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Article

The WTO and the Covid-19 "Vaccine Apartheid": Big Pharma and the Minefield of Patents

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Abstract
Unequal access to vaccines for the Covid-19 pandemic, also referred to as "vaccine apartheid," has marginalized low-income countries again. In October 2020, India and South Africa proposed a temporary waiver from certain provisions of the TRIPS Agreement for the prevention of Covid-19 at the World Trade Organization (WTO). An agreement was later reached in Geneva on June 17, 2022. The objective of this article is to analyze the negotiation and agreement reached at the WTO. This article explores the difficulties of creating international public good in the field of public health within the milieu of powerful actors, namely big pharmaceutical companies with vested interests. The central argument of this article is that this agreement alone will not solve the vaccine access problem for low-income countries. It is too restrictive, does not cover trade secrets and know-how, production capacity, availability of raw materials, and even adds new limitations that did not exist before. The best option to promote the production of quality vaccines in low-income countries is to share technology and know-how on a voluntary basis through production agreements. One way to facilitate the cooperation of large pharmaceutical corporation is to make it easier for low-income countries to use compulsory licenses. Simplifying the use of this mechanism could help encourage pharmaceutical companies to enter into voluntary licensing agreements.

Keywords
Big Pharma; Covid vaccine; TRIPS Agreement; intellectual property rights; waiver of patents; World Trade Organization

Issue
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1. Introduction

In his seminal article on embedded liberalism, John Ruggie argued that the post-war economic order was forged on the basis of a historical compromise (Ruggie, 1982, p. 393). This compromise was to establish a balance between multilateral trade regimes but was to be tempered and governed by national regulation and social objectives including public health. In the field of public health, this balance has never been found for low-income countries and the Covid-19 crisis has completely shattered the last illusions in this regard. Intellectual property and unequal access to vaccines and health supplies needed to respond to the Covid-19 pandemic, also referred to as "vaccine apartheid" by a UN human rights independent expert, and have yet again marginalized low-income countries (Achiume, 2022; Torreele & Amon, 2021). How high-income countries, including the US, Canada, and the European Union maneuvered to monopolize the supply of vaccines from the outset of the crisis had the effect of excluding other countries from the market.

Yet the resolution of the Covid-19 crisis cannot be anticipated until vaccination is truly global because of countries' interdependence. If high-income countries are vaccinated first, but a large proportion of low-income countries have limited access to the vaccine and health materials, the virus will continue to circulate, likely

mutate, and return in a different form throughout the world. For low-income countries, the current crisis is indicative of the hypocrisy of high-income countries not living up to the promises they made at the time of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) negotiations in 1994 and the 2001 Doha Declaration at the World Trade Organization (WTO). This is the case, particularly, with aspects related to technology transfer and building productive capacity for the poorest countries (Council for Trade-Related Aspects of Intellectual Property Rights, 2021; Deere, 2009, p. 12).

To partially solve the problem of "vaccine apartheid," India and South Africa proposed a waiver of patents in October 2020 on vaccines and health materials needed to combat Covid-19 at the WTO. An agreement was reached in Geneva on June 17, 2022 (WTO, 2022b). The central argument of this article is that this agreement alone will not solve the "vaccine apartheid" problem for low-income countries. The agreement is too restrictive because it does not cover, for example, testing and treatment of the coronavirus, it is silent on the difficult issue of supply, and adds new limitations that did not exist before. On top of that, the agreement does not cover trade secrets. The best option to promote the production of quality vaccines in low-income countries is to share technology and know-how voluntarily through production agreements. One way to facilitate the cooperation of large pharmaceutical corporations is to make it easier for low-income countries to use compulsory licenses. Simplifying the use of this mechanism could help to encourage pharmaceutical companies to enter into voluntary licensing agreements.

This article thus focuses on the difficulties of creating global public good in the field of public health in the milieu of powerful actors, namely the big pharmaceutical companies with vested interests. This article analyzes the negotiation and the agreement reached at the WTO on the issue of patents for Covid-19 vaccines from primary sources. This includes negotiation documents from the WTO and public statements by key actors, as well as secondary sources, such as analyses by international economic law scholars, focusing on the interests of powerful actors.

2. Theoretical Framework

A global public good is not limited to the idea that the good, like a vaccine, is "good" for the international community. As Samuelson (1954) pointed out in a seminal article on the subject, a public good must meet certain characteristics to be defined as such. It must be both "non-rival" and "non-excludable." A non-rival public good means that its use by one person does not reduce its availability to others. A non-excludable good means that it must be impossible to prevent an individual from benefiting from it. There are several examples of international global public good in public health, such as open access public health research and data (Moon et al., 2017).

The situation becomes more complex when we look specifically at health products such as drugs (R. D. Smith, 2003). While it is fair to assume that drugs in pill form or even vaccines in a vial are subject to rivalry and exclusivity, the formula from which a pill or vaccine is produced is not in this category (Quigley, 2017, p. 98). In other words, while a vaccine in a vial is a rival and exclusive good, the formula and process for making the vaccine is a non-rival and non-exclusive good. In this case, it is the intellectual property rights or patents held by Big Pharma that transforms the public good into a private good (Stiglitz, 1999; Yamey et al., 2018).

On top of that, while a private good provides a benefit to the person consuming it, at a certain threshold (that of herd immunity) it becomes non-excludable as it produces positive externalities. In a world faced with severe cholera and measles epidemics and now with the Covid-19 pandemic, for example, the need for affordable and accessible vaccines is fundamental. The eradication of a vaccine-preventable disease such as smallpox fulfills the requirements of international public good because everyone benefits from the outcome, whether or not they contributed to the eradication effort.

The importance of this issue explains why in the past scientists have proposed solutions to turn a private good into a public good. Academics and a growing number of research granting agencies, for example, require that research results be open access. Similarly, scientists in the past also decided to make certain technology free for the benefit of all. The inventor of the first synthetic malaria vaccine, for example, gave his patent to the WHO, while the inventor of insulin gave his to the University of Toronto for the nominal sum of $1 (Quigley, 2017).

