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THE TRIPS WAIVER AND GLOBAL HEALTH EQUITY

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ABSTRACT

This research paper critically examines the proposal for a patent waiver under the TRIPS Agreement in response to the COVID-19 pandemic, with a primary goal of evaluating its effectiveness in promoting global health equity. The study adopts a qualitative research design, employing a doctrinal legal methodology to analyze international legal frameworks, WTO documents, and scholarly literature. It assesses both the arguments supporting and opposing the PW, focusing on its potential to enhance vaccine accessibility and affordability, particularly in least developed nations. The analysis reveals that while the waiver could facilitate wider vaccine production by eliminating intellectual property barriers, it faces significant opposition due to concerns about undermining incentives for innovation and weakening the global intellectual property regime. The paper also highlights practical challenges in implementing such a waiver, including legal complexities and the absence of a robust enforcement mechanism. Furthermore, it explores existing TRIPS flexibilities, such as compulsory licensing, as alternative strategies that might balance intellectual property protection with public health needs. The findings suggest that although the patent waiver has symbolic and practical merit in addressing immediate health crises, its long-term viability as a model for future pandemics is limited. The study concludes that rather than relying solely on patent waivers, a more sustainable approach would involve strengthening domestic intellectual property legislation, promoting voluntary licensing, and fostering international cooperation to ensure equitable access to essential medicines and vaccines during global health emergencies.

Keywords: TRIPS Agreement, Patent Waiver, Intellectual Property Rights, COVID-19 Vaccines, Global Health Equity, Public Health

1. INTRODUCTION

The COVID-19 pandemic has swept the globe, causing devastation in its aftermath Kolodziejczyk and Kołodziejczyk (2022). The worldwide health crisis has placed nations in a dangerous position, necessitating medical supplies such as vaccines, treatments, and diagnostics that are both affordable and easily accessible Bown (2022). In contrast, unrestricted access to the aforementioned vital healthcare resources was significantly impeded by safeguarding intellectual property rights (IPR), particularly patents Rae (2021). In light of the gravity of the situation, the World Trade Organization (WTO) Document IP/C/W/677 suggested

the possibility of a TRIPS Agreement[1] patent waiver (PW) World Trade Organization. (2021), which emerged as a potential strategy to mitigate the detrimental impacts of the pandemic and develop additional remedies for medical concerns Thiendej and Giordano (2022).

The TRIPS Agreement, a significant global accord overseen by the WTO, sets forth essential regulations for safeguarding intellectual property rights (IPRs), including patents. In addition to its significant contribution to fostering innovation and increasing investments in research and development (R&D), the agreement establishes a structure to protect pharmaceutical commodities and technologies Taubman and Wager, 2020. TRIPS specifically mandates that nations must grant exclusive rights to patent holders to develop, utilize, and commercialise pharmaceuticals and vaccines for a minimum of twenty years after the patent application date (TRIPS, arts. 28 & 33). As a result, IPRs will likely restrict manufacture and distribution, which will drive up costs Kumar and Bharti, N. (2023). Put another way, in times of international emergency, such as the COVID-19 pandemic, this protection would make it more challenging to obtain timely access to reasonably priced pharmaceuticals.

