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Analysis and Debate of TRIPS Waiver

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ABSTRACT

This paper analyzes and debates the TRIPS Waiver decision in the context of the COVID-19 pandemic, focusing on its implications for vaccine access and pharmaceutical innovation. It begins by examining the TRIPS Agreement and compulsory licensing mechanisms, highlighting their limitations in addressing global health inequalities. The proposal and eventual decision to waive certain intellectual property rights, particularly related to COVID-19 vaccines, are discussed, along with the debates surrounding this decision. Proponents argue for prioritizing public health and equitable access to medications, while opponents express concerns about the impact on innovation and quality control. The paper evaluates the TRIPS Waiver decision as a positive step but calls for its expansion to include diagnostics and therapeutics. It emphasizes the importance of addressing disparities in vaccine distribution and pharmaceutical access, advocating for coordinated global efforts to ensure fairness and resilience in healthcare systems. Ultimately, the paper underscores the need for a comprehensive approach that balances intellectual property rights with public health priorities.

Keywords*: Covid-19, Vaccine, TRIPS, WIP, WTO.*

I. INTRODUCTION

Globally, the COVID-19 pandemic has had a significant impact on society, health, and the economy. By February 2023, there were more than 700 million confirmed cases worldwide and more than 6 million deaths reported[2]. By 2024, the estimated economic consequences are expected to amount to $12.5 trillion[3]. Even though the World Health Organisation (WHO) stated in May 2023 that COVID-19 is no longer a Public Health Emergency of International Concern (PHEIC)[4], the threat to public health still exists, and countries are advised to exercise caution. The pandemic has highlighted the inequalities in health that exist both within and across countries. Intellectual property rights, particularly those outlined in the Agreement on

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[2] *WHO Coronavirus (COVID-19) Dashboard,* WHO, https://covidl9.w ho.int/ (last visited Feb. 24, 2023).

[3] IMF Sees Cost of COVID Pandemic Rising Beyond $12.5 Trillion Estimate, REUTERS (Jan. 21, 2022, 12:29 AM), https://www.reuters.com/business/imf-sees-cost-covid-pandemic-rising-beyond-125-trillion-estimate-2022-01-20/.

[4] *Statement on the Fifteenth Meeting of the IHR (2005) Emergency Committee on the COVID-19 Pandemic,* WHO (May 5, 2023), https://www.who.int/news/item/05-05-2023-statement-on-the-fifte enth-meeting-of-the-internatio nal-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic.

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Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), impede efforts to remedy these imbalances. The Doha Declaration on the TRIPS Agreement and Public Health recognised the crucial relationship between intellectual property rights and public health, and it upheld members' rights to use flexibilities like mandatory licencing to promote health goals. Nonetheless, the glaring disparity in COVID-19 medication availability exposes weaknesses in the Doha Declaration's intended promotion of fair access. 2020 saw the explicit proposal of South Africa and India to temporarily waive intellectual property rights in response to growing pressure, with a focus on COVID-19 vaccines. Following lengthy international discussions, WTO members agreed to give up their patent rights under certain restrictions. This article explores the effects of the TRIPS Waiver Decision on COVID-19 vaccines and critically evaluates the mandatory licencing mechanism under the TRIPS Agreement. The waiver's proponents and opponents are analysed, with a focus on expanding its application to include diagnostic and therapeutic services..

II. TRIPS AGREEMENT AND COMPULSORY LICENSE

The management of intellectual property rights (IPRs) is important in the context of the World Trade Organisation (WTO), which integrates a system of trade rules among countries and acts as a forum for trade agreement negotiations. These rights, which include copyrights, patents, and trademarks, are essential for promoting economic expansion and innovation. To guarantee effective protection of intellectual property related to commerce, WTO members signed the TRIPS Agreement in 1994[5]. Under this agreement, states are required to protect the intellectual property of other WTO members. However, Article 31bis of the Agreement allows governments to get around IPRs in extraordinary circumstances, acknowledging the possible obstacles that IPRs provide to equitable access, particularly for low-income nations. This clause permits generic versions of necessary medical products to be imported or manufactured locally without obtaining patent holders' permission.

WTO members approved the Doha Declaration in 2001[6], realising how important it was to improve the availability of reasonably priced medications in underdeveloped areas. The right of members to use TRIPS flexibilities to further public health goals was reaffirmed in this declaration. Mechanisms like mandatory licencing for pharmaceutical patents and unique regulations for medications in the world's least developed nations are examples of these

[5] Agreement on Trade-Related Aspects of Intellectual Property Rights Preamble, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 J.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

[6] WTO, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2 (2001)

flexibilities. In addition, collaborative strategies for pooling intellectual property and voluntary patent licencing have surfaced as WTO regulation-compliant ways to guarantee fair access to medical innovations and goods. A vital tool that allows governments to manufacture copyrighted goods without the permission of patent holders is compulsory licencing[7]. This is especially important in cases where vital medications are either too expensive or too difficult to obtain.