Samuelson's (1954) definition of public good implies that the market is not the best way to produce enough of a public good, since it is impossible to make this investment profitable. It is only when a company can charge a high price for the consumption of the good that the situation becomes profitable for them. In order to do that, the state must thus play a role by, for example, prohibiting the use of the formula to make a drug or vaccine, then exclusivity is created where none existed (Quigley, 2017, p. 98). State intervention is a balancing act because if the state does not intervene enough, the good will not be produced in sufficient quantity. If the state strengthens intellectual property protection too much, it risks harming innovation and also creating a situation where companies can impose monopoly prices (Galasso & Schankerman, 2014). Additionally, in the absence of government intervention, vaccine patent holders have the ability to refuse to transfer their trade secrets, even in the context of a vaccine shortage during a pandemic (Stiglitz, 1999).

This situation explains why American, British, European, and Japanese pharmaceutical companies have mobilized in the past to put pressure on governments to adopt national and international standards. This has happened for example at the WTO, but also in

preferential trade agreements, to strengthen intellectual property protection. The situation is such nowadays that it is even described as "a minefield of patents" by experts (Kianzad & Wested, 2021, p. 74). Indeed, big pharmaceutical companies are multiplying patents to strengthen intellectual property protection measures. With trade secrets on the know-how, these strategies are essential to keeping their profitability high (Flynn, 2011, p. 150; Sell, 2003; Steele, 2021). Since low-income countries cannot keep up with the price of vaccines, it creates a "vaccine apartheid" (Singh Bajaj et al., 2022).

There are, however, several strong arguments for considering vaccines as a global public good. Since public funds have contributed massively to the development of vaccines, the situation is one in which the costs of research and innovation are largely provided by the public sector, but the huge profits are reaped by the big pharmaceutical companies. By 2021, the public sector had invested over $93 billion in Covid-19 vaccine development (Thambisetty et al., 2021, p. 13). Public funds accounted for 97% to 99% of the research and development funding for the Oxford-AstraZeneca vaccine, for example (Cross et al., 2021, p. 2). In the same year, the US government invested $1 billion in AstraZeneca, $1.5 billion in Johnson & Johnson, and $2.5 billion in Moderna (Bansal, 2021). In addition, global academic research around the Covid-19 issue is largely open access and massively publicly funded. This research was crucial to the development of vaccines.

The call by many countries and non-governmental organizations (NGOs) to make vaccines and health materials available, affordable, and accessible to all—essentially, to make vaccines an international public good—is rooted in the idea of universal health coverage (Moon et al., 2017; Quigley, 2017; R. D. Smith, 2003). Today, as in the days of Nelson Mandela's struggles on the issue of HIV/AIDS treatment, the opposition is taking place among powerful interests (Paquin, 2022). This conflict emerges between large multinational pharmaceutical companies united under the name Pharmaceutical Research and Manufacturers of America (PhRMA) and several countries, groupings of countries, NGOs such as Médecins sans Frontières, and experts (Bollyky & Bown, 2020).

From the perspective of international political economy (which focuses on the interests of powerful actors) institutions, whether formal or informal, are rules to follow that frame international negotiations on the lifting of patents at the WTO. Institutions help shape how actors perceive and understand their interests. Analyses of international political economy that focus on interests have, as a central assumption, that when a group is negatively affected by a policy proposal, it will mobilize against it (Paquin, 2016). What fundamentally determines the preferences of actors is the importance of an issue to them. If an issue is critical and the effects of a policy measure are highly concentrated, this creates an incentive for stakeholders to act vigorously to defend their interests. For example, large pharmaceutical companies that invest massively in highly specialized sectors, such as vaccine production, will demand strong protectionist measures such as strengthening intellectual property measures in trade agreements to maximize their profit (Sell, 2003; Milner, 1988). In this context, as Olson (1965) argued in *The Logic of Collective Action*, the most difficult policy measures to pass are those with diffuse benefits but concentrated costs. Those who suffer the costs—in this case, the big pharmaceutical companies when lifting patents on Covid-19—will strongly oppose these changes while those who could benefit from them will not mobilize as effectively.

For pharmaceutical companies, the worst-case scenario is the lifting of patents on all health materials needed to combat Covid-19 and make vaccines an international public good. This option would have a significant impact on their profits, their ability to attract investors in the future, and the value of their shares on the stock markets. This resistance from Big Pharma explains why patent removal at the WTO is so difficult, since it requires a consensus of WTO member countries to adopt the policy or if it goes to a vote, a three-fourths majority in accordance with Article IX of the WTO Agreement. Big Pharma vigorously defends its interests and favors voluntary production agreements (i.e., in negotiation with the owner of the patent) over patent removal. The countries where Big Pharma is located are being intensely lobbied and are divided between protecting the pharmaceutical industry on their territory, and all the well-paying jobs it entails, and working to solve the health crisis.

3. Intellectual Property and Public Health at the WTO

The TRIPS Agreement is the most comprehensive multilateral agreement on intellectual property protection (Council for Trade-Related Aspects of Intellectual Property Rights, 2021; Deere, 2009). It defines the intellectual property regime and regulates trade in knowledge-based products such as vaccine formulas and health materials. With TRIPS, countries commit to granting the same protection to all patents, whether national or international, over a 20-year period, and national patents cannot have the effect of discriminating against a patent from another member country (Flynn, 2011, p. 150). This agreement recognizes the importance of the links between intellectual property protection and international trade.

The 2001 Doha Declaration, which was adopted in the context of the South African government's mobilization on the issue of HIV/AIDS treatment, is also important in clarifying the scope of the TRIPS Agreement and public health. In the 2001 Doha Declaration, WTO member countries agreed that the TRIPS Agreement should be part of a broader set of national and international actions to address public health problems in developing countries, including the least developed ones. In the declaration, WTO members recognize the sovereign right of

governments to take measures to protect public health (Article 4). Member states agreed on the importance of interpreting the TRIPS Agreement in a manner that supports public health. The Declaration reaffirms the right of governments to take advantage of the "flexibilities" in the Agreement (Article 4). It also states that countries have the right to determine what constitutes a national emergency, and the text even mentions that the HIV/AIDS epidemic constitutes a national emergency, as do tuberculosis and malaria (WTO, 2001, Art. 5).