The WTO Council on Trade-Related Aspects of IPRs declared in document IP/C/W/668 during its meeting on October 1, 2020, that the majority of commodities covered by intellectual property (IP), including pharmaceuticals, are just too expensive for the least developed nations (LDNs) to afford under TRIPS Article 66.1 World Trade Organization. (2020). In light of the COVID-19 pandemic emergency, India and South Africa presented their petition for a PW under the TRIPS Agreement in document IP/C/W/669 during a meeting of the TRIPS Council on 2 October 2020 Kumar and Bharti (2023). The purpose of the waiver was to temporarily suspend several patent clauses within the TRIPS Agreement. This suspension would allow countries to produce generic versions of COVID-19 medical supplies without infringing on any patents Mercurio (2021). The waiver endeavours to promote the production and extensive availability of medical supplies, particularly in LDNs where affordable healthcare is frequently limited, by eliminating these IPRs obstacles Agejoh (2022) to meet the current elevated demand required to contain and manage the pandemic. The proposition rapidly sparked global discourse, inciting fervent deliberations among member organisations of the World Trade Organisation, the pharmaceutical industry, public health organisations, and civil society groups Kohler et al. (2022). A minority of developed nation members voted against it[2], while the majority of developing nation members supported it. Because the deadline passed without a satisfactory agreement being reached[3], the proposal was resolved to remain on the agenda of the TRIPS Council for 2021 (Mercurio, 2021). Finally, in 17 June 2022, a decision was made in WTO document WT/MIN(22)/30 WT/L/1141, waiving only one provision as opposed to the 35 provisions that were initially proposed to be waived, but vaccines are limited to export under a compulsory license. The decision was intended to be re-evaluated within six months of its adoption. Since then, however, WTO members have been unable to agree on whether to extend the waiver Paquin and Plouffe-Malette (2023).

Theoretically, a TRIPS Agreement patent waiver could facilitate access to COVID-19 vaccines and make the fight against the virus easier and more effective by removing barriers to IP. However, there are numerous viewpoints that this

[1] Agreement on Trade-related Intellectual Property Rights, 15 April 1994.
[2] Including the United States, the United Kingdom, the European Union and Canada.
[3] The deadline of ninety days as set out in Article IX:3 of the Agreement Establishing the WTO.

elimination is not intended to occur because it poses significant risks to the R&D sector Mercurio (2021), which could lead to negative effects on COVID-19 prevention and repellency, resulting in the use of a PW is not expected to materialize shortly or serve as a template for addressing comparable global pandemic. This paper will undertake a critical analysis of the aforementioned argument by examining the subsequent aspects: (i) The benefits of utilizing patent waivers to combat COVID-19, as argued by proponents; (ii) The opponents' counterarguments on the applying PW in addressing COVID-19; (iii) Barriers to the adoption of future PW models to cope with similar health crises; and (iv) Alternative approaches that strike a balance between IP protection and medication accessibility, Instead of depending on a PW.

2. THE POTENTIAL OF PW AS A STRATEGY TO COMBAT THE COVID-19 PANDEMIC

The waiver promotes equitable distribution of vaccines throughout the globe by facilitating the global production of vaccines

The proposed PW for COVID-19 vaccines could significantly boost the efficiency of vaccination production. In order to remove the legal barriers that prevent other manufacturers from producing vaccinations, the waiver temporarily terminates patent protection. The increased manufacturing capacity has the potential to mitigate the worldwide shortage of vaccines, particularly in developing countries where the availability of sufficient quantities is restricted Erfani et al. (2021). The waiver's ability to facilitate the development of generic COVID-19 vaccines is one of its biggest advantages. Producers of generic drugs are not required to enter into licensing agreements with patent holders to use their abilities and assets to develop vaccines. As a result, more producers can enter the market, increasing the production of vaccines and expanding the supply chain Aerts (2021). As a result, more producers can enter the market, increasing the production of vaccines and expanding the supply chain.

Additionally, despite the endeavors of numerous organizations in industry and government, the current voluntary sharing channels need to be fixed as intended. In actuality, COVID-19 vaccines and biological medications being produced are complicated, making them more challenging to replicate than small molecule drugs[4] without technology transfer. Moreover, transfers of technology, data, know-how, and cell lines are also necessary to scale up biologics such as vaccines and the simple transfer of patents. However, the waiver supporters claim that no pharmaceutical business has agreed to share its IP and technologies in the Covid-19 Technology Access Pool (C-TAP)[5] since its debut several months ago Mercurio (2021). Thus, the waiver could aid in promoting vaccine makers to enter voluntary licensing arrangements. Patent holders can license their patents to other producers, enabling them to make vaccines on agreed-upon terms. This collaborative strategy can speed up vaccine production and allow a wider distribution of doses to needy countries. Erfani et al. (2021)

[4] Such as vaccines used to combat HIV/AIDS.

