INTELLECTUAL PROPERTY WAIVER VERSUS COMPULSORY LICENSING IN COVID-19 PANDEMIC: A DEVELOPING COUNTRY PERSPECTIVE

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Abstract

When new COVID-19 vaccines and other medical items are created, it is vital to ensure that they are inexpensive and available to people in all nations. Monopoly marketplaces may result in high pricing. Experience has shown that generic competition is the most effective means of assuring reduced pricing. By late June 2021, 46% of people in high-income countries had received at least one dose of the covid-19 vaccine compared with 20% in middle-income countries and only 0.9% in low-income countries[1] *The difficulty today is not a shortage of vaccine alternatives or even theoretical production capacity; it is the intellectual property (IP) protection controlling vaccine production and access—and, eventually, the political and moral resolve to waive these rights in a time of global catastrophe. Without such freedom, there would be an insufficient vaccine to prevent the spread of variations, unnecessary deaths, and the continuous suffocation of low and medium-income countries (LMICs) by bad health. This policy brief analyses the current WTO recommendations aimed at resolving the issue of COVID-19 vaccine manufacturing shortages. This comprises two important proposals, namely the IP waiver plan from South Africa and India, which is largely backed by the United States, and the EU proposal to clarify the use of compulsory licensing. While each of these techniques may assist to increase COVID-19 vaccine manufacturing to varying degrees, there is much disagreement over which of these suggestions is the most successful. It finds that the proposed IP waiver is a more effective way of dealing with the current crisis.*

Keywords: *Compulsory licensing, WTO IP waiver, pharmaceutical wars, vaccine property rights, EU proposal on compulsory licensing, COVID-19 vaccines, patents, trade secrets*

Introduction

Following the COVID-19 pandemic, the cost of patented medications has been at the forefront of global debate since the implementation of the TRIPS agreement in the 1990s, coinciding

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[1] Coronavirus disease (COVID-19): Vaccines, (World Health Organization, 2022), available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a detail/coronavirus-disease-(covid-19)-vaccines?adgroupsurvey={adgroupsurvey}&gclid=CjwKCAj whdWkBhBZEiwA1ibLmFARgpM7xzRQLOwtVu-35r 0ifqrCGMA5Z8pw6I9BjSZKBkfiuRxOBoC9y8QAv D_BwE (last visited on October 17, 2022).

with the HIV/AIDS epidemic. Global health budgets have already been stretched in recent decades as a result of substantial increases in health spending compared to overall GDP growth. This failure might be compared with the list development of COVID-19 vaccines as an example of innovation policy success.

The world is about to experience a catastrophic moral failure, and the people and economies of the world's poorest countries will pay the ultimate price, the director general of the WHO said. While some governments and businesses talk a good game about equal access, they consistently choose bilateral agreements that benefit neither party, avoid COVAX, drive up costs, and race to the front of the line. It's wrong to do this.

Add to it a little-known detail about vaccination prices, according to several publications[2]. Health officials in nations like South Africa and Uganda were able to demonstrate that they are paying more per vaccine dose than their European counterparts because of a now-deleted tweet by a Belgian Minister that accidentally revealed the European Union's pricing. The European Union reportedly paid anything from $18 for a shot made by Moderna to €1.78 for an AstraZeneca injection. The European Commission is remaining silent on the price problem, claiming nondisclosure agreements with vaccine producers as its justification[3]. It's important to keep in mind that Pfizer has previously warned that prices would go up after the pandemic, so consider them to be "epidemic pricing." Pfizer had predicted a price of $150 "post-pandemic" and had already raised the amount it billed the European Union for each dose by 60[4]. National governments like the United States, Germany, and China, and the Coalition for Epidemic Preparedness Innovations, provide the bulk of the public funding for COVID-19 vaccine research (CEPI). Data made available to the public indicates that more than $ 6 billion, or 98%, of the total expenditure on vaccine development, came from public sources. Private investments in COVID-19 vaccine research and development are not completely disclosed but are captured when accessible in the above. Janssen, Moderna, and BioNTech received the most investment, according to the statistics[5].

[2] Jon Queally, "Deeply Alarming': AstraZeneca Charging South Africa More Than Double What Europeans Pay for Covid-19 Vaccine", *available at*: https://www.commondreams.org/news/2021/01/22/deeply-alarming-astrazeneca-charging-south-africa-more-double-what-europeans-pay (last visited on June 23, 2021).
[3] *Supra* note 1.
[4] Poppy Wood, "Pfizer hikes cost of Covid vaccine for EU by 60 percent", *available at*: https://www.cityam.com/pfizer-hikes-cost-of-covid-vaccine-for-eu-by-60-per-cent/ (last visited on June 23, 2021).
[5] Global Health Center, Knowledge Portal for COVID-19 vaccines, *available at*: https://www.knowledgeportalia.org /covid19-r-d-funding (last visited on June 22, 2021).