The flexibilities identified in the Doha Declaration include "the right to grant compulsory licenses" (WTO, 2022a). A compulsory license is issued by a government authority or court to make certain use of a patented invention without the consent of the patent owner. This mechanism is generally present in most patent laws and is recognized as an option or permissible flexibility under TRIPS, and this approach has been used in the past by WTO members.

The 2001 Doha Declaration on the TRIPS Agreement also recognizes that the compulsory licensing system could hamper effective use by countries with insufficient or no manufacturing capacity in the pharmaceutical sector (Steele, 2021). It thus aims to remove this obstacle by creating an additional form of compulsory license that did not previously exist: a compulsory license specifically designed for the export of medicines to countries that lack manufacturing capacity. This mechanism has sometimes been referred to as the "paragraph 6 system," because of its origin in the Doha Declaration (WTO, 2001). The new Article 31 of the TRIPS Agreement gives full legal effect to this system and allows for the production and export of low-cost generic drugs under a compulsory license exclusively for the purpose of meeting the needs of countries that cannot manufacture these products themselves (Fisher & Rigamonti, 2005, p. 14). For example, Canada was able to produce a generic version of an HIV/AIDS drug for Rwanda under this clause because Rwanda did not have industrial capacity at the time (WTO, 2007).

The options referred to as "flexibilities" in the Declaration were also recognized in the 2015 United Nations Sustainable Development Goals. For public health advocates, the 2001 Doha Declaration represents a remarkable achievement in that it gave primacy to public health, not intellectual property, and clarified the rights of WTO members to use TRIPS safeguards ('t Hoen, 2002). Despite significant progress, the Covid-19 crisis has demonstrated the extent to which the situation remains advantageous to Big Pharma.

4. India and South Africa's Proposal

The Covid-19 crisis has reignited the debate on intellectual property protection and public health. In October 2020 India and South Africa proposed (and then revised in May 2021) a temporary waiver of Sections 1, 4, 5, and 7 of the second part of the TRIPS Agreement for at least 3 years (Council for Trade-Related Aspects of Intellectual Property Rights, 2020, 2021). After that time, the WTO General Council would have to determine whether patent removal is still warranted (Berger, 2021). The patent waiver proposal does not focus exclusively on vaccines; it also focuses on other patent-protected subject matter such as health products and technologies, including diagnostics, therapeutics, medical devices, personal protective equipment and their materials or components, as well as methods and means of manufacture for the prevention and treatment of Covid-19. The rationale for this proposal was that, in order to manufacture a vaccine, one must not only lift a patent on a single drug but do it on a wide variety of IP-protected elements also, whether it be an mRNA or an adenovirus, for example (Bostyn, 2021; Hilty et al., 2021, p. 3).

This proposal, which was quickly supported by 100 countries, including China and Russia, is also supported by the WHO and UNAIDS. Hundreds of Nobel Prize winners, Médecins sans Frontières, and the editorial team of the journal *Nature* also support the measure (Nature Editorial Team, 2021). Importantly, the US, historically resistant to such a proposal, has changed its position. Indeed, in keeping with a campaign promise to the left wing of his party, President Biden has supported the temporary lifting of intellectual property rights to promote vaccine production. That said, the US government was not prepared to go quite as far as the Indian and South African proposal requested.

When Joe Biden changed the US position on this issue, pharmaceutical companies quickly mobilized to lobby the US government and elected officials (Bansal, 2021). Several companies, including Pfizer and Johnson & Johnson, supported a public relations campaign initiated by PhRMA. This lobby group sought to undermine Biden's position on patent relief (Schwartz, 2021). Among the initiatives taken were strategies targeted at members of Congress. The group argued that Biden's policy will destroy jobs in the US and allow China to benefit from American innovations (Fang, 2021). Several Republican and Democratic elected officials and personalities (Tom Cotton, Thom Tillis, Scott Peters, Ron King, and Howard Dean) have even publicly endorsed the pharmaceutical companies. In a public email sent to consultants working for PhRMA, some arguments were put forward, including national security issues, since the lifting of patents could strengthen the powers of Russia and China. In addition, according to PhRMA, lifting patents could undermine the global response to the pandemic (Diamond et al., 2021; Steele, 2021). A study by the research center Corporate Europe Observatory (2021) found that pharmaceutical companies have also spent at least €36 million lobbying the European Union. The industry employs 290 lobbyists to defend its interests in Brussels, not counting lobbyists hired by consulting firms. Between March 2020 and May 2021, EU commissioners and their staff met members of Big Pharma more than 160 times about the production and

distribution of Covid-19 vaccines but only had one meeting with an NGO in favor of the waiver (Corporate Europe Observatory, 2021).

Several countries clearly opposed the proposal of India and South Africa. This is the case for the UK, Switzerland, Japan, and South Korea for example. As for the European Union countries, some such as Germany, Portugal, and Belgium expressed reservations while France and Italy were in favour (Titievskaia, 2021). On June 4, 2021, the European Commission communicated to the WTO another proposal concerning compulsory licenses that address the issue of export restrictions and increased production rather than the lifting of patents.

Unsurprisingly, pharmaceutical companies put forward the idea that lifting patents would slow down pharmaceutical innovation in the long term and hurt investment (even though vaccines are largely publicly funded; PhRMA et al., 2021). World Bank President David Malpass and European Union President Ursula von der Leyen have also publicly supported the same position (Blenkinsop, 2021). Those who argue against this standpoint note the dangers of setting such a precedent for the next pandemic.