Nevertheless, despite its importance, mandatory licencing has drawbacks, particularly when it comes to containing the COVID-19 epidemic. The process, which involves negotiations between nations and patent holders, is frequently complex and drawn out. Furthermore, it just discusses patents; it leaves out other crucial components, such trade secrets that are necessary for the development of vaccines. Furthermore, even if adequate remuneration for patent holders is a requirement of compulsory licencing, economically disadvantaged countries may find it difficult to bear the accompanying costs. Furthermore, negotiations about resolving unequal access to pharmaceuticals have been prompted by differences in intellectual property rights norms between industrialised and poor nations. The proposal put up by South Africa and India in October 2020 to temporarily waive intellectual property protections under the TRIPS Agreement is an example of how proposals for a broad IP waiver have been sparked by this imbalance.[8]

III. TRIPS WAIVER PROPOSAL AND THE DEBATES

As of December 2022, eleven vaccinations have been issued an Emergency Use Listing (EUL) by the World Health Organisation (WHO)[9]. China, the European Union, India, and the United States are the primary producers of these vaccines and together account for about 91.6% of the world's vaccine production. Nonetheless, there is still a sizable immunisation disparity between wealthy and developing countries, even with the quick development and dissemination of COVID-19 vaccinations. Global COVID-19 vaccination administration reached 13.25 billion doses by January 22, 2023, with roughly 69.4% of the world's population having received at least one dose. However, the differences are striking: just 16% of people in low-income countries (LICs) and 80% of people in high-income countries have ever received a single dose of the COVID-19 vaccination.[10] The disproportionate concentration of vaccine research,

[7] Compulsory Licensing of Pharmaceutical sand TRIPS, WTO, https://www.wto.org/english/tratop_e/tripse /publichealthfaqe.htm (last visited Apr. 5, 2024).
[8] Council for Trade-Related Aspects of Intellectual Prop. Rights, *Waiver from Certain Provisions of the TRIPS Agreementfor the Prevention, Containmentand Treatment of COVID-19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020) [hereinafter TRIPS Waiver Proposal].
[9] *COVID-19 Vaccine Tracker*, WHO, *https://covidl9.trackvaccines.org/agency/who/* (last visited Mar. *5*, 2023).
10 COVAX Calls for Urgent Action to Close Vaccine Equity Gap, GAVI, https://www.gavi.org/news/media-

development, and manufacture in a small number of high- and middle-income nations is the reason for this stark disparity in immunisation rates. Richer countries have been buying a lot of vaccines and necessary medicinal ingredients, which has resulted in a tendency called "vaccine nationalism." [11] Due to this technique, more dosages than are needed right away have accumulated.

It is not only morally required, but also economically significant, to address this issue. A global moral and financial crisis of catastrophic proportions would result from the failure to address vaccination disparity. Thus, coordinated measures are required to guarantee fair access to COVID-19 vaccinations around the globe[12].

(A) TRIPS Waiver Proposal and Decision: The Cure?

In October 2020, South Africa and India made a proposal to the WTO in response to worries that intellectual property rights were impeding timely access to reasonably priced COVID-19 medical supplies. This proposal asked for a three-year minimum temporary waiver on a number of intellectual property rights (IPRs), including patents, industrial designs, copyrights, and undisclosed knowledge, all of which are protected under the TRIPS Agreement. The idea sought to rectify the unequal distribution of COVID-19 vaccinations, treatments, and diagnostics throughout the world.

WTO members finally came to an agreement on the TRIPS Waiver proposal, despite opposition from wealthy nations—mostly those that are home to significant pharmaceutical industries. A Ministerial Decision regarding the TRIPS Agreement was reached on June 17, 2022, at the Twelfth Ministerial Conference of the World Trade Organisation (MC12). This ruling, which is a watered-down version of the original TRIPS Waiver proposal, temporarily waives, but subject to certain restrictions, patent rights for COVID-19 vaccinations for a period of five years. Although the Decision made eligibility available to all Members who are developing countries, it recommended against using the waiver for those who already had the capacity to manufacture vaccines. Notably, during the crucial MC12 discussions, China—a major supplier and producer of COVID-19 vaccines—announced that it would not be using the

room/covax-calls-urgent-action-close-vaccine-equity-gap (last visted Aug. 18, 2023)

[11] Nurith Aizenman, *Low Income NationsNeed COVID Vaccines. Rich CountriesHaveMillions of Unused Doses,* NPR (Nov. 8, 2021), https://www.npr.org/202 1/1 *1/08/1053647185/low*-income-nations-need-covid-vaccines-rich-countries-have-millions-of-unused-do.

[12] *Director-General'sClosing Remarks at 148th Session of the Executive Board,* WHO (Jan. 26, 2021), https://www.who.int/director-general/speeches/detail/who-director-general-s-closing-remark s-at-148th-session-of-the-executive-board.

TRIPS Waiver [13].