Vaccines developed with significant public funding are anticipated to benefit private companies, with Pfizer and Moderna predicted to collect $45 billion in sales in 2021. Nonetheless, In October 2020, Moderna announced that, under certain circumstances, it will not defend the patents on its vaccines during the pandemic. Internal documents showed that AstraZeneca had a rough plan to proclaim the epidemic "gone" by July 2021, despite early indications that the company wanted to keep its vaccine accessible at a cheap cost for the length of the pandemic. In addition, Gilead received a mandatory license in Russia for Remdesivir. This prompted criticism and a lawsuit, as well as requests to ramp up compulsory licensing measures. The instance of Remdesivir in Bangladesh and the United States, respectively, exemplifies the complicated function of IPRs in connection to access to COVID-19-related therapies. The United States' decision to ban the entire global supply of remdesivirin until June 2020 under Gilead Sciences' patent was met with great international outcry since remdesivir was hailed as a viable therapeutic for COVID-19[6].

There was a "willingness to pay," but there weren't enough pills to go around, so physicians had to make some tough choices about how to distribute the medication. Additionally, Bangladesh may approve a generic form of Remdesivir under the TRIPS exception since it is a Least Developed Country (LDC). With the production of the drug in Bangladesh reaching such heights, the country started shipping out surplus quantities to countries like India and others across the world.[7]

This story illustrates the pros and cons of protecting pharmaceutical intellectual property rights since easy access might lead to the diversion of commerce, counterfeit products posing health security risks, and an obvious threat to long-term innovation and investment. According to ICER's report on Remdesivir cost, it's also important to keep in mind that the treatment's efficacy hasn't been fully proven yet, which prevents a thorough cost-effectiveness analysis. One research assessed the manufacturing cost of Remdesivir at $ 0.93 per day, however, the drug's actual worldwide price was $390, and the amount paid by US clients was $520. Although this does not account for the money Gilead has spent on clinical trials or other regulatory activities related to Remdesivir as a COVID-19 treatment, it does show how important it is to

[6] The Guardian, "US secures world stock of key Covid-19 drug remdesivir", *available at*: https://www.theguardian.com/us-news/2020/jun/30/us-buys-up-world-stock-of-key-covid-19-drug (last visited on June 27, 2021).

[7] The Hindu, "Coronavirus - Bangladesh gifts India 10,000 Remdesivir vials", *available at*: https://www.thehindu.com/news/national/coronavirus-bangladesh-gifts-india-10000-remdesivir vials/article34 499574.ece (last visited on June 27, 2021).

be able to see the whole cost and benefits picture.[8] This economic interdependence has been shown in demands for People's Vaccine and Vaccine Justice, which go beyond the human rights framework that drives Right-to-Health discourse.[9] The next paragraphs illustrate the complex interplay between the human right to health and IP protections like pharma patents.

Right-to-Health versus Intellectual Property Rights

Due to the high costs and high risks associated with pharmaceutical innovation, there must be a balance struck between the need to safeguard investments and the need to ensure that all people have access to and can afford life-saving medications. The foundations of the Right to Health are laid forth in this part, followed by a discussion of the internationalization of intellectual property law.

1. The Legal Norm of the Right to Health

The Universal Declaration of Human Rights (henceforth UDHR) was adopted in 1948, and subsequent treaties and conventions codified various aspects of international human rights law. This process can be traced back to Cyrus Cylinder in 539 BC and has culminated in the UDHR and other treaties and conventions.[10][11] More specifically, "every human being has a fundamental right to the enjoyment of the best attainable quality of health," as stated in the WHO constitution.

This set the framework for what became known as the paragraph 6 system, as well as the eventual revision of the TRIPS Agreement under Article 31bis.[12] The objective was to ensure that those with lower incomes could still get their hands on patented medicines at reduced costs. A ratio legis for public health echoed all throughout the TRIPS agreement, and a codification of social decisions on the importance of such things as health insurance and low-cost pharmaceuticals as part of the Right to Health.

2. Intellectual Property Rights as a Legal Norm

[8] Gilead, 'An Open Letter from Daniel O'Day, Chairman & CEO, Gilead Sciences' <https://stories.gilead.com/articles/an-open-letter-from-daniel-oday-june-29> (last visited on June 27, 2021).
[9] Sophie Harman et al, 'Global Vaccine Equity Demands Reparative Justice — Not Charity' (20201) 6 BMJ Global Health 6.
[10] Universal Declaration of Human Rights. (U.N. Doc A/810 at 71 (1948)). *G.A. res. 217A (III)*.
[11] A Brief History of Human Rights <http://www.humanrights.com/what-are-human-rights/brief-history/cyrus-cylinder.html> (last visited on June 23, 2021).
[12] World Trade Organization, General Council, WT/L/641 8 December 2005, 'Amendment of the TRIPS Agreement Decision of 6 December 2005', *available at*: https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> (last visited on June 27, 2021).

