector, making it a highly representative group. Organizations with observer status to the UN General Assembly are

privy to critical procedural negotiations. This extension exemplified the increasing prominence of multistakeholder governance, allowing corporate world members a seat at the table; the UN recognizes that the business community is a vital and viable partner (Wilson and Huneke, 2016). As per Gleckman (2014: 184), multistakeholder governance is rooted in the following conditions:

> "First, that multistakeholder structures do not mean equal roles for all stakeholders; second, that the corporation is at the center of the process; and third, that the list of WEF's multistakeholders is principally those with commercial ties to the company: customers, creditors, suppliers, collaborators, owners, and national economies."

Under this framework, players outside these descriptions are considered government and society. So, while multistakeholder governance can allow for legitimate corporation involvement, there are also instances where stakeholder allegiances to their mandates allow for questionable actions from corporate stakeholders. For example, former Pfizer Chairman Edmund Pratt and former IBM chairman John Opel were influential in mobilizing corporations to form the Intellectual Property Committee at the start of the Uruguay Round negotiations (Ryan, 1998). Pratt and Opel were deeply committed to expanding intellectual property protections globally. The two served on the United States President's Advisory Committee on Trade Policy and Negotiations (ACTPN) during the Carter and Reagan administrations; Pratt chaired the committee, and Opel was head of the IP task force between 1970 through 1989 (Ryan 1988; Devereaux, Lawrence, and Watkins 2006; and Zaitchik, 2021). The ACTPN worked to influence multilateral policy by enlisting lobbying efforts of other corporation-based stakeholders such as the Pharmaceutical Research and Manufacturers of America and the Chemical Manufacturers Association, both of whose members were concerned about trade secret protection (Ryan 1998). In 1986, Pratt and

Opel founded the Intellectual Property Committee, 13 CEOs committed to moving intellectual property onto the international agendas.

2.2. Stakeholders: Big Pharma vs. Nongovernmental Organizations

The three biggest global vaccine-producing pharmaceutical corporations by market value are GlaxoSmithKline (GSK), Merck, and Sanofi, none of which are leading producers of COVID-19 vaccines. Altogether, GSK, Sanofi, and Merck have received over $2 billion from the US government to support vaccine development efforts (Dransfield, 2021). Other biopharmaceutical companies are developing vaccines and treatments, Pfizer, Moderna, and AstraZeneca are leading initial vaccine development and deployment efforts. Pfizer was founded in 1849 and is headquartered in the United States; meanwhile, AstraZeneca was founded in 1999 and is based in the United Kingdom. Moderna is a relatively new company that is often referred to as a biotech startup; it was founded in 2010 and is headquartered in the United States (Kollewe, 2021). Pfizer focuses its science on internal medicine, information and immunology, rare disease, vaccines, and oncology (Pfizer, 2022). Some well-known brands under Pfizer's corporation include Advil, Robitussin, Xanax, and Viagra (Llamas, 2021). AstraZeneca focuses on cardiovascular, renal, and metabolic diseases, oncology, infection and vaccines, neuroscience, respiratory, and gastrointestinal (AstraZeneca 2021). Moderna's therapeutic areas include infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases, and autoimmune diseases (Moderna, 2021a).

Big pharma only represents a few non-governmental stakeholders relevant to the COVID-19 pandemic. Civil society organizations and initiatives have been pushing for open innovation, using public or philanthropic funds to collectively produce research for treatments (Mullard and Aarvik, 2020). Such organizations are concerned with ensuring that public health

remains central to efforts made by all stakeholders. Notably, patent pooling has been put forward as a multistakeholder mechanism for intellectual property and public health management (see Appendix C for an explanation of what patent pooling is). The Medicines Patent Pool is the first patent pool in public health "designed to enhance access to affordable medicines in developing countries through the negotiation of access-oriented and transparent voluntary licenses with the pharmaceutical industry" (Burrone, 2018: 93). The MPP is rooted in transparency and publishes all licenses made available by its corporate patent partners. The MPP operates as an independent nonprofit Swiss Foundation under UNITAID, which the World Health Organization hosts.[6] In response to the pandemic, the MPP expanded its mandate to include COVID-19 as a disease area under which it aggregates research to aid in solidarity.

Voluntary pooling initiatives like the MPP do face some limitations: private sector decision-making leadership, limitations on countries allowed to receive licenses, the reliance on a case-by-case designation on the part of private companies, and government hesitation in granting compulsory licenses (Abbott and Reichman, 2020).

A distinction also ought to be made between the roles of the state and the role of the private sector in the intellectual property discourse. The resources corporations allocate to create intellectual assets and the protected knowledge used in production and consumption are in question. The private sector is heavily dependent on patents to achieve their corporate objectives, though their actions are actually directed toward addressing public interest goals (Taubman, 2010). In the same way that the private sector approach should not be conflated with exclusivity through stringent intellectual property protections that stimulate growth, public interest

[6] France, the United Kingdom, Norway, the Bill & Melinda Gates Foundation, Brazil, Spain, the Republic of Korea, and Chile are the majority funders of UNITAID (UNITAID, 2022). The Bill & Melinda Gates Foundation has been heavily involved in WHO initiatives.

intellectual property principles need not eschew the potential benefits of intellectual property concerning innovation (Taubman, 2010). Government subsidies have been used as a tool for funding innovation, though they can also be understood as an alternative to intellectual property rights.