It is in this context that quadrilateral discussions between India and South Africa, as well as the European Union and the US, began in December 2021. On 15 of March, 2022, a first draft of the compromise was leaked to the public. This document provoked strong reactions from various actors. Yet despite this, an agreement was reached in Geneva during the 12th Session of the Ministerial Conference, in the form of a "Ministerial Decision on the TRIPS Agreement," adopted on the 17 of June 2022 (also simply referred to as the Agreement). In announcing the Ministerial Decision, Katherine Tai, the US trade representative, described it as:

> The text-based negotiations with other WTO members that we called for have produced accommodations to the intellectual property rules for Covid-19 vaccines that can facilitate a global health recovery. Through difficult and protracted discussions, members were able to bridge differences and achieve a concrete and meaningful outcome to get more safe and effective vaccines to those who need it most. (Office of the United States Trade Representative, 2022)

The South African government, for its part, said the compromise does not go far enough. In a public statement, it welcomed the compromise on patent removal, but it added that "to scale up the production on the continent, further partnerships will be needed including access to know-how and technologies" (WTO, 2022b). On top of that, the current agreement excludes tests and costly therapeutic treatments against Covid (AFP, 2022).

PhRMA, on the other hand, stated that the WTO Agreement was a "political stunt" since, in their view, the global context is one of vaccine overproduction and many low-income countries are refusing the doses offered to them due to a lack of demand and vaccination capacity. PhRMA noted that the industry has already produced more than 13 billion doses of Covid vaccine (Dunleavy, 2022).

Several NGOs that have been following the issue were extremely disappointed. According to Max Lawson who is the Head of Inequality Policy at Oxfam:

> This is absolutely not the broad intellectual property waiver the world desperately needs to ensure access to vaccines and treatments for everyone, everywhere. The EU, UK, United States, and Switzerland blocked that text. This so-called compromise largely reiterates developing countries' existing rights to override patents in certain circumstances. And it tries to restrict even that limited right to countries which do not already have the capacity to produce Covid-19 vaccines. (Oxfam International, 2022)

Médecins sans Frontières agrees. In a statement, the NGO writes:

> This agreement fails overall to offer an effective and meaningful solution to help increase people's access to needed medical tools during the pandemic; it does not adequately waive intellectual property on all essential Covid-19 medical tools, and it does not apply to all countries. The measures outlined in the decision will not address pharmaceutical monopolies or ensure affordable access to lifesaving medical tools and will set a negative precedent for future global health crises and pandemics. (Médecins sans Frontières, 2022)

4.1. Ministerial Decision on the TRIPS Agreement, 17 of June, 2022

What does this Ministerial Decision (2022b) on the TRIPS Agreement contain and is it likely to work? The Agreement contains two pages and nine articles. Article 1 states:

> Eligible member may limit the rights provided for under Article 28.1 of the TRIPS Agreement…by authorizing the use of the subject matter of a patent required for the production and supply of Covid-19 vaccines without the consent of the right holder to the extent necessary to address the Covid-19 pandemic. (WTO, 2022b, p. 1)

Article 2 states that:

> For greater clarity, an eligible member may authorize the use of the subject matter of a patent under Article 31 without the right holder's consent through any instrument available in the law of the member

> such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a member has a compulsory license regime in place. (WTO, 2022b, p. 1)

In other words, this Ministerial Decision allows the use of a product protected by a patent without having to first seek authorization from the company that owns the patent. The member may also export part of this production to "eligible members," but the former must make reasonable efforts to prevent the re-export and import of a product under patent. This decision is valid for five years due to the exceptional nature of Covid-19.

The WTO Ministerial Decision clarifies and expands some existing mechanisms for compulsory licensing, under which governments override intellectual property restrictions to allow the manufacture of drugs in emergencies. The Agreement is silent on India's and South Africa's requests to exempt all vaccines, treatments, and diagnostics related to Covid, but the decision also requires WTO members to agree within six months on extending these measures to cover "the production and supply of Covid-19 diagnostics and therapeutics" (WTO, 2022b, Art. 8, p. 2). The deadline has now passed (17 of December, 2022) and no agreement has been reached on this issue.

The original proposal from India and South Africa was much more ambitious. This earlier proposal was about lifting patents but would also have allowed countries to manufacture generic vaccines, diagnostics, and treatments without cumbersome procedures, and would have facilitated production by allowing local manufacturers to access manufacturing data. The Agreement does not cover testing and treatment of the Coronavirus, which are also priorities for low-income countries. Treatments such as Molnupiravir or Paxlovid are not part of the Agreement even though they are generally cheaper, more easily administered since they are given orally, and simpler to transport and store.

5. Assessing the Ministerial Declaration

Is this Agreement likely to promote vaccine production in low-income countries? The way the Agreement is written and considering the five-year limit, it would be surprising if it promotes vaccine production in countries that do not yet have production capacity. Overall, there are three basic reasons why this Agreement will probably not have much effect. The first is financial, the second is the five-year limit, and the third is that the Agreement does not include know-how.

The lifting of patents is only applicable for five years as noted above unless extended by the General Council of the WTO. Vaccine production requires significant investment. It is therefore unlikely that a low-income country that does not already have production capacity would develop the necessary infrastructure in this context and time frame. It would be surprising if private investors and governments were to invest large sums of money to build production capacity when it is simpler and cheaper to obtain vaccines on the international markets because the world is not in a vaccine shortage situation anymore. In effect, therefore, the Agreement comes too late and is far too modest in scope to significantly affect the global vaccine supply (Robbins & Nolen, 2022). The main barriers to immunization rates in low-income countries are more related to distribution and facility set-up issues, not the supply itself.