Following the United Nations Convention on the Protection of Industrial Property, "intangible property that is the outcome of the thought" is protected by intellectual property rights." hence, societies that foster innovation, creativity, and the protection of intellectual property. Despite the wide variety and constant evolution of their subject matter, they all have one thing in common: they confer an exclusive property and ownership right on the author's original idea and creative work.[13] The exclusive use of intellectual work and the power to forbid its unauthorized use by others are two of the benefits of the legal protections given to its authors by the law.

Assigning property rights to mental discoveries has two justifications: first, they can be imitated easily, and second, the protection is temporary and localized, enabling the creator to recuperate his costs. In exchange for the ability to keep others out of the market and recoup research and development costs, the holder of these rights might demand a high price. The patent duration or the scope of protection should not be too long or too wide, for example, since this might discourage innovation and hurt consumers in the long run. What must also be considered are transaction costs, i.e., the expenses suffered by underdeveloped nations without the legal and infrastructure to enforce IP laws.

The Berne Convention for the Protection of Literary and Artistic Works that followed[14] Books, pamphlets, films, sketches, architectural plans, and the like that were considered "works of art" in 1886 were also considered "similar scientific labor."[15] Limitations on patent enforcement and subject matter protection were included in both agreements. For instance, several countries only offered weak patent protection for pharmaceuticals and/or had mandatory licensing programs.

The World Intellectual Property Organization Convention comes into force in 1970, replacing the BIPRI and establishing an international body for IP law. All UN members have the right, but not the duty, to join the WIPO since it was founded in 1974 as a specialized agency of the UN. There are now 188 members of WIPO.

[13] Chandra Nath Saha and Sanjib Bhattacharya, "Intellectual property rights: An overview and implications in pharmaceutical industry", *Journal of Advanced Pharmaceutical Technology & Research* 88 (2021).
[14] Berne Convention for the Protection of Literary and Artistic Works, 1886, 1161 U.N.T.S 31.
[15] *ibid*, Art 2.1.

When it comes to intellectual property protection and enforcement, the 164 countries that are part of the WTO as of 2021 all believe that the TRIPS agreement and WTO, both of which were established in 1994 as a consequence of the Uruguay Round, are major improvements.

Article 1.3 of the TRIPS agreement specifies that WTO members must guarantee that both international right-holders and their nationals have access to appropriate enforcement processes and remedies under domestic law for intellectual property rights entrenched in the Paris and Berne treaties.[16] Unlike the earlier Paris and Berne accords, which permitted developing countries to opt out of the treaties and therefore escape any responsibilities connected to IPR protection, the TRIPS agreement requires all signatories to defend intellectual property rights. Since TRIPS integrated membership in the World Trade Organization with the TRIPS Agreement in the Annex, the outcome was a global, unified, and highly enforceable IPR system.

The World Trade Organization (WTO) created the Dispute Settlement Body (DSB) to hear claims from different right-holders by Article 67 of the Trade Related Intellectual Property Rights (TRIPS) Agreement, which is a cornerstone of the new international IP-law regime. The DSB's decision is binding on its member countries and may be enforced by the revocation of trade concessions, effectively establishing a strong global intellectual property system. Developing nations, many of which do not safeguard intellectual property rights (even emerging countries such as India just began to protect pharmaceutical patents in 2005)[17] were given a transition period to pass laws and establish appropriate enforcement bodies.

Notable in this regard is the TRIPS+ agreements that the United States and the European Union inked with developing countries on their initiative.

TRIPS, Right-to-Health and Compulsory Licensing

By repeating that IPRs are employed for the public good, even if that benefit takes the shape of temporary monopoly rights for private companies, this all-encompassing policy seeks to maximize the public good.

And, most critically for the ongoing Right-to-Health vs. IPRs dispute, Article 8 states:

[16] TRIPS Agreement, art 3.

[17] The New York Times, 'India Alters Law on Drug Patents', *available at*: https://www.nytimes.com/2005/03/24/world/asia/india-alters-law-on-drug-patents.html (last visited on June 27, 2021).

To prevent right holders from engaging in conduct that unjustly restricts commerce or harms the international transfer of technology, it may be necessary to take appropriate measures, so long as they are consistent with the obligations of this Agreement.[18]

The members are concerned that the techniques of licensing intellectual property or the constraints placed on competition may have unintended consequences for business and slow down the spread of new technologies.