The COVID-19 Vaccine Global Alliance (COVAX) is another initiative that was formed in April of 2020, shortly after the coronavirus was deemed a pandemic situation; it was formed out of Gavi the Vaccine Alliance, which is a longstanding global health partnership that is involved in coordinating global public health aid (Goldhill, 2021). Advocacy groups Biotechnology Innovation Organization (BIO) and the Association of Pharmaceutical Research and Manufacturers of America (PhRMA) are influential lobbyists on behalf of biopharmaceutical companies. BIO is the "world's largest advocacy association representing member companies, state biotechnology groups, academic and research institutions, and related organizations across the United States and in 30+ countries" (BIO 2021). PhRMA is a self-described advocate for “public policies that encourage the discovery of important, new medicines for patients by biopharmaceutical research companies” in the United States (PhRMA, 2021).

2.3. Stakeholders: Intergovernmental Organizations

Governments have limited power and are not able to effectively combat global issues, at least not on their own; this is the reality that governments are facing in the COVID-19 pandemic (Arcuri, 2020). Intergovernmental organizations (IGOs) emerge as fora, creating spaces to allow multilateral negotiations on pressing issues. COVID-19 is a precarious situation that has required action from a diverse set of stakeholders. These organizations convene to provide systems of checks and balances for member states. The World Health Organization, World Intellectual Property Organization, and the World Trade Organization have a longstanding commitment to

work together on global issues, often referred to as the Trilateral Cooperation (Krattiger et al., 2015; WIPO, 2021). These organizations and their associated treaties hold significant influence in the intellectual property debate on vaccine equity in the COVID-19 pandemic, though they tend to prioritize different issues in responding to the needs of citizens around the world.

2.3.1. *World Health Organization*

The World Health Organization (WHO) was founded in 1948 as a specialized agency of the United Nations. WHO has 194 members and collaborates with governments, civil society, and other organizations and foundations to lead global efforts to attain the highest level of health (WHO, 2022). It is the primary organization concerned with protecting global health, and it has been influential in vaccine procurement efforts. WHO has a history of working at the intersection of public health, innovation, and intellectual property. In 2008, WHO adopted the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, which aims to promote creative ideas on innovation and access to medicines and to solidify "an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases that disproportionately affect developing countries" (WHO, 2011: 38). In collective settings, WHO offers vast expertise in all areas of public health, including medicine and vaccine policies, medical devices, regulatory issues, pricing and procurement, research, development, and innovation (Krattiger et al., 2015: 2).

2.3.2. *World Intellectual Property Organization*

The convention establishing the World Intellectual Property Organization (WIPO) convened in Stockholm on July 14, 1967. The General Agreement on Tariffs and Trade was in place but applied to the greater global trade regime. Specific provisions did address intellectual property, but WIPO was established with a particular purpose to promote intellectual property

protection in the world through the cooperation among states and applicable international organizations (Anechitoae, 2012: 867). As per its website, WIPO is a global forum for intellectual property services, policy, information, and cooperation. It is a United Nations specialized agency, though it is self-funded. There have been times when WIPO offers its expertise to the WHO, notably in establishing the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property. WIPO offered one of the earliest frameworks on intellectual property through the provisions outlined in the Paris Convention.

2.3.2.1. *The Paris Convention*

The Paris Convention, formally known as the International Convention for the Protection of Industrial Property, commenced in 1883; the Agreement has since undergone revisions six times in 1900, 1911, 1925, 1934, 1958, 1967 and 1979 (WIPO, 2021; Yu, 2019: 3). Its focus was on patents, trademarks, industrial designs, utility models, service marks, trade names, geographical indications, and the repression of unfair competition (WIPO 2021*).* This history merely highlights that intellectual property debates have long permeated international borders. In part, the Paris Convention provided a multilateral agreement in the absence of an "agreed framework for IP protection adversely affected commercial relations involving industrial products, branded goods, and creative works" (Watal and Taubman, 2015: 15).

Three main provisions guide the Paris Convention: national treatment, right of priority, and common rules. The national treatment provision stipulates that each state privy to the Convention must grant the same protection to other member states given to its nationals (WIPO *2021).* The condition related to the right of priority notes that applicants may apply for protection in any other Contracting States within designated time frames; those nations seeking protection are allowed to do so in several states over 6 or 12 months (WIPO *2021).* The rules may be

regarded as flexible as they could be tailored to a country's socio-economic conditions and development status. In the case of the Paris Convention, laws protecting industrial property allowed states to exclude sectors and identify the length of intellectual property protection (Jecker and Atuire, 2021: 595). The final provision describes the parameters that all contracting states subscribe to upon acceptance of the Paris convention. These standard rules revolve around the following forms of intellectual property as outlined on WIPO's website (*2021*):

> "(a) *Patents* granted in the different Contracting States for the same invention are independent of each other: the granting of a patent in one Contracting State does not oblige the other Contracting States to grant a patent; a patent cannot be refused, annulled, or terminated in any Contracting State on the ground that it has been refused or annulled or has terminated in any other Contracting State.
>
> (b) The Paris Convention does not regulate the conditions for the filing and registration of *marks* which are determined in each Contracting State by domestic law. Consequently, no application for the registration of a mark filed by a national of a Contracting State may be refused, nor may a registration be invalidated, on the ground that filing, registration, or renewal has not been affected in the country of origin.
>
> (c) *Industrial designs* must be protected in each Contracting State, and protection may not be forfeited on the ground that articles incorporating the design are not manufactured in that State.
>
> (d) Protection must be granted to *trade names* in each Contracting State without there being an obligation to file or register the names.