The third reason, and probably the most important, is related to the fact that patent release does not include know-how. Thus, according to pharmaceutical industry representatives, the main barrier to vaccine production is not the patent, but the production capacity or the know-how (Hilty et al., 2021, p. 1). Pharmaceutical companies are not obliged to share this essential information about vaccine manufacturing. Covid-19 vaccines are complex products and know-how and expertise are scarce. The lifting of patents will not allow for the rapid creation of laboratories capable of working under safe conditions if Big Pharma does not collaborate (Correa et al., 2021). For the moment, their reaction to the Agreement suggests that they will not collaborate. And producing poor-quality vaccines would be detrimental to the global immunization campaign, as the public could lose confidence in vaccines (Kianzad & Wested, 2021, p. 87). Moreover, a company that wanted to manufacture vaccines from a competing firm would not be able to produce a vaccine until 2024–2025, at best. In sum, this is a medium-to-long-term solution.

It is true that Moderna stated in 2020 that it would not sue countries that copy its Covid-19 vaccine during the pandemic (this did not stop Moderna from launching a lawsuit against Pfizer in 2022). That said, Moderna's position did not include all intellectual property, know-how, and trade secrets, and excluded technology transfer. The company even acknowledged that without the know-how and technology transfer, the difficulties of replicating the vaccine would be extensive (Bansal, 2021).

According to pharmaceutical companies, supply difficulties for essential vaccine components are a more significant problem than patents (Bostyn, 2021, p. 12; Hilty et al., 2021, p. 1). Pfizer-BioNTech's vaccine, for example, contains 280 different ingredients from 19 countries. Vaccines from Moderna, Johnson & Johnson, and AstraZeneca also rely on components from various countries (Kianzad & Wested, 2021, pp. 87–88). Additionally, the pandemic has had the effect of reinforcing economic nationalism and protectionism in several countries. At the height of the crisis, more than 80 countries had passed more than 137 pieces of legislation banning the export of health materials needed to control the crisis (Bollyky & Bown, 2021). In the US, no vaccine exports were allowed until the US population was sufficiently vaccinated (Bollyky & Bown, 2021). India prohibited the Serum Institute of India (the main producer of vaccines)

to supply the COVAX initiative, which provides free vaccines for low-income countries, from exporting its vaccines during the second wave. This made it more difficult to produce vaccines on a massive scale in the early stages of the pandemic, leading to some calls to negotiate a WTO agreement to liberalize health trade rather than lift patents (Bown & Bollyky, 2021). Even the US has experienced supply difficulties. These aspects are ignored in the Ministerial Declaration on vaccines.

6. The Issue of Compulsory Licenses

The Ministerial Declaration also raises questions about compulsory licensing. In one of the WTO's founding agreements on intellectual property rights (TRIPS), it is stated that in the event of a health emergency, member states may grant a national company a "compulsory license" to copy a foreign drug. This right was reaffirmed by the Doha Declaration of 2001 and, since 2003, has allowed countries whose companies produce generic drugs, such as Canada, India, and Brazil, to sell copies of patented products to countries that do not have the manufacturing capacity themselves in the context of a health emergency.

Compulsory licensing has not been easy in the past. Indeed, the "flexibilities" in the WTO agreements have not had the desired effect, partly because the rules and procedures were too complex and lengthy (Kianzad & Wested, 2021, pp. 82–90). Although the Doha Declaration allowing parallel imports of generic drugs dates from 2001, and the protocol to amend the agreement dates from 2005, this amendment did not take effect until 23 January 2017, i.e., after two thirds of member countries had ratified the amendment, a gap of 16 years (Yu, in press, p. 9). In the case of HIV/AIDS, it took eight years before treatment was made available at an affordable price for a country like South Africa. Moreover, parallel importation requires negotiation with another country and the product is limited to a specific quantity and a specific time period (Yu, in press, p. 4).

Thus, the compulsory licensing system was difficult to use, particularly because the countries that use it are subject to enormous pressure from pharmaceutical companies and even to sanctions from several Western countries, including the US, the European Union, and the UK This is the reason why South Africa and India argued that the current situation is unprecedented and that past policies are insufficient. Brazil was one of the first countries to amend its national patent legislation following TRIPS. The Brazilian process was complex and fraught with difficulties, not least of which was because of strong resistance from pharmaceutical companies (Flynn, 2011, p. 164). The US filed a complaint against Brazil's compulsory licensing provisions with the WTO. The dispute was resolved through a negotiated settlement between the parties. Brazil and the US jointly notified the WTO that an agreement had been reached in which Brazil agreed to hold prior discussions with the US government should it find it necessary to apply the provisions in question to grant compulsory licenses on patents held by US companies (Fisher & Rigamonti, 2005, p. 13).

The best-known case of political pressure and legal action, however, is the crusade of the South African government led by Nelson Mandela. As early as 1997, Mandela took steps to have his country obtain cheaper generic versions of HIV/AIDS drugs from abroad (Quigley, 2017, p. 111). In response to this action, PhRMA sued the South African government from 1998 onwards for violation of patent law and WTO rules (Fisher & Rigamonti, 2005, p. 5). PhRMA has joined forces with many other pharmaceutical companies such as the British SmithKline Beecham and Glaxo, the German Bayer, the Swiss Roche, and the French Rhône-Poulenc. It has retained the services of an expert in the field of drug regulation. It has also hired a consulting firm founded in 1988 by the two Podesta brothers. One of the founders of this firm, heavily involved in the financing of the Democratic Party in the US, was, at the time of the events, the chief of staff of US President Bill Clinton (Robinson, 2016).

For these companies, as in the case of Covid-19 vaccines, the lucrative market was in rich countries, and to avoid having to lower prices in those countries, they set a minimum price. As a result, when adjusted for purchasing power, these drugs were much more expensive in South Africa than in the US, for example. The estimated cost of AIDS therapy was more than $1,000 per patient per month, while the average annual income in the country at the time was $2,600 (Fisher & Rigamonti, 2005, p. 3). Recall that in 2000 there were approximately 30 million HIV cases in low-income countries. These cases represented 95% of the world's cases (Chirac et al., 2000, p. 502). South Africa was the most highly affected country in the world at the time with an HIV prevalence rate of nearly 25% among women of childbearing age (Quigley, 2017, p. 154).