Thus, TRIPS permits long-term flexibilities, exclusions, and restrictions to IPRs based on both public health and anti-competitive practices rationales.

1. **TRIPS Compulsory Licensing and Access to Medicines**

The HIV/AIDS pandemic in many poor and least-developed nations may qualify as a national emergency, and Article 30 of the TRIPS agreement, when read in combination with Articles 7 and 8, would allow the issuance of compulsory licensing in such instances, The various Article 31 criteria, especially Article 31(f), acted as a major impediment.

2. **Doha Ministerial Declaration on Public Health**

We understand that under WTO rules, no nation should be barred from adopting actions to preserve human, animal, or plant life or health,' the declaration added.[19]

The criteria for what constitutes a public health emergency and national emergency were left up to the judgment of individual members. The Declaration also acknowledged that many developing countries without the industrial capacity to make these medicines benefited the most from compulsory licensing to get access to patented essential pharmaceuticals.[20]

3. **August 30th Decision and its Implication**The purpose of the Paragraph 6 System was to facilitate cooperation between member states with manufacturing capacity and less developed countries that lacked such capacity but had an urgent need for life-saving drugs. Despite being praised for its adaptability, this approach has so far failed to provide the expected results. This is mostly because of the maze of rules and protocols'

[18] TRIPS Agreement, Art 8.
[19] Doha Ministerial Declaration, WT/MIN (01)/DEC/2 14 November 2001.
[20] Anthony Taubman et alia, A Handbook on the WTO TRIPS Agreement, 2012, p. 183ff.

that surrounds it.[21] Because of the time and money it takes for both nations involved in exporting and importing.

You may summarise these guidelines as follows:

First, a national health emergency must be declared in the importing country.

Second, an application for compelled licensing must be filed and approved if the importing country is unable to get a voluntary license from the patent holder.

Third, the nations doing the importing have to prove that their domestic production capacities are inadequate (LDCs are exempt from this demand).

It is the importing country's responsibility to inform the TRIPS Council of its desire to implement mandatory licensing.

Fifth, the nation doing the importing must locate a potential exporter.

To ensure that the imported drugs are utilized to meet public health needs, the importing nation must enact laws preventing the trade diversion of imported pharmaceuticals.

Seventh, specific medicine names and dosages must be included in the notification.

First, the nations doing the exporting need to voluntarily apply for a license with commercially acceptable terms and a reasonable timeframe.

If this proposal is turned down, the exporting country will have to apply for a mandatory license from its government. If you're able to get such a license, step 10 is to create the necessary medication while giving it its own identity in comparison to the patented product in terms of shape, color, packaging, and so on.

Make an effort to get testing and safety information from the data processor, or create its study on toxicity and effectiveness.

If an exporting country intends to produce a patented medicine by the mandatory licensing structure described in paragraph 6, that country must notify the TRIPS Council of its intentions.

Exported goods are limited to the quantities specified by the importing country (see clause 14).

[21] Raadhika Gupta, "Compulsory Licensing under TRIPS, How far it addresses Public Health Concerns in Developing Countries", *Journal of Intellectual Property Rights* 15, 359 (2010).

After an award has been made and terms have been established, the exporting country is required to inform the TRIPS Council.

All participants must ensure that exports are not being diverted or re-imported for any reason. To avoid trade diversion and re-importation, Article 17 requires the exporting country to make available to the customs departments of other member states information on the quantities given and the distinguishing qualities of the commodities.[22].

This onslaught of rules makes achieving the required flexibility envisioned by the Doha Declaration and following the August 30th Decision, if not impossible, at least highly complex and time-consuming.

The little number of lawsuits filed in the almost two decades following the August 30th Decision attests to this. The case of Rwanda is the most important notice made under Paragraph 6 System / August 30th, 2003 judgment.[23] as an importer, informing the TRIPS Council in July 2007, and Canada as an exporter[24]

On May 5, 2021, Bolivia notified the World Health Organization that it will be importing 15 million doses of the COVID-19 vaccine via the paragraph 6 system (now dubbed special obligatory licensing system after TRIPS change under Article 31bis).

It's also worth noting that drug manufacturers in Bangladesh, India, Denmark, and Canada have supposedly been unable to get licenses from the relevant parties to produce vaccinations.[25]

Drug management, importation, and re-exportation to other RTA countries are also the responsibility of the country seeking the mandatory license.[26]

Developing and least-developed countries already struggle with issues like corruption, inadequate infrastructure, and border protection, which are further exacerbated by these mandates.