(e) Measures must be taken by each Contracting State against direct or indirect use of a false *indication of the source* of goods or the identity of their producer, manufacturer, or trader.

(f) Each Contracting State must provide adequate protection against *unfair competition."*

As of 2017, there are 178 contracting parties to the Paris convention.[7] The following eight members became signatories in March of 1883: Belgium, Brazil, France, Italy, Netherlands, Portugal, Spain, and Switzerland. These countries are the only parties to have ratified the Paris Convention, though all other contracting states are legally bound to the Paris Convention (WIPO IP Portal, 2021).

The Paris Convention was influential in the adoption of the Agreement on the Trade-Related Aspects of Intellectual Property that would come nearly a century later. The international community sought the creation of global protection of intellectual property rights codified in explicit provisions to foster international cooperation. While the agreements under the Paris convention may have worked for a while, further action would be needed to address broader areas of intellectual property. As will be discussed, the TRIPS agreement aims to build upon the Paris Convention's treatment of compulsory licensing, which the Convention did not require parties to embed in domestic law (Watal and Taubman, 2015: 142).

2.3.3. *The World Trade Organization*

The World Trade Organization (WTO) is the premier organization for regulating, facilitating, and enforcing trade relations. It emerged out of the General Agreement on Tariffs and Trade (GATT) as a global system of trade rules, a forum for negotiating trade agreements, an arbiter for settling trade agreements between member states, and a support mechanism for

[7] The Republic of Kiribati was the most recent accession to the Paris Convention and plans to enter the Convention into force in February of 2022 (Miller, 2021).

developing countries. The GATT, established in 1947, aimed to sustain free trade essentially by limiting trade barriers. Thirty-five articles dictate the agreements; of the most notable are the two articles condemning internal and external discrimination. Other important guiding principles include the prohibition of non-tariff barriers to trade, reciprocity amongst trading partners, safeguards established as commercial considerations or exceptions in order to address specific problems (Winham 2014). In addition, Winham (2014) notes the Uruguay round of trade negotiations that aimed to strengthen previous GATT policies. Interestingly, the United States did not ratify the agreements that came out of these negotiations as treaties but rather instead implemented them through legislation and administrative action (NYU Law Library, 2020). What emerged from the negotiations was a new international governing body, the World Trade Organization.

The Uruguay Round, the final round of GATT negotiations, commenced in 1986 and lasted until 1994, a year before the official start of the WTO. Whereas GATT focused on trade in goods, the world was advancing, so the WTO and its agreements moved to cover trade in services and traded inventions, creations, and designs; intellectual property has become increasingly contentious under this framework for regulating international trade.

The WTO is one of the most influential international organizations today, and corporations are typically aligned with its stance on bolstering intellectual property protection. Kucik and Surmacz (2019) emphasize that the WTO is indeed a powerful organization, with the committees and bodies under it being pivotal in maintaining relatively successful trade relations. Dispute settlement under the WTO is governed by the Dispute Settlement Understanding and carried out by the Dispute Settlement Body (DSB). The WTO also serves as a forum, championed against protectionism in the face of an increasingly globalized world. Trade

liberalization is certainly a goal of the WTO, supporting the cessation of non-tariff barriers to trade and also poised to limit tariffs (Rivoli 2015:159). The Ministerial Conference is the highest decision-making body of the WTO (WTO, 2022). Under the Marrakesh Agreement, the Ministerial Conference is attended by trade ministers and other senior officials from the organization's members. It is set to meet at least once every two years. Further, this round of negotiations resulted in the Doha Declaration on the TRIPS Agreement and Public Health. In 2007, WIPO adopted the Development Agenda adopted in 2007, which to some extent, demonstrates an interest in flexibilities related to international intellectual property law, including the health-related flexibilities identified explicitly in the Doha Declaration (Krattiger et al., 2015).

A critical aspect of the WTO to global relations is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which provides standards for intellectual property rights, though certain provisions are sometimes left open to interpretation. Besides the TRIPS Agreement, the WTO has overseen the creation of several hundred other agreements; however, the efficiency and success of some agreements have been called into question on the basis of consensus and efficiency among the 164 members of the WTO (Rivoli 2015, p. 277).

2.3.3.1. *Agreement on Trade-Related Aspects of Intellectual Property (TRIPS)*

The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) provides a framework for intellectual property rights, including patents, copyrights, trademarks, trade secrets, and other intangible assets (Shadlen et al., 2005). The TRIPS agreement establishes global minimum standards for trade and intellectual property, though Article 1 does maintain that countries may implement stronger protections than those put forth by the WTO (Volman, 2018). In addition, it serves as the mechanism binding member states to multilateral agreements and

decisions related to trade. It is comprised of 73 articles that outline the contracting members' obligations at the intersection of trade and intellectual property. Articles 27 to 38 are dedicated to discussing patents dealing with topics including patentable subject matter and rights conferred upon the patent holder; Article 31 is of particular importance. Article 31*f* applies the use of compulsory licenses to the domestic market of a Member State authorizing its use (Dziuba, 2010; TRIPS, art. 31f). Article 31b*is* highlights an exception, extending this flexibility to other member states (Volman, 2018; Dziuba, 2010). Compulsory licensing would allow for the more widespread production of affordable generic medicines versions of patented medicines, including vaccines (Garrison, 2020). Members that cannot domestically produce the needed medicines in sufficient quantities would be able to do so with less reliance on exports from their more developed counterparts (WTO, 2017; Garrison, 2020).