The US, under Bill Clinton's administration, as well as several European governments, initially supported pharmaceutical companies in their crusade against South Africa (Quigley, 2017). According to Nathan Robinson, the Clinton administration went to "war" with South Africa's anti-AIDS campaign (Robinson, 2016). Vice President Al Gore, who was preparing his presidential campaign and had benefited greatly from Big Pharma's funding in the US, also supported them (Quigley, 2017, p. 157). He put intense pressure on Mandela and, starting in June 1999, on President Thabo Mbeki to abandon South Africa's plans. At the time, US Trade Representative Charlene Barshefsky even withdrew tariff reductions for South Africa's exports to the US. In April 1998, the US even placed South Africa on the "Section 301 watch-list" (Yu, in press). This action is the step prior to trade sanctions and represents a call for a bilateral effort to address a problem that is deemed serious (Fisher & Rigamonti, 2005, p. 7).

This practice is not new to the US. Between 1985 and 1994 (when the agreement on TRIPS was signed in the Final Act of the Uruguay Round), the US government used the "Section 301 watch-list" procedure

on intellectual property issues against Brazil in 1985, 1987, and 1993, India in 1991, Argentina in 1988, South Korea in 1985, Thailand in 1990 and 1991, China in 1991 and 1994, and even against Taiwan in 1992 (Drahos & Brathwaite, 2004, p. 15).

The situation, however, fostered the mobilization of the international and epistemic communities, a mobilization facilitated by Nelson Mandela's charisma and international reputation (Quigley, 2017, pp. 153–170; R. A. Smith & Siplon, 2006). The NGO Médecins Sans Frontières, which won the Nobel Peace Prize in 1999, supported Mandela's initiative and opposed the pharmaceutical companies. The organization highlighted its campaign for access to essential medicines for countries in need (Mbali, 2013, pp. 136–166). Several demonstrations took place, including at the international AIDS conferences in 1999. The pressure was so strong that the US government eventually changed its position (Fisher & Rigamonti, 2005, p. 8). It also withdrew its support for the pharmaceutical companies' lawsuit against the South African government.

7. New Limitations?

From the way the Agreement is written, it puts forward new limitations. Indeed, the Agreement excludes countries such as Brazil, Russia, India, China, and even South Africa from the decision since these countries already have production capacity. A note to the Agreement states:

> For the purpose of this Decision, all developing country members are eligible members. *Developing country members with existing capacity to manufacture Covid-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision*. (WTO, 2022b, p. 2, emphasis added)

The declaration refers to the right of countries such as Brazil, China, or India, to produce generics for their populations and those of countries unable to afford the originals. To export generics, these countries must instead use the mechanism of voluntary licenses or production agreements in collaboration with the patent holder, in short, with pharmaceutical companies. One of the reasons for the introduction of these measures is that the US wanted to keep China out of the current trade dispute. The US did not want its rival to come away from the negotiations with an advantage.

8. Conclusion

The issue of intellectual protection in trade agreements and the lifting of patents on vaccines and health materials to fight the Covid-19 pandemic profoundly affects the interests of powerful actors, as well as the global society. The big pharmaceutical companies, aided by several governments from high-income countries, have mobilized, as they have done in the past, to defend their interests against the Indian and South African proposal. It is not surprising, therefore, that the Agreement is ultimately unambitious and it is unlikely to have a significant impact on vaccine production in low-income countries that do not have production capacity.

As we have seen, the Ministerial Decision on the TRIPS Agreement adopted on 17 of June 2022 is too restrictive, silent on the issue of the shortage of raw materials and protectionism, or production capacity problems, and even adds new limitations that did not exist before. The lifting of patents at the WTO will not solve the vaccine apartheid problem in itself (Singh Bajaj et al., 2022).

Most importantly, as mentioned, it does not cover trade secrets and know-how. Producing mRNA vaccines is very complex. To produce them, specific manufacturing processes must be mastered, many aspects of which are not disclosed in a patent. Thus, the lifting of patents will not lead to greater disclosure of information unless the patent holders themselves are willing to cooperate.

One way to facilitate the cooperation of large pharmaceutical companies is to make it easier to use compulsory licenses. Compulsory licenses do not extinguish or suspend patent rights, but rather consist of the government granting licenses to third parties against the will of the patent holder. In a pandemic situation, it is probably easier to use this approach even if it means removing some remaining irritants. Simplifying the use of this mechanism could help to encourage pharmaceutical companies to enter into voluntary licensing agreements. Some precedents in Africa seem to confirm this (Motari et al., 2021).

For Big Pharma, supported by WTO Director-General Ngozi Okonjo-Iweala prior to the Ministerial Declaration, the best option to promote the production of quality vaccines is to share technology and know-how on a voluntary basis through production agreements (Hilty et al., 2021, p. 2). Indeed, there are precedents with emerging economies, such as the agreement between AstraZeneca and the Serum Institute of India, and Fiocruz in Brazil, or the partnership between BioNTech and ironically Fosun Pharmaceuticals in China (Thambisetty et al., 2021, p. 9). According to PhRMA, more than 300 voluntary agreements have been established that include technology and knowledge transfer (PhRMA et al., 2021).

But much more needs to be done. Contrary to their past promises, the countries of the North have not sufficiently strengthened the capacities of the countries of the South in these matters. Simply put, there is a lack of infrastructure, including equipped factories and laboratories, and readily available raw materials to rapidly produce and distribute Covid-19 vaccines as envisioned in the current waiver proposals.

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Conflict of Interests

The authors declare no conflict of interests.