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[22] Jenny Wakely, "Compulsory licensing under TRIPS: an effective tool to increase access to medicines in developing and least developed countries" *European Intellectual Property Review*, 304 (2011).
[23] IP/N/9/RWA/1 19 July 2007, *available at*: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=67527&CurrentCatalogueIdIndex=0&FullTextSearch= (last visited on July 27, 2021).
[24] IP/N/10/CAN/1 8 October 2007, *available at*: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=44973&CurrentCatalogueIdIndex=0&FullTextSearch= (last visited on July 27, 2021).
[25] [25] AlJazeera, 'Explainer: What are patent waivers for COVID vaccines?', *available at*: https://www-aljazeera-com.cdn.ampproject.org/c/s/www.aljazeera.com/amp/news/2021/6/29/explainer-what-are-covid-vaccine-patent-waivers (last visited on July 02, 2021).
[26] (n 100) 307.

To begin, the complexity of the paragraph 6 system under TRIPS has made it not only harder but also much smaller, for generic manufacturers to provide the rest of the world with patent drugs during times of crisis. However, this might change if health crises arise more often and advocates succeed in convincing policymakers to make more changes. Second, developing countries may be at a technological (and sometimes regulatory) disadvantage when it comes to innovative therapies since they may be biologics. An obligatory license is of little value in this situation if there are no other viable options for obtaining the patent drug.[27]

WTO TRIPS Council Patent Waiver Proposal

The history of the COVID-19 IPR waiver started with a situation that seemed to follow the pattern of IPR discussions around healthcare items over the last few decades: The developing world, led by the European Union, favors strict IPR protection and an expansive interpretation of TRIPS flexibilities like article 31bis, whereas the developing world, led by the poor and least developed states, prefers decreasing IPRs. The background to the waiver is discussed here, along with the content of the (proposed) waiver and several arguments for and against it.

First, Freedom from Impediments: Symbols and the Past

Strong patent laws developed in regions like Europe as a result of the merging of science and industry in the expanding chemical industry of the 19th century.

In 1994, the World Trade Organization's TRIPS agreement established a baseline for intellectual property protection across all sectors of the technology industry. Due to their TRIPS obligations, countries like India, which had previously opted not to issue patents on medicinal products, are now obligated to do so.

Access to HIV medication was a top priority for the Mandela government, but negotiating with the pharmaceutical industry proved difficult and time-consuming despite the obvious risk to public health.[28] As a consequence, in 2001, the TRIPS agreement's current flexibilities were confirmed in the Doha Declaration. The statement was written to set the record straight on whether or not countries may utilize methods like compulsory licensing to deal with national health crises or circumvent other parts of the patent system to guarantee access to life-saving pharmaceuticals. The symbolic significance of the patent system has been shaped in large part by the history of the pharmaceutical industry's fierce resistance to HIV-compulsory licensing

[27] Urias and Ramani, 'Access to Medicines after TRIPS' (2020) J Int Bus Policy 2.
[28] Emily Saslow, "Compulsory licensing and the AIDS epidemic in South Africa" (2019) AIDS patient care and STDs 13.10, 577-584.

in South Africa. The patent's symbolic importance has been bolstered by reports of significant price increases on essential pharmaceuticals made possible by patent monopoly, and the patent institution has become a prime suspect in the uneven distribution of medical resources across the world's people and nations.

Invention-Process-Related-Protection-Rights Waiver

Both India and South Africa submitted an IPR waiver application to the TRIPS Council on October 2, 2020.[29] Social isolation and other pandemic-fighting strategies say India and South Africa, have disproportionately hurt developing and disadvantaged countries. To respond effectively, medical supplies including surgical masks, kid testing, immunizations, and ventilators must be readily available.

The global economic and health problems were also predicted to have a disproportionately negative impact on the world's poor and least developed countries. Developing and least developed nations, like India and South Africa, are especially vulnerable to the effects of the COVID-19 pandemic and would benefit greatly from access to diagnostics, treatments, and vaccines as soon as possible, in enough numbers, and at affordable rates. It has been said that producers are venturing into a "patent minefield."

This, say India and South Africa, proves that intellectual property rights (IPRs) may impede progress in areas like expanding access to low-cost therapeutic items and bringing production of the life-saving COVID-19 virus up to speed. The WTO members are divided along traditional fault lines when it comes to curbs on the security provided by intellectual rights:

The initiative, which was backed by some NGOs, was met with support from developing and least-developed countries but was met with opposition from the European Union, the United States, Australia, Canada, and Japan.

All the back-and-forth failed to break the stalemate. The developed countries, led by the European Union, contended that the TRIPS agreement already gave sufficient flexibility and that no new rules were needed.

[29] WTO communication from India and South Africa, Waiver of certain provisions of the TRIPS agreement for the prevention, containment, and treatment of COVID-19, IP/C/W7669, 2. October 2020.