[5] The WHO developed the C-TAP platform to enable increased production of medical products connected to COVID-19. Any research facility, public agency, or for-profit organisation that possesses knowledge, information, or intellectual property on items that can be used to combat COVID-19 may make it available to other qualifying producers anywhere in the world through C-TAP. These non-exclusive license arrangements broaden the scope of output and lessen reliance on a small number of producers. Owners of rights who divulge information through C-TAP may be fairly compensated.

For example, Moderna, a leading COVID-19 vaccine manufacturer, decided in 2020 not to enforce the patent on its vaccine. This decision aimed to support LDNs that lacked the financial resources to purchase large quantities of the vaccine. By not enforcing the patent, Moderna encouraged these countries to develop their own versions of the vaccine using more affordable resources, thereby increasing production and improving access to the vaccine in resource-constrained regions. Dasari (2023)

In short, the waiver can help achieve extensive vaccination coverage, which is essential for preventing the virus's transmission and reducing its effects on public health and the global economy. This is done by making it easier to produce vaccines. In addition to reducing vaccine shortages and ensuring more fair access to vaccinations globally, it can assist in overcoming supply chain bottlenecks.

The waiver expands COVID-19 vaccine accessibility on a global scale.

A shortage of cost-effective vaccine accessibility is among the concerns raised by the sponsors of the waiver. Therefore, IPRs pertaining to COVID-19 health technologies harm manufacturing growth, prevent the entry of numerous suppliers, and limit competition that may lead to reduced prices. The sponsors referred to Gilead Sciences as an illustrative example, citing the licensing contracts for Remdesivir, also known as Veklury, is a broad-spectrum antiviral drug manufactured by the pharmaceutical company Gilead Sciences. Throughout the worldwide outbreak of COVID-19, Remdesivir was granted approval or permitted for urgent use in several countries in order to treat COVID-19 Beigel et al. (2020), claiming the contracts restrict production and prohibit affordable supply to almost half of the world's population Ison et al. (2020). Critics have raised concerns regarding the restrictive nature of these contracts and their subsequent impact on the accessibility of affordable materials Mercurio (2021).

The easing of patent restrictions would enable these manufacturers to produce COVID-19 vaccines at an affordable price, augmenting the global supply and guaranteeing enhanced accessibility. The increased manufacturing capacity is expected to stimulate competition among manufacturers, potentially reducing prices. Furthermore, the presence of multiple vaccine manufacturers enhances competition within the sector, leading to reduced costs and improved distribution. This would be particularly advantageous for countries grappling with limited financial means, otherwise poses challenges in procuring vaccines at market prices Sekalala et al. (2021). Besides, hundreds of other manufacturing sites in 35 developing nations could be utilized to make COVID-19 vaccines if a TRIPS waiver is issued Thambisetty et al. (2022). An exemplary example can be found in the endeavors of GAVI[6] to reduce the exorbitant expenses associated with the HPV[7] vaccine, which presently assumes responsibility for more than 300,000 annual fatalities, with approximately 90% of those incidents occurring in LDNs (as of 2020, approximately 80 LDNs have yet to adopt the vaccine from its inception in 2006). Mermelstein and Stevens, H. (2021)

As a result, by terminating patent rights, the waiver seeks to eradicate barriers that impede access to these critical medications, especially in developing nations. By effectively addressing the pressing requirement for equitable distribution, the patent waiver possesses the capacity to enhance global accessibility to affordable COVID-19 vaccinations significantly.

[6] GAVI: The Vaccine Alliance
[7] The human papillomavirus.

3. COUNTERARGUMENTS RAISED BY OPPONENTS REGARDING THE USE OF PW TO COMBAT COVID-19

While supporters assert that the waiver is essential for facilitating worldwide vaccine production, advancing fair distribution, and expanding affordable vaccine accessibility. However, opponents argue that the waiver should not be applied for certain reasons:

The effect of patent waiver on IPRs protection may have a negative impact on combating the COVID-19 pandemic