References

Achiume, E. T. (2022, June 14). *UN expert urges states to end "vaccine apartheid"* [Press Release]. https://www.ohchr.org/en/press-releases/2022/06/un-expert-urges-states-end-vaccine-apartheid

Agence France-Presse. (2022, June 18). South Africa hails COVID-19 vaccine patent waiver. *VOA*. https://www.voanews.com/a/south-africa-hails-covid-19-vaccine-patent-waiver/6623167.html

Bansal, T. (2021, May 6). It's time for Big Pharma to waive their patents on COVID-19 vaccines. *Forbes*. https://www.forbes.com/sites/timabansal/2021/05/06/its-time-for-big-pharma-to-waive-their-patents-on-covid-19-vaccines/?sh=29b37e036573

Berger, M. (2021, May 6). What it means for the U.S. to back waivers on coronavirus vaccine patents. *The Washington Post*. https://www.washingtonpost.com/world/2021/05/06/coronavirus-vaccine-patent-waiver-biden-wto

Blenkinsop, P. (2021, June 4). Resisting patent waiver, EU submits vaccine plan to WTO. *Reuters*. https://www.reuters.com/world/europe/eu-present-wto-plan-boost-vaccine-production-2021-05-19

Bollyky, T. J., & Bown, C. P. (2020, December 29). Vaccine nationalism will prolong the pandemic. *Foreign Affairs*.

Bollyky, T. J., & Bown, C. P. (2021, June 24). The real vaccine procurement problem. *Foreign Affairs*.

Bostyn, S. J. R. (2021). *Why a COVID IP waiver is not a good strategy*. SSRN. https://doi.org/10.2139/ssrn.3843327

Bown, C. P., & Bollyky, T. J. (2021 October 13). The world needs a COVID-19 vaccine investment and trade agreement. *Peterson Institute for International Economics*. https://www.piie.com/blogs/trade-and-investment-policy-watch/world-needs-covid-19-vaccine-investment-and-trade-agreement

Chirac, P., von Schoen-Angerer, T., Kaster, T., & Ford, N. (2000). AIDS: Patent rights versus patient's rights. *The Lancet*, *356*(9228), 502.

Corporate Europe Observatory. (2021). *The Commission's pharma echo chamber*. https://corporateeurope.org/en/2021/05/commissions-pharma-echo-chamber

Correa, C. M., Syam, N., & Uribe, D. (2021). *Implementation of a TRIPS waiver for health technologies and products for COVID-19* (Research Paper 135). South Centre.

Council for Trade-Related Aspects of Intellectual Property Rights. (2020). *Waiver from certain provisions of the TRIPS agreement for the prevention, containment, and treatment of Covid-19. Communication from India and South Africa* (P/C/W/669). World Trade Organization. https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True

Council for Trade-Related Aspects of Intellectual Property Rights. (2021). *Waiver from certain provisions of the TRIPS agreement for the prevention, containment, and treatment of Covid-19* (IP/C/W/669/Rev.1). World Trade Organization. https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True

Cross, S., Rho, Y., Reddy, H., Pepperell, T., Rodgers, F., Osbourne, R., Eni-Olutu, A., Benerjee, R., Wimmer, S., & Keestra, S. (2021). Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine? *BMJ Journals*, *6*(12). http://doi.org/10.1136/bmjgh-2021-007321

Deere, C. (2009). *The implementation game: The TRIPS Agreement & the global politics of intellectual property reform in developing countries*. Oxford University Press.

Diamond, D., Pager, T., & Stein, J. (2021, May 5). Biden commits to waiving vaccine patents. *Washington Post*. https://www.washingtonpost.com/health/2021/05/05/biden-waives-vaccine-patents

Drahos, P., & Brathwaite, J. (2004). *Who owns the knowledge economy? Political organising behind TRIPS* (Briefing Paper 32). The Corner House. http://www.thecornerhouse.org.uk/resource/who-owns-knowledge-economy

Dunleavy, K. (2022, June 21). PhRMA says COVID-19 vaccine patent waiver is a "political stunt" while advocate argues it doesn't go far enough. *Fierce Pharma*. https://www.fiercepharma.com/pharma/wtos-patent-waiver-covid-vaccines-political-stunt-phrma-says

Fang, L. (2021, May 14). *Documents reveal pharma plot to stop generic COVID-19 vaccine waiver*. The Intercept. https://theintercept.com/2021/05/14/covid-vaccine-waiver-generic-phrma-lobby

Fisher, W., & Rigamonti, C. (2005). *The South Africa AIDS controversy*. Harvard Law School. https://nrs.harvard.edu/URN-3:HUL.INSTREPOS:37373367

Flynn, M. (2011). Corporate power and state resistance: Brazil's use of TRIPS flexibilities for its national AIDS program. In K. C. Shadlen, S. Guennif, A. Guzmán, & N. Lalitha (Eds.), *Intellectual property, pharmaceuticals, and public health* (pp. 149–177). Edward Elgar.

Galasso, A., & Schankerman, M. (2014). Patents and cumulative innovation: Causal evidence from the courts (Working Paper 20269). NBER.

Hilty, R. M. H., Batista, S., Carls, D., Kim, M., Lamping, P., & Slowinski, R. (2021). *Covid-19 and the role of intellectual property: Position statement of the Max Planck Institute for Innovation and Competition*. Max Planck Institute for Innovation and Competition.

https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_25_Position_statement_Covid_IP_waiver.pdf

Kianzad, B., & Wested, J. (2021). "No-one is safe until everyone is safe"—Patent waiver, compulsory licensing, and COVID-19. *European Pharmaceutical Law Review*, *5*(2), 71–91.

Mbali, M. (2013). *South African AIDS activism and global health politics.* Palgrave Macmillan.

Médecins sans Frontières. (2022, June 17). *Lack of a real IP Waiver on COVID-19* [Statement]. https://www.msf.org/lack-real-ip-waiver-covid-19-tools-disappointing-failure-people

Milner, H. V. (1988). *Resisting protectionism: Global industries and the politics of international trade*. Princeton University Press.

Moon, S., Røttingen, J. A., & Frenk, J. (2017). Global public goods for health. *Health Economics, Policy, and Law*, *12*(2), 195–205.