U.S. President Joe Biden and his administration approved the COVID-19 IPR Waiver on May 6, 2021, citing "extraordinary times necessitating exceptional actions."[30] However, the European Commission agreed to endorse the waiver on June 4, 2021.[31]

Plan for a Declaration

The most up-to-date waiver is dated May 25, 2021, and it revises the original language that was written on October 2, 2020. Recitals highlight the importance of unrestricted, timely, and secure access to high-quality, risk-free, effective, and cost-efficient health products.

Also included is language stressing the need to preserve funding for scientific inquiry and creative endeavours.

These changes are meant to counteract some of the initial arguments against the IPR waiver policy. To begin, the public health issue may be made worse instead of better if the waiver allowed medications to be made without enough regulatory control of their quality, efficacy, and safety. The regulatory framework, including regulatory exclusivities, must thus be evaluated alongside IPR.

The second is that it addresses the concern that a waiver may discourage future investments in research and development (R&D), which is important since incentives for R&D are so important. The revised decision language defines the intended scope of the waiver by defining a minimum timescale that is not dependent on evaluations that may be contested, such as when "widespread vaccination" is in place.[32]

The State of Vaccine Innovation and Intellectual Property

To ensure that vital protective gear, pharmaceutical commodities, and other things used in the fight against the disease may be made available, the waiver is intended to cover a wide variety of IPRs. The potential impact of an IPR waiver on COVID-19 vaccine production and accessibility has, nevertheless, been the primary focus of the debate. Here, we use a quadruple of different approaches to vaccination: those based on Adenovirus(s) as vectors, on inactivated coronavirus, on messenger RNA, and recombinant nanoparticles. Vaccines from companies

[30] White House Fact Sheet, *available at*: https://www.whitehouse.gov/briefing-room/statements-releases/2021/05/17/fact-sheet-biden-harris-administration-is-providing-at-least-80-million-covid-19-vaccines-for-global-use-commits-to-leading-a-multilateral-effort-toward-ending-the-pandemic/ (last visited on June 27, 2021).

[31] WTO document IP/C/W/680, *available at*: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=@Symbol=IP/C/W/680&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true (last visited on June 27, 2021).

[32] Recital 13 of the initial proposal., (n 113)

including AstraZeneca, Johnson & Johnson, and Sputnik V use adenovirus vectors. The Indian Council of Medical Research and Sinovac, a Chinese pharmaceutical company, back the inactivated coronavirus vaccine COVAXIN (r). mRNA technology is used in vaccines developed by Moderna, Pfizer-Biontech, and CureVac AG.

Covovax, a vaccine developed by Novovax, uses recombinant nanoparticle technology. The patent landscapes for each of the four vaccine technologies are different. Not surprisingly, J&J has the lion's share (28) of the patents for well-established vaccination methods based on AdenoVirus vectors, inactivated viruses, and recombinant nanoparticles.

Sadly, more than half of them have already expired or will do so within the year. Additionally, five patents covering the recombinant nanoparticle vaccine (Novavax) will lapse during the next three to five years. However, there are 59 patents for mRNA vaccine technology; 14 belong to Curevac, 28 to Moderna, and 16 to Pfizer BioNTech. The patent protection period for the vast majority of these inventions is ten years or more. In addition, the public usually doesn't find out about patent applications until 18 months after they've been filed.

So, the next year should disclose the fruits of the enhanced research efforts sparked by the epidemic during the last 18 months, greatly enhancing the patent landscape. As a result, patent thickets are a real possibility in the vaccine industry, bringing with them the risks of double-dipping royalties, higher transaction costs for IP licensing for manufacturers, and more lawsuits.

The International Federation of Pharmaceutical Manufacturers and Associations (IFRMA) has said, "Vaccine supply networks are international," highlighting the complexity of vaccines and the potential challenges they provide for compulsory licensure programs. There are 280 components from 19 countries in the BioNTech/Pfizer vaccine. Complex goods are common at Moderna, AstraZeneca, and J&J. Export restrictions endanger these supplier chains. This is a concern that has been raised several times by those in attendance thus far throughout the briefing.

Competence and Confidential Information

Knowledge is just as important as patents when it comes to obtaining immunization technology. The use of mRNA technology in vaccines is a relatively new endeavour, in contrast to the long-established and well-understood adenovirus vector-, recombinant nanoparticle-,

and inactivated viral technologies. The patented invention must be described in sufficient detail for a person skilled in the art to implement it.[33]

However, there aren't enough individuals with the necessary expertise to implement the most recent mRNA technology. Moreover, the technology utilized to create mRNA vaccines is not patented and is instead protected as a trade secret. Even if know-how is intended to be covered by the waiver, it is considerably more challenging to impart tacit information than to read a patent document, and the transfer of knowledge is permanent as opposed to patents. Nonetheless, there have been recent reports of many initiatives in South Africa to distribute the nebulous expertise around mRNA vaccine technology.[34], boosting optimism that the situation would not devolve into a pointless stalemate of politics and discussions.