In response to the TRIPS Agreement, "rich and poor countries alike have [reformed] their copyright, patent, and trademark regimes, introducing new legislation and creating new administrative and judicial institutions to facilitate the enforcement of these new rights" (Shadlen et al., 2005: 46). While there has been increasing activity in the intellectual property space over time, a distinction between rich and poor countries is not enough to contextualize the ways in which the TRIPS Agreement has affected the world. Reforming intellectual property has come at a significant cost to developing countries, especially in terms of dispute settlement at the WTO (Yu, 2019). All TRIPS-related disputes brought before the WTO are to be addressed by the DSB, a crucial difference from the earlier Paris Convention that had no such mechanism. However, only developed economies could afford to do so in the WTO's early days. While large emerging countries, such as the BRICS, have begun to use the process more frequently (Yu, 2019).

2.3.3.2. *TRIPS Agreement Implications*

The TRIPS agreement is controversial for a number of reasons. Zaitchik (2021) describes it as a "profoundly undemocratic expression of concentrated corporate power—the work of 'less than 50 individuals,'" though all members of the WTO are bound to its provisions. According to Joseph Stiglitz, after developing the Agreement:

> "The trade ministers were so pleased they had finally reached an agreement that they did not notice they were signing a death warrant for thousands of people in the poorest countries of the world" (Stiglitz 2007; Zaitchik, 2021).

After all, the TRIPS Agreement "was drafted after extensive lobbying by international pharmaceutical manufacturers and reflected many values [appealing] to large multi-national corporations" (Shapiro, 2004: 50). Another downside to the TRIPS Agreement is its interpretive nature, which makes uniform standards difficult to impart on its contracting member states.

The 2001 Doha Declaration clarified the conditions under which governments could use compulsory licensing as an accommodation. The general case is when a generic copy is produced mainly for the domestic market, not for export. Still, the patent holder has the right to be compensated for copies of the product. The Doha Declaration notes that countries' governments can determine when granting a compulsory license is appropriate. Article 31 of the TRIPS Agreement specifies certain emergency conditions under which compulsory licensing may be granted. While there has been debate amongst member states about what constitutes an emergency, the COVID-19 pandemic should be regarded as such.

In 2003, WTO members agreed on a decision to waive the domestic market provision of the TRIPS article on compulsory licensing for products that would aid in the treatment and prevention of HIV/AIDS, malaria, tuberculosis, and other epidemics (Akhtar, Fergusson, and Wong, 2020). This courtesy was extended to least developed countries and those with

insufficient production and manufacturing capacity. In 2005, members formally amended TRIPS to make the waiver permanent, also extending compulsory licensing to medicinal and other pharmaceutical products; this amendment entered into force in 2017 (WTO, 2017). The trouble lies in the fact that several high-income countries, including "Australia, Canada, the European Communities with…its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States," asserted that they would not make use of the compulsory licensing flexibility as importers, effectively opting out of the systems put in place by the Article 31 b exceptions (Garrison, 2020). Various stakeholders have put pressure on these high-income, developed countries to take any actions to address the COVID-19 pandemic.

Part 3. The COVID-19 Challenge: Vaccine Equity and Access

3.1. The Ongoing COVID-19 Pandemic

The World Health Organization (WHO) declared the spread of the COVID-19 a pandemic on March 11th, 2020. What began as a mysterious outbreak in Wuhan, China, has transitioned into an ongoing global health crisis. As of January 17th, 2022, global populations have reported 326,279,424 confirmed cases of COVID-19 to the WHO, and 5,536,609 deaths. As of January 14th, 2022, a total of 9,358,243,627 vaccine doses have been administered worldwide (WHO, 2022). WHO Director-General Tedros Adhanom Ghebreyesus notes that the organization is calling for openly sharing vaccine manufacturing technology, intellectual property, and know-how through some form of pooling, temporarily waiving intellectual property barriers, and expanding voluntary contracting between manufacturers to ensure that vaccines are getting to the people who need them (Adhanom Ghebreyesus, 2021). Biopharmaceutical corporations have the same end goal but are also vying to garner profit in the process. Wu and Khazin (2020) consolidate these interests, identifying two policy goals

concerning the COVID-19 pandemic: affordable public access to medicines and adequate incentives for research and development efforts. In the face of the ongoing pandemic, government aid for the pharmaceutical industry has escalated, though not all pharmaceutical companies have decided to take advantage of government aid. Intellectual property protections that cover the private sector ensure pharmaceutical corporations' autonomy and protection, making it challenging for regulatory bodies to step in and dictate the production and distribution of vaccines and other critical items to fight the outbreak. COVID-19 enabled some level of oligopsony power, though having governments as the primary buyers poses some benefit to civilians if the government can sell medical treatments, namely vaccines, at cost. While companies argue that high prices are necessary to provide capital for further research and development, many stakeholders are concerned with addressing these issues to ensure vaccine equity and access to realize the end of the COVID-19 pandemic.

A patent waiver could serve as a potential solution to ensuring affordable access to medicines, but coming to any consensus would not be a seamless process. Any waiver would still require lengthy implementation by WTO member states, considering the protracted nature of trade negotiations. As previously established, countries have different developmental statuses, so there is no uniform mechanism for implementing policy changes. Krishtel and Malpani (2021) provide a framework for criteria that would make an effective intellectual property waiver: saving lives cannot be confined solely to vaccines when other medical technologies can save lives, negotiations should happen relatively quickly, a waiver should be direct and well outlined, and the processes should be fully disclosed. Also, a successful waiver would ensure that the patent holder cannot block production or access to COVID-19 technologies.