Motari, M., Nikiema, J. B., Kasilo, O. M. J., Kniazkov, S., Loua, A., Sougou, A., & Tumusiime, P. (2021). The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement. *BMC Public Health*, *21*, Article 490. https://doi.org/10.1186/s12889-021-10374-y

Nature Editorial Team. (2021). A patent waiver on COVID vaccines is right and fair. *Nature*, *593*. https://www.nature.com/articles/d41586-021-01242-1

Office of the United States Trade Representative. (2022, June 17). *Statement from ambassador Katherine Tai on an intellectual property response to the COVID-19 Pandemic* [Press Release]. https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/june/statement-ambassador-katherine-tai-intellectual-property-response-covid-19-pandemic

Olson, M. (1965). *The logic of collective action*. Harvard University Press.

Oxfam International. (2022, June 17). *WTO agrees a deal on patents for COVID vaccines, but campaigners say this is absolutely not the broad intellectual property waiver that world desperately needs* [Press Release]. https://www.oxfam.org/en/press-releases/wto-agrees-deal-patents-covid-vaccines-campaigners-say-absolutely-not-broad

Paquin, S. (2016). *Theories of international political economy*. Oxford University Press.

Paquin, S. (2022). La levée des brevets à l'OMC: du combat de Mandela à celui contre la Covid-19 [The lifting of patents at the WTO: From Mandela's fight to the fight against Covid-19]. *Négociations*, *36*(2), 29–47.

PhRMA, ABPI, EFPIA, & IFPMA. (2021). *WTO Twelfth Ministerial conference: A critical opportunity to strengthen the global trade and health agenda* [Press Release].

Quigley, F. (2017). *Prescription for the people: An activist's guide to making medicine affordable for all*. Cornell University Press.

Robbins, R., & Nolen, S. (2022, April 23). The drive to vaccinate the world against Covid is losing steam. *The New York Times*. https://www.nytimes.com/2022/04/23/health/covid-vaccines-world-africa.html

Robinson, N. (2016, May 10). The money in AIDS. *Jacobin*. https://jacobin.com/2016/10/bill-clinton-aids-south-africa-mbeki-phrma-drugs

Ruggie, J. G. (1982). International regimes, transactions, and change: Embedded liberalism in the postwar economic order. *International Organization*, *36*(2), 379–415.

Samuelson, P. A. (1954). The pure theory of public expenditure. *The Review of Economics and Statistics*, *36*(4), 387–389.

Schwartz, B. (2021, June 1). Big Pharma lobbyist launches campaign against Biden over COVID vaccine patent waiver. *CNBC*. https://www.cnbc.com/2021/06/01/big-pharma-launches-campaign-against-biden-over-covid-vaccine-patent-waiver.html

Sell, S. (2003). *Private power, public law: The globalization of intellectual property rights*. Cambridge University Press.

Singh Bajaj, S., Maki, L., & Stanford, F. C. (2022). Vaccine apartheid: Global cooperation and equity. *The Lancet*, *399*(10334), 1452–1453. https://doi.org/10.1016%2FS0140-6736(22)00328-2

Smith, R. A., & Siplon, P. D. (2006). *Drugs into bodies: Global AIDS treatment in developing countries*. Praeger.

Smith, R. D. (2003). Global public goods and health. *Bulletin of the World Health Organization*, *81*(7), 475. https://apps.who.int/iris/bitstream/handle/10665/268992/PMC2572508.pdf?sequence=1&isAllowed=y

Steele, C. (2021, May 5). The Biden administration supports waiving patents on coronavirus vaccines. Big Pharma won't be happy. *Washington Post*. https://www.washingtonpost.com/politics/2021/05/05/biden-administration-supports-waiving-patents-coronavirus-vaccines-big-pharma-wont-be-happy

Stiglitz, J. (1999). Knowledge as a global public good. In I. Kaul, I. Grunberg, & M. Stern (Eds.), *Global public good: International cooperation in the 21st Century* (pp. 308–326). Oxford University Press.

Thambisetty, S., McMahon, A., McDonagh, L., Yoon Kang, H., & Dutfield, G. (2021). *The TRIPS intellectual property waiver proposal: Creating the right incentives in patent law and politics to end the COVID-19 pandemic* (Working Paper 6/2021). London School of Economics and Political Science. http://eprints.lse.ac.uk/id/eprint/112227

't Hoen, E. (2002). TRIPS, pharmaceutical patents, and access to essential medicines: A long way from Seattle to Doha. *Chicago Journal of International Law*, *3*(1), 27–46.

Titievskaia, J. (2021). *World Trade Organization TRIPS waiver to tackle coronavirus* (PE 690.649). European Parliament. https://www.europarl.europa.eu/RegData/etudes/ATAG/2021/690649/EPRS_ATA(2021)690649_EN.pdf

Torreele, E., & Amon, J. J. (2021). Equitable Covid-19 vaccine access. *Health and Human Rights Journal*, *23*(1), 273–288.

World Trade Organization. (2001, November 14). *Declaration in the TRIPS agreement and public health* (WT/MIN(01)/DEC/2). https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

World Trade Organization. (2007, October 4). *Canada is first to notify compulsory licence to export generic drug*. https://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm

World Trade Organization. (2022a). *The Doha Declaration explained*. https://www.wto.org/english/tratop_e/ dda_e/dohaexplained_e.htm#:~:text=In%20the%20Doha%20declaration%2C%20WTO, market%20access%20for%20these%20exports.

World Trade Organization. (2022b). *Ministerial Decision on the TRIPS Agreement adopted on 17 June 2022*. https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True

Yamey, G., Ogbuoji, O., & Kennedy McDade, K. (2018, November 20). We need a consensus on the definition of "global public goods for health." *Brookings*. https://www.brookings.edu/blog/future-development/2018/11/20/we-need-a-consensus-on-the-definition-of-global-public-goods-for-health

Yu, P. K. (in press). A critical appraisal of the COVID-19 TRIPS waiver. In T. E. Pihlajarinne, J. Mähönen, & U. Pratyush (Eds.), *Intellectual property rights in the post pandemic world: An integrated framework of sustainability, innovation and global justice*. Edward Elgar Publishing.

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