Controversy Over the Waiver

The CEO of Pfizer has said that he is not concerned that the proposed waiver would jeopardize Pfizer's patent portfolio. As an alternative, he voiced concern that a waiver would spur a worldwide rivalry for raw materials, putting the secure and effective production of immunizations at risk.

Other voices have spoken out against the waiver, and they mostly echo three main themes:

There is a line of reasoning that suggests the waiver won't have the intended result. Nothing will change in terms of production, distribution, or the loosening of regulations. Furthermore, little to no impact on prices or confidential information is expected. There is an alternative line of reasoning that counters the pro-waiver arguments: The negative effects of patents may be mitigated via the use of TRIPS flexibilities; there is no rationale for adopting a waiver based on the desire to maximize profits for IP holders or public expenditure.

Although many in the business world and the intellectual property rights (IPR) community has argued against it, influential politicians and non-governmental organizations have pushed for a decision in favor of granting IPR waivers. In April of 2021, more than 170 former heads of state and Nobel laureates petitioned for a waiver of intellectual property rights related to COVID-19.

[33] TRIPS agreement art 29 and European Patent Convention art 83. (n.d.).
[34] Kerry Cullinan, South Africa to Become Africa's First mRNA Vaccine Manufacturing Hub – WHO Asks Big Pharma to Support Scaleup, Health policy watch, *available at*: https://healthpolicy-watch.news/africas-first-mrna-hub-to-be-set-up/ (last visited on July 02, 2021).

Medicines Sans Frontières (MSF) and Oxfam were among the international NGOs who organized this effort. When it comes to the COVID-19 IPR waiver, it seems that the previous distinction between developing countries and developing nations of the poorest and least developed regions no longer holds. The business community and several IP law experts are against a waiver, but many politicians on both sides of the long-standing ideological divide have come out in favour of granting one.

Both businesses and universities have spoken out against the waiver, arguing that it will do nothing to improve the situation and may perhaps make things worse. To counter this, the United States and the European Union have both publicly indicated their support for a COVID-19 IPR waiver.

Issues and Challenges for Developing Countries

There are three aspects to Holger Hestermeyer's argument that low-cost access to essential pharmaceuticals should be recognized as a fundamental human right. To begin, the notion that people have a right to get medications is often drawn from the concept of a "right to health," even though such a right is not explicitly stated in any legally binding agreement. Second, it is said that the presence and enforcement of patents encourage patent holders to charge higher costs for pharmaceutical items, making them unaffordable for the majority of developing nations. This is because of the implementation of patent laws (as stipulated by TRIPS). Third, it is argued that these prohibitive prices undermine citizens' constitutional protection against arbitrary denial of healthcare. Without "additional reasons," such as the requirement for patents to aid R&D, there is no justification for the infringement.[35]

There is also no doubt about the enormous costs of such discovery, clinical testing, and eventual commercialization, which amount to billions of dollars, reinforcing the rationale for patent protection to recoup such expensive and sometimes deadly expenditures.

1. The Cost of Pandemic Vaccines and Their Aftermath

In the wake of the worst of the pandemic, the pharmaceutical industry has gained a lot of goodwill, but any price hikes for COVID-19 vaccines might damage that reputation. In the United States, industry approval has increased by 50% compared to pre-pandemic indications.

[35] Holger Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicines (Oxford University Press, 2007).

Since yearly immunization is necessary to protect against new variants and strains of COVID-19, if vaccine producers chose to price these vaccines similarly to influenza vaccines (ranging from $150 to $300), this would have a substantial effect on already stretched health resources.

Since 2000, the average cost of an influenza shot has increased by 149% in the public sector and 163% in the private sector, as noted by Ramachandran et al. There seems to be no correlation between the availability of different brands of flu vaccine and their prices... This demonstrates that there is little price competition and progressive price increases in the United States influenza vaccine industry, despite growing government purchasing commitments and increasing numbers of advised users.

Dramatic price increases may be detected by competition authorities via excessive pricing restrictions, at least in the EU, however, the US Federal level lacks a corresponding clear-cut ban. Nonetheless, the price gouging legislation enacted at the federal level, in light of the significant public support for vaccines, may prompt Congressional inquiries and demands on the Department of Justice to initiate antitrust allegations related to price gouging.

If vaccination costs rise, the likelihood of compelled licensing rises exponentially.