Firstly, the IP system aims to support society by fostering and rewarding creativity and innovation Wirten (2004). Access to COVID-19 vaccinations, for example, may potentially be accelerated by waiving IPRs in the short term, but long term, eroding IPRs would remove the incentives that drive innovation. The creation of new technology or items that the world needs would be hampered by this. Synthetic mRNA is an illustration of the need for IP protection, the genetic technique used in both Pfizer and Moderna's COVID-19 vaccines. Several governments and investors have squandered enormous amounts of money on the R&D of this extremely difficult but potentially fruitful technology Paquin and Plouffe-Malette (2023). The elimination of the IP barrier and the globalization of technology could hamper their ability to create profits. If a subsequent worldwide pandemic arises, would researchers be motivated to pursue this path if IPRs were not assured? Moreover, research funds, which can be prohibitively expensive, will be drained if investors withdraw when they cannot guarantee incomes. Mercurio (2021)

Secondly, IP protection is crucial for preventing the introduction of fraudulent and hazardous products and preserving the safety of vaccines. To manufacture or "copy" the vaccine production process, additional time and regulatory oversight are necessary due to the increased complexity of vaccine products. Therefore, innovators must employ foresight and accuracy when determining to whom they grant licenses so as to safeguard global health and ensure the responsible dissemination of their concepts. Moreover, with the ongoing COVID-19 pandemic, the global circulation of counterfeit medications has grown. According to Interpol[8], criminals have manufactured counterfeit medications and marketed them in underdeveloped nations for large profits. This might have severe repercussions, including exacerbated sickness, mortality, and a slowing of herd immunity. Intellectual property regulations are essential and practical in mitigating the dangers posed by counterfeit and illegal pharmaceuticals, thereby safeguarding the public during this critical period. By waiving all IPRs associated with COVID-19, the danger that tainted or false vaccines will access the market increases, putting millions of lives at risk and undermining public confidence in vaccines. Mercurio (2021)

3.1. CURRENT SYSTEMS ARE CAPABLE OF PROTECTING PUBLIC HEALTH

The global framework was established to address any circumstance, including pandemics of international scope such as COVID-19. Article 7 of the TRIPS Agreement provides that the “protection and enforcement of IPRs [shall be] in a manner conducive to social and economic welfare” while Article 8 states that WTO Members “may, in formulating or amending their laws and regulations, adopt

[8] The International Criminal Police Organization.

measures necessary to protect public health". Together, these two clauses should enable a variety of policy decisions and health precautions to be adopted in the event of a medical emergency like COVID-19. Article 73, which permits Members to take "any action it considers necessary for the protection of its essential security interests... taken in time of war or other emergency in international relations," provides further flexibility. Instead of requesting a waiver of IPRs, countries should modify their domestic legislation to leverage the flexibilities provided by the TRIPS Agreement effectively. This approach would enhance the efficacy of ensuring equitable distribution of vaccinations amidst the pandemic. In fact, several countries[9] modified their legislation to make it easier to use compulsory licensing for public health purposes, suggesting that many other countries may not fully utilize TRIPS flexibilities. Mercurio (2021)

4. THE PATENT WAIVER WILL BE HARD TO APPEAR AS A MODEL FOR FUTURE SIMILAR HEALTH CRISES

The idea that the patent waiver will serve as a model for future health crises encounters substantial barriers. Although the idea of a patent waiver may appear attractive in theory, since it may accelerate vaccine development, promote fair distribution, and reduce costs, there are many challenges that impede its practicality as an effective solution. As previously stated the suggestion caused varied viewpoints and is unlikely to achieve agreement among members of the WTO. The waiver has the possibility to indirectly harm worldwide efforts to address COVID-19 by harming the protection of IPRs, which are crucial for promoting innovation and research. Sponsors of the waiver claim that eliminating IP barriers will improve accessibility. However, opponents argue that the current framework for IPRs does not present a significant obstacle to obtaining necessary healthcare services. They contend that the focus should be placed on other factors such as production capacity, obstacles to supply chains, and fair distribution rather than decreasing the IP regime. Addor (2023) Additionally, they emphasize that the sponsor of the waiver was unable to provide real evidence proving that the IPRs protection provisions outlined in the TRIPS Agreement hamper people's access to COVID-19 pharmaceuticals. Mercurio (2021)

Furthermore, the concerns expand beyond the immediate impact of the COVID-19 response. The global community has raised concerns about the potential long-term impacts of affecting the protection of IPRs. The patent waiver, through lowering the safeguarding of IP, has the potential to discourage investment in future developments in medicine and impede the evolution of new therapies and technology. This could have an impact on addressing not just the present global health issues but also future ones.