The TRIPS Agreement is highly relevant to the waiver discourse on intellectual property, especially in the case of the COVID-19 pandemic. Jecker and Atuire (2021) look at the two proposals set before the World Trade Organization related to the ongoing COVID-19 pandemic: the WTO Director-General proposal and that which BRICS countries India and South Africa spearheaded. Jecker and Atuire (2021) and Florio and Gamba (2021) express support for temporarily suspending intellectual property protection to bring an end to the global pandemic by providing low-income and middle-income countries with vaccines. The Director-General's proposal petitioned the WTO for a temporary waiver of intellectual property rights for COVID-19 related products.

In October of 2020 India and South Africa proposed a waiver to lift restrictions for aspects of the TRIPS Agreement (Jecker and Atuire, 2021: 596). This initiative called for the implementation, application, and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS agreement; these sections are concerned with copyrights, industrial design, patents, and the protection of undisclosed information (Zuhn, 2021; TRIPS Agreement). Instead of temporarily suspending intellectual property protections, patent holders have been licensing manufacturing capabilities to pharmaceutical companies in countries with limited know-how.

3.2. Biopharmaceutical Perspectives

Some pharmaceutical companies at the forefront of vaccine production have expressed opposition to waiving patent rights. Corporations like Pfizer and Johnson & Johnson argue that intellectual property bolsters innovation. Johnson & Johnson's chief IP counsel, Robert DeBerardine, claims that a waiver would result in vaccines that "would never come out right" **(**Lopez and Bultman, 2021). Senator Chris Coons describes intellectual property rights as a "facilitator of critical, cutting-edge innovation" (Lopez and Bultman, 2021). DeBerardine and

other individual stakeholders fear that openly sharing intellectual property would result in ineffective and possibly unsafe vaccines. Along with these debates, there are other factors relevant to the slow distribution of vaccines, including limited know-how that would be vital to research and develop vaccines.

In May of 2021, Pfizer CEO and Chairman Albert Bourla wrote a letter to colleagues, claiming that the company has prioritized fair and equitable distribution of the vaccine as discussions have surfaced around whether or not Pfizer has done enough. Bourla is a firm proponent of intellectual property rights, noting these protections as the “blood of the private sector” (Pfizer, 2021). He upholds Pfizer’s legacy of being a strong proponent of stringent intellectual property protection. Former CEO Edmund Pratt worked to put intellectual property protection on multilateral agendas, and lobbyists have since worked to bolster those protections. Bourla conveys that the company’s priorities for vaccine access were: a price that anyone could afford and maintaining vaccine manufacturing to meet their goals. In the letter, he details the tiered pricing structure established in June of 2020 is as follows:

> "The wealthier nations [pay] in the range of about the cost of a takeaway meal and would offer it to their citizens for free. The middle-income countries were offered doses at roughly half that price, and the low-income countries were offered doses at cost. Many of the poorest communities will receive their doses through donation."

What is not captured in this pricing scheme is individual countries’ need for vaccines in relation to their COVID-19 incidence. Bourla notes that the company is focused on “how many doses [Pfizer has] and who wants to get them” (Baker and Silver, 2021). As such, most of the discussions have been with middle and high-income countries, those who can readily afford them. The underlying message here is big pharma’s commitment to profits. Pfizer had an internal

manufacturing target of 3 billion doses for 2021, and at the time of Bourla's letter, 450 million doses had been manufactured, primarily for high-income countries (Pfizer, 2021).

Bourla states that the waiver would create more problems instead of improving the situation, claiming it is based on the false notion that manufacturing is the keystone for limited vaccine access in developing nations (Baker and Silver, 2021). He speaks to the uniqueness of the Pfizer vaccine, noting that the mRNA technology used to develop the vaccine is relatively new and very complicated to replicate. Bourla also states that the scarce materials used to develop the vaccine could be jeopardized by overutilization should a patent waiver be realized (Baker and Silver, 2021). Bourla goes on to voice concern for smaller biotech innovators who "are totally dependent on accessing capital from investors who invest only on the premise that their intellectual property will be protected" (Pfizer, 2021). Even if big pharmaceutical companies like Pfizer are not in support of a waiver, there are other actions that they can take to address vaccine supply shortages for the people in developing nations with limited production efforts.

Regardless of any timeline, multistakeholder cooperation is necessary to work toward a solution for providing vaccines to those in need. This kind of cooperation under multistakeholder governance is not limited to interactions among governments and non-governmental bodies, as corporations, especially those that produce vaccines and treatments are highly implicated in the ongoing COVID-19 pandemic. While there are only a handful of successful vaccine producers, other companies can still take action that does not require eliminating patents (Abbot and Reichman, 2020). Merck has since discontinued its vaccine development for both potential candidates due to a lack of success in the trial phases. Sanofi and GSK are still pursuing vaccine ventures but have yet to bring any successful solutions to the market. Interestingly, Merck is

willing to support manufacturing and production efforts in its facilities, an offer that Johnson & Johnson has taken up. These cooperative efforts have been shared among unsuccessful COVID-19 vaccine producers, demonstrating some commitment to vaccine production for as many people as possible (Lopez, 2021a).