2. Responsibility of the State - Public Health VS Intellectual Property Protection

Can a state reasonably be expected to fulfill both its responsibility to ensure public health (including the right to health and access to medicines) and its responsibility to protect intellectual property rights (through treaties like TRIPS)? Which begs the question: if that's the case, how do we get over this impasse?

When trying to make sense of the apparent contradiction between states' responsibilities for public health and states' obligations for patent protection as outlined in TRIPS, it can be helpful to review a few of the agreement's "gateway paragraphs," which provide context for reading and interpreting the rest of the document.

If anti-competitive conduct is found to exist, Article 31(k) of the TRIPS Convention mandates the limitation and enforcement of patent rights.

However, the examination of competition law requires that such enforcement adheres to procedural criteria (such as the right to appeal) and legal-economic principles. Some activities, for example, royalty stacking as well as patent thickets[36] may potentially appear in the future

[36] Carl Shapiro, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting,' (2001) 1 Innovation Policy and the Economy 34.

to COVID-19 vaccinations, although reluctance to license and high cost, as previously noted, deserve more examination.

3. Legal and Economic Arguments for IPR Limitations

There are the societal, healthcare system, and consumer expenses associated with intellectual property rights (IP rights), such as patents, that may be quantified using legal and economic analysis. In the eyes of the law, there is a societal benefit to protecting patents for their exclusive use. The patent holder has the right to set a higher price for their product while the patent is in effect.

This drives up prices for consumers, yet the treatment would not be available without the patent-enabled premium pricing, or the added cost is seen as justified by the health benefits it provides.

Since patents genuinely prevent competitors from entering, this is undeniably one sector where anti-competitive practices, such as pricing substantially above marginal costs, may have a significant negative impact on society and consumers. In this way, clients are negatively affected by high or excessive prices, which results in deadweight losses.[37]

Depending on the values and goals that are sought, the aforementioned factors may be taken into account while deciding on and crafting innovation laws and policies, such as pharmaceutical patents and life-saving medicines.

Economists, however, have not yet come up with a conclusive answer. We only have estimates based on simulations, and they reflect a modestly positive social return to innovation, but they are indicative of a low rate of surplus capture by innovators. While informative, concluding the impact of innovation on society always requires some educated guesswork. The response to this inquiry is crucial. If there is such a thing as too much innovation, then public and private payers are wasting money on excessive incentives for businesses that generate innovations. Conversely, if innovation rates are too low, people would die young due to a lack of technological and medical advances.

Conclusion

In a conclusion, the TRIPS agreement offers a sound legal basis for granting exceptions to IPR protection to accomplish other public policy goals, such as preventing and responding to national health crises. Refusal to license and excessive pricing are two instances of IPR abuses

[37] Marcel Canoy and Jan Tichem, 'Lower Drug Prices Can Improve Innovation' (2018) 14 European Competition Journal 2, 278–304.

that have a firm legal footing under the TRIPS agreement and are therefore subject to exceptions and limits.

When trade secrets and know-how are not immediately covered by mandatory patent licensing, obtaining a large number of patents for COVID-19 vaccines may be very challenging and time-consuming. Time is important in the event of an impending health disaster, such as a global epidemic.

Future research is needed to clarify and fill in the research gaps about the true effect of compulsory licensing on the pace of innovation of originator enterprises and the overall impact on health expenditures.

Indeed, neither mandatory licensing nor a surrender of intellectual property rights is a suitable response to a global crisis brought on by inequality, injustice, and countless broken promises in the quest for global economic development and various health objectives.

Pharmaceutical companies may be less eager to rush to human relief during the next pandemic if a waiver is granted, but this argument seems to overlook the 'compulsory' element of compulsory licensing and the vast resources available to the Sovereign in an emergency, as evidenced by the United States use of the Defense Production Act.[38]

With the current epidemic and the potential of abandoning IPR rights, it seems unlikely that we will continue to pursue our current policy of promoting pharmaceutical innovation via a market-driven innovation system that includes state investment for basic research. If the waiver is implemented and isn't weakened by political negotiations, it would be a major break from the conventional wisdom that strong IPR protection is the bedrock upon which pharmaceutical research and the following market/profit orientation are built. Protecting incentives and investments will be crucial regardless of the incentive model selected, as it has been famously remarked that although everyone wants to share the cake, someone has to create the cake in the first place.

As such, it has the potential to pave the way for a worldwide healthcare innovation system that relies on public-private partnerships throughout the healthcare technology development and delivery process. Recovery of the global economy and the development of new drugs would benefit from such progress.

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[38] FEMA, The Defence Production Act, *available at*: https://www.fema.gov/disasters/defense-production-act (last visited on June 241 2021).v