The lack of a defined mechanism for both implementation and enforcement further hinders the feasibility of the patent waiver. Applying the waiver effectively could present major obstacles, even if it were to be approved by WTO members. The complicated characteristics of IPRs laws, variable regulations at the national level, and the participation of several parties contribute to complicated circumstances for operating a waiver. Mitchell (n.d.). In the absence of a strong and comprehensive system, uncertainty, legal conflicts, and even unforeseen outcomes may be possible to weaken the waiver's desired advantages.

Given these obstacles, it is clear that applying a PW as a sustainable strategy for future health crises is highly challenging. Although the goal of improving access to

[9] Including Australia, Germany, Canada and Hungary.

critical medical supplies is commendable, several issues regarding the protection of IPRs exist, such as the lack of solid evidence supporting the necessity for a waiver and the challenges connected with its implementation.

5. ALTERNATIVE STRATEGIES THAT COULD ACHIEVE A BALANCE BETWEEN SAFEGUARDING INTELLECTUAL PROPERTY RIGHTS AND ENSURING THE AVAILABILITY OF MEDICATIONS

As analyzed above, it appears that certain nations have not effectively utilized the flexibilities provided by the TRIPS Agreement in their response to the COVID-19 pandemic, although several developed nations have done so. When available flexibilities are not used, the confused and unsustainable national framework typically appears to be the stumbling barrier rather than the current international system. Perhaps the best example of this is mandatory licensing. For example, in Zimbabwe, the legal structure and ability to successfully execute and benefit from TRIPS flexibility are unduly cumbersome. A required licensing decision needs the consent of two government departments[10] with "overlapping roles and responsibilities."

Instead of seeking a PW, governments should modify their own legislation to better take advantage of the flexibilities granted by the TRIPS Agreement. Implementing this strategy will guarantee an equitable allocation of vaccinations throughout the pandemic and offer a sustainable, feasible, and conducive approach to development. Each WTO member should have the authority to determine whether and how to alter their nation's IP rules within the permissible limitations.

In order to effectively combat the pandemic, it is imperative for members of the WTO to distribute the advantages of current COVID-19 vaccines, treatments, and diagnostics. Additionally, efforts should be made to encourage and support more innovation in various regions across the globe. Advanced nations should cease or at least reduce vaccine nationalism, and any restrictions on the export of COVID-19 commodities and technologies should be minimized to encourage production and voluntary transfer of technology. Implementing a fair, transparent, and impartial voluntary license can enhance the IPRs system and contribute to the fight against COVID-19 and even future ones. Zaman (2022)

6. CONCLUSION

In conclusion, the proposition to PW under the TRIPS Agreement in regard to the COVID-19 pandemic has generated substantial conflict and consideration. Although the waiver may offer certain advantages, such as expanding affordable vaccine accessibility and promoting worldwide vaccine production, it confronts significant obstacles and is improbable to serve as a blueprint for forthcoming health emergencies. The waiver can potentially reduce the incentives fundamental to R&D sectors, which are supported by the safeguarding of IPRs. Moreover, existing mechanisms and provisions for flexibility in the TRIPS Agreement offer ways to manage public health emergencies while safeguarding IP. The enforcement and implementation processes, which are complicated, and the possible ongoing effects of violating IPRs, further undermine the practical value of the waiver. Rather than opting for PW, it is advisable to consider alternative strategies that balance access

[10] The Ministry of Health for medicines procurement and the Patent Office for enquiry on the patent status of medicines.

to pharmaceuticals with IP protection. These strategies should center on productive capacity, supply chain concerns, and fair distribution. Implementing such strategies can guarantee a future response to global health crises that is both more efficient and sustainable.

CONFLICT OF INTERESTS

None.

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