While cooperation amongst corporations is not a new phenomenon, it is especially important during the COVID-19 pandemic. Dransfield (2021) notes the possibility that the production efforts in some areas are underutilized, considering the physical manufacturing space among emerging vaccine producers. AstraZeneca recently acquired Alexion Pharmaceuticals to advance its research in rare diseases and is investing $360 million in a new manufacturing facility in Ireland (Ring, 2021). Early in 2021, Danish pharmaceutical company Bavarian Nordic offered the capacity for others to produce 240 million doses of COVID-19 vaccines in its factories. The Serum Institute in India has used its factories to produce hundreds of millions of COVID-19 vaccines on AstraZeneca and Novavax designs (Dransfield, 2021). Also, Novartis plans to support production efforts by filling at least 24 million doses of the Pfizer/BioNTech mRNA-based vaccine into vials at Novartis Technical Operations state-of-the-art facility in Ljubljana, Slovenia in 2022 (Novartis, 2021). This plan follows an agreement between the companies for Novartis to support Pfizer's production efforts at its Stein Site in Switzerland (Novartis, 2021).

Moreover, successful COVID-19 vaccine producers are expanding production efforts and catering their vaccine rollout to developing nations. In mid-2021, Pfizer announced a deal with South African biopharmaceutical company BioVac to produce over 100 million doses of the Pfizer/BioNTech vaccine for distribution across African nations (Lopez, 2021b). While this is commendable, further action is required to adequately address the COVID-19 pandemic in

developing areas, especially on the African continent. Further, vaccine manufacturing facilities should be strategically placed to cater to infrastructure capabilities and distribution needs, especially in the face of a pandemic. A pooled procurement strategy could benefit developing countries that need the most support, but production and procurement can even be an issue for high-income countries. Some developing countries have the inadequate manufacturing capacity to produce vaccines on their own, but this does not make it any less worthwhile to implement manufacturing processes.

3.3. Multistakeholder Initiatives Related to COVID-19

COVID-19 vaccines and treatments were developed and approved during the ongoing pandemic have been developed at unprecedented speeds, and this is due, at least in part, to substantial state support and multistakeholder involvement. Agreements by governments to purchase vaccines, especially the United States, guaranteed that the leading COVID-19 vaccine producers would have a market for the vaccines through oligopsony power. Interestingly, the United States has not taken consistent stances on intellectual property protection and, on a few occasions, has actually taken on actions that differ from its typical foreign and trade policies. As per Zaitchik (2021), in 1955, Dwight Eisenhower offered to share manufacturing information and know-how with every country that requested it, even with the Soviet Union, demonstrating a commitment to global public health in the face of political strife. In 1963 President John F. Kennedy encouraged government-financed research, especially concerning public health.

More recently, letters from former heads of state, Nobel laurates, and human rights and medical groups urged United States President Joe Biden to show support for waiving intellectual property rights (UNAIDS, 2021 and Jamali, 2021). The letter from over 170 former heads of state, Nobel Laureates Professor Joseph Stiglitz, and other notable stakeholders specifically

urged President Biden to support the proposal led by India and South Africa (UNAIDS, 2021). At the same time, oppositionists such as biotechnology advocacy groups BIO and PhRMA wrote to the Biden administration in response to India and South Africa's waiver proposal, highlighting how society benefits from innovation due to patent protection (Zuhn, 2021). Both groups noted that the possibility of a waiver ignites divisive stances from various companies and organizations about whether or not a waiver would hinder vaccination efforts. Notably, Pfizer, Johnson and Johnson, and AstraZeneca were three of thirty biopharmaceutical companies whose CEOs signed the PhRMA letter, though the other COVID-19 vaccine leader Moderna was not among those to sign.

Ultimately, the Biden administration did support limiting intellectual property protection in the face of COVID-19, though the United States ended up as a leading buyer of vaccines (Land and Scale Speedometer, 2022). While the U.S. has donated vaccines, there is an apparent disconnect between its commitments and its actions, though it is not the only stakeholder with inconsistent actions. The United States and other influential countries have supported vaccine developers without requiring contributions to COVAX (Jecker and Atuire, 2021). COVAX and the Gavi Alliance made similar promises as the governments, that manufacturers would have a market, but both these failed for a few reasons: these entities were overly ambitious in their promises of being able to deliver on their targeted vaccine rollout; states opted to push their interest over other states' interests; some countries experienced erratic COVID-19 changes, making them worse off and redirecting attention to suit their needs (Goldhill, 2021).

As Krishtel and Malpani (2021) and Florio and Gamba (2021) argue, the intellectual property waiver is appropriate, considering that vaccine manufacturers have relied heavily on publicly funded research into coronaviruses. Wu and Khazin (2020) aggregated information on

the patent landscape of medical treatments and technologies related to COVID-19, demonstrating how civil society groups, NGOs, and government entities work together in response to COVID-19. A few collective initiatives below are essential to highlight.

The COVID-19 Clinical Research Coalition (CRC) consists of more than 800 individual and institutional members, including governmental agencies, international organizations, non-governmental organizations, public research institutes, and academia from at least 56 countries and at least 84 individual health experts from 35 countries (Wu and Khazin, 2020). The CRC started as a community of researchers and scientists who aimed to accelerate research efforts by collecting, peer-reviewing, and sharing COVID-19 related health solutions and information (Wu and Khazin, 2020).

The Access to COVID-19 Tools (ACT) Accelerator is an international collective pledging bid initiated by the European Union in late April 2020 to ensure the collaborative development and universal deployment of diagnostics, treatments, and vaccines with equitable access to all (WHO, 2021a). It was co-hosted by the Director-General of the WHO, the President of France, the European Commission, and the Bill and Melinda Gates Foundation. The ACT took effect from May 4th to May 31st of 2020 and was able to raise about US$ 8 billion to support research efforts. The COVID-19 Therapeutics Accelerator was launched in late June 2020 by Bill & Melinda Gates Foundation, Wellcome, and Mastercard. It aimed to use more than $125 million in both new funding and money already earmarked to tackle the epidemic, identify potential treatments already in existence for COVID-19, and accelerate the development of COVID-19 therapeutic treatments (Wu and Khazin, 2020).

WHO has been heavily involved in various initiatives, forming the WHO Solidarity Response Fund (the Fund) and The Solidarity Trial shortly after declaring a global health

pandemic. The Fund was created by the United Nations Foundation and the Swiss Philanthropy Foundation, together with WHO, to support actions outlined in the WHO COVID-19 Strategic Preparedness and Response Plan (SPRP), which is aimed at helping countries respond to the COVID-19 pandemic. In February of 2020, WHO prepared the SPRP to outline the public health measures that the international community stands ready to provide to support all countries to prepare for and respond to the then-novel virus (WHO, 2020). An updated plan came into effect a year later, one that aims to help guide the public health response to COVID-19 at national and sub-national levels and to update the global strategic priorities in support of this effort (WHO, 2021). The 2021 SPRP will remain in effect through January of 2022.

The WHO Solidarity Trial is a multinational clinical trial launched in March 2020 and was joined by more than 100 countries. It sought to address the significant need for a timely and large-scale clinical trial to evaluate potential treatments for the disease, comparing the effectiveness of the local standard of care against four different drugs – hydroxychloroquine, remdesivir, LPV/r, and LPV/r plus interferon among patients hospitalized for COVID-19. During the time of these trials, vaccines were not being developed, and healthcare workers were relying on existing treatments to address COVID-19 symptoms.

3.4. Brief Overview of Big Pharma's Financial Prospects

The People's Vaccine Alliance argues that big pharmaceutical companies are taking limited production and distribution measures for the COVID-19 vaccines, noting that they plan to produce enough COVID-19 vaccines for only 1.5 % of the global population in 2021 (Dransfield, 2021). Oxfam's Health Policy Manager Anna Marriott describes actions taken by Pfizer/BioNTech and Moderna as artificially rationing the supply of successful vaccines with the hopes of reaping huge financial rewards (Dransfield, 2021; Adhanom Ghebreyesus, 2021). While

production is no simple feat, the leading vaccine producers could offer up patent information and provide insight on their know-how to speed up efforts in meeting the global demand for vaccines. Geoffrey Porges, an analyst for SVB Leerink, an investment bank in Boston, claims that Pfizer's efforts are a public relations pursuit and they are also concerned with substantial financial return (LaFraniere, Thomas, Weland, Stolberg, and Grady, 2020). Porges also claims that Moderna's efforts are a validation opportunity considering that they have not yet brought a biomedical solution to market; in fact, the Moderna COVID vaccine was the company's first to make it to phase 3 in clinical trials (LaFraniere, Thomas, Weland, Stolberg, and Grady, 2020).

However, Pfizer's CEO has since pledged to produce upward of 3 billion doses, already having inoculated over one billion people as of November 2021 (Baker and Silver, 2021; Bourla, 2021). Though they have markedly different situations, Pfizer, Moderna, and AstraZeneca are the leading global vaccine producers. While AstraZeneca has sold the majority of its doses to developing countries at cost, Pfizer/ BioNTech and Moderna have sold almost all of their doses to rich nations; even so, approximately half of Moderna's doses have gone to the United States, pursuant to the relationship between the two (Dransfield, 2021). AstraZeneca planned only to profit from wealthier nations but considering that its vaccine is not yet authorized for use in some more affluent countries, most notably, the United States.

Ultimately, Pfizer will profit more than any other player from vaccine revenue. Pfizer did not accept government funding because they could afford not to (LaFraniere, Thomas, Weland, Stolberg, and Grady, 2020). It is predicted that the Pfizer/BioNTech vaccine could bring in up to $36 billion U.S. dollars for COVID-19 vaccine sales in 2021, up from estimates ranging between $15 and $30 billion (Jecker and Atuire, 2021; Baker and Silver, 2021). Moderna is expected to generate less than half of Pfizer's COVID vaccine revenue, estimated to bring in $12.2 to $20

billion U.S. dollars (Jecker and Atuire, 2021; Baker and Silver, 2021). Moderna has worked closely with the United States government. Due to the U.S. heavily funding the company's vaccine development, it vowed not to enforce patent restrictions in its COVID-19 vaccine for the duration of the pandemic (Moderna, 2021b). Despite Moderna having made some information public, it is unclear whether others are making attempts to use the research to replicate (Garde, Branswell, and Herper, 2021). After lower-than-expected earnings led shares to fall, AstraZeneca switched to a for-profit model in early November of 2021 (Ring, 2021; Baker and Silver, 2021). AstraZeneca plans to appeal to the United States' emergency use authorization regulators to bring the vaccine to the U.S. market in the coming year. This change comes as news considering that AstraZeneca vowed that the company would not profit from the vaccine during the pandemic; they have since claimed that the ongoing pandemic was moving into an endemic phase.

Conclusion

Governments initially responded to the pandemic out of self-interest, which exacerbated the difficult situations for low- and middle-income, developing countries (Arcuri, 2021). This paper initially discussed what debates on trade and intellectual property rights reveal about COVID-19 vaccine equity and access, especially in developing countries and less developed ones. The most developed nations have inoculated significant portions of their populations. However, developing countries conceivably experience difficulty in doing the same for their populations, especially considering that they are disadvantaged in securing intellectual property rights in the first place. Moreover, wealthy nations have offered booster shots as another defense mechanism against COVID-19 months after distributing successful vaccines. Meanwhile, only 6% of people in Africa have been fully inoculated as of early November of 2021 (Baker and

Silver, 2021). Inadequate access to essential vaccines is predictable in a system that prioritizes concentrated market power, such as those prevalent across the pharmaceutical industry.

The WTO and WHO are prominent stakeholders in the vaccine debates around COVID-19. The WHO and civil society organizations are concerned with protecting global health. The Gavi Alliance and COVAX have made considerable efforts in vaccine deployment, with COVAX being a leading global vaccine purchaser. On the other hand, the corporate interests of biopharmaceutical companies and their advocates are aligned with the WTO's concerns about patents. Pfizer and BioNTech, Moderna, and AstraZeneca, though not the only companies to develop vaccines, have, in very different ways, pulled off a remarkable feat by developing a vaccine that appears safe and effective (LaFraniere, Thomas, Weland, Stolberg, and Grady, 2020). In the past, this would have taken several years to achieve, but the world needed a solution in a matter of months. These companies deserve recognition for that. At the same time, society is left to question if any more could have been done. Even with a significant portion of the world fully vaccinated, the current pandemic highlights the need for more clearly defined protocols concerning intellectual property protection as they affect public health pandemics. The IP waiver is essentially a matter of policy change. Anne Pritchett, senior vice president with the industry group PhRMA, asserts that lifting patent waivers for COVID-19 vaccines could backfire in the next global health crisis, taking away the incentive for future innovation by granting licenses to other developers (Jamali, 2021). This perspective is harmful to preserving public health. While profits are important to the big biopharmaceutical corporations, they exist to research solutions to diseases and infections that pose a risk to good health. Stakeholders deliberating the COVID-19 patent waiver should consider the implications pertaining to future

pandemics and social justice, the latter of which has been often overlooked in the decision-making process.

New COVID-19 variants pose more risks to global health since they may potentially affect the body in different ways. Future research should be done on continued vaccination efforts in light of new variants of COVID-19. If the trend continues, developing countries will continue to be behind without the flexibility offered by easing intellectual property protection. Moreover, further discussions and negotiations are necessary to prepare protocols to ensure that intellectual property does not limit production possibilities for a future pandemic.

Even more important than this is the need for investment into developing countries' intellectual property capacity. This capacity includes knowledge, funding, and physical infrastructure. In 1951, the UN offered to fund India's penicillin facility through grants to allow for innovation toward antibiotics and essential medicines. The UN only required that India keep the factory as a public institution and share research with related UN projects; the United States backed the UN venture, and Nehru accepted (Zaitchik, 2021). This same support needs to be offered to other emerging economies. At the same time, solutions need to be developed for developing countries to have more stake in the intellectual property space. The WTO's 12th Ministerial conference was initially planned for June 2020 in Kazakhstan but has been postponed indefinitely due to the COVID-19 pandemic. Even though the WTO continues to release information related to negotiations, a waiver decision has not yet been realized.

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Appendix A

Pandemic vs. Endemic

A public health concern must escalate through a series of stages to be considered a pandemic: endemic, outbreak, epidemic, and pandemic (Grennan, 2019; Morens, Folkers, and Fauci, 2009). An endemic condition describes the baseline conditions at a reasonably stable, predictable rate among a group of people (Grennan, 2019: 910). An outbreak occurs when there is a sudden increase in the number of people with a condition more significant than is expected, which can be very as little as one case if the outbreak occurs in an unexpected area (Grennan, 2019: 910). An epidemic is an outbreak that spreads over a larger geographical area, such as the Ebola outbreak in West Africa between 2014 and 2016 (Grennan, 2019: 910). A pandemic is an epidemic that spreads globally (Grennan, 2019). The SARS-Cov-2 virus is highly communicable, rapid escalation through each stage, leaving the world limited time to assess the situation and act accordingly.

Appendix B

Intellectual Property Waiver

As will be discussed, a few countries proposed an intellectual property waiver to address the COVID-19 vaccine equity and access issues. A waiver would allow exemptions from adhering to certain patent provisions, especially those laid out in the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) (Akhtar and Fergusson, 2021). It is important to note that international organizations do not hold patents, but a few are authorized to enforce patents that affect international products. The WTO contends that its member states remain committed to the common goal of providing timely and secure access to effective and equitable vaccines and medicines for all, but disagreement persists on the fundamental question of whether a waiver is the most effective way to address the shortage and inequitable distribution of and access to vaccines and other COVID-related products (WTO, 2022).

Appendix C

Patent Pooling

In the biotechnology space, patent pooling refers to a form of collective intellectual property rights licensing (Merges, 1999). Pools bring together public health-oriented entities and private pharmaceutical companies (Burrone, 2018). A pool will make all included patents available to each member of the pool, and members of the pool join, understanding that they are not to discriminate amongst other members (Merges, 1999; Burrone, 2018). Members of the pool may still license to outside companies, and the pool will allocate a portion of these fees and the royalties generated to each member (Merges, 1999; Burrone, 2018). Abbott and Reichman (2020) and Chimpango (2021) propose establishing licensing facilities to streamline the pooling process. These facilities would allow innovators to readily access information for researching, manufacturing, and developing patented products.