The Decision only deals with COVID-19 vaccine patents, in contrast to the original broad scope of the TRIPS Waiver petition. Additionally, it waives certain of the conditions imposed by the TRIPS compulsory licencing system, including the necessity that prior authorization from the patent owners be obtained. It also recognises that components and procedures used in the production of vaccines are included in the scope of patents. In terms of mandatory licencing, the Decision permits its issue in qualified member nations in the absence of particular legal authority. On the other hand, it requires that patent holders receive sufficient compensation while taking charitable and non-profit objectives into account. Furthermore, the Decision postpones until December 17, 2022, the decision on whether to expand the waiver to include diagnostic and therapeutic uses. WTO members decided to suggest extending the date for this decision after lengthy discussions among trade diplomats. Later, on June 14 and 15, 2023, during a meeting of the Council for TRIPS, the waiver extension was still being discussed. After the August recess, members agreed to host a theme session with outside stakeholders to evaluate COVID-19-related developments and to foster an evidence-based conversation.

(B) The Debates: To Waive or Not to Waive

TRIPS Waiver has generated intense debates around the world, with different points of view emphasising the possible effects of waiving intellectual property rights (IPRs) in relation to public health and pharmaceutical innovation. The Waiver's opponents warn against disrupting the delicate balance between commercial interests and public benefit[14], expressing grave concerns about the alleged erosion of incentives for pharmaceutical research and development. Critics frequently assert that the TRIPS flexibilities currently in place, such as compulsory licencing, provide adequate means for nations to handle IP-related issues during emergencies involving public health[15]. Furthermore, they stress how important it is to defend intellectual property rights (IPRs) in order to guarantee the efficacy and safety of vaccines and other medical supplies, protecting the public's health from the spread of inferior goods[16]. Concerns are also expressed on how losing intellectual property protection can affect vaccine quality and

[13] *China Makes Significant Contributions to WTO WaiverofCOVID-19 Vaccine Patents*, The State Council Of The People's Republic Of China (June 20, 2022, 8:52 PM), https://english.ww*w.gov.cn/statecouncil/ministries/202206/20/content_WS62b06d9cc6d02e533532c6c6.html*.

[14] Bryan Mercurio, *WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review*, 62 Va. J. Intl L. Online 9, 16-17 (2021).

[15] Tahir Amin & Aaron S. Kesselheim, *A Global Intellectual Property Waiver Is Still Needed to Address the Inequities of COVID-19 and Future Pandemic Preparedness,59 Inquiry* 1, 3 (2022).

[16] Ellen Thoen, *The Arguments Against Sharing Covid-19 Intellectual Property Don't Add Up*, BARRON'S (May 3, 2021, 11:43 AM), https://www.barrons.com/articles/the-arguments-against-shar ing-covid-19-intellectual-property-dont-add-up-51620056595.

lead to the rise of fake goods. Waiver supporters, on the other hand, assert that public health should take precedence over private interests and that access to necessary medications should be regarded as a fundamental human right.[17] In addition, it is argued that fair access for all should be warranted by the significant public funds allocated to the development of the COVID-19 vaccine, rather than promoting monopolistic control over distribution channels. Pharmaceutical corporations claim to be prepared to exchange innovations and intellectual property, but detractors contend that this kind of sharing is frequently restricted to specific partners inside existing networks.

Furthermore, estimations point to significant financial benefits for both high- and low-income nations from the equal distribution of vaccines. These highlights the economic significance of vaccination equity. The interdependence of global health and economic success is highlighted by the possibility that denying low-income countries access to vaccines could cause high-income countries to suffer large annual losses.

In the end, the arguments over the TRIPS Waiver are a reflection of larger ideological conflicts between socialist goals for fair distribution and capitalist notions of IP ownership. Both strategies have specific benefits and drawbacks; the Waiver might meet short-term requirements while jeopardising future innovation, and retaining IPRs might prolong international inequality. Stakeholders evaluate each approach's benefits in relation to their larger goals for economic fairness and global health, and the outcome of these discussions rests on intricate considerations of fiscal priorities and ideological beliefs.

IV. TRIPS WAIVER DECISION: CORRECT BUT INSUFFICIENT

In spite of the ongoing discussions, the decision to renounce patent rights for COVID-19 vaccinations is a positive step towards resolving global injustices. It does concede, though, that this action is insufficient to completely address the global problem of unequal access to pharmaceuticals. The existing Waiver must be expanded to cover a wider variety of Intellectual Property Rights (IPRs) in order to guarantee equal access to COVID-19 vaccines, tests, treatments, and other medical tools. Furthermore, diagnostics and treatments become crucial in reducing uneven effects because of the pandemic's disproportionate impact on many countries and the ensuing vaccine disparities. Thus, it is imperative that the waiver be expanded to include IPRs for COVID-19 treatments and diagnostics. Although the Waiver mostly deals with legal obstacles, nations must also make investments in building their industrial capacities

[17] Nabeel Mahdi Althabhawi & Ali Adil Kashef Al-Ghetaa, *The COVID-19 Vaccine Patent: A Right Without Rationale*, 49(1) MED. HUMANITIES 128, 128 (2022).

to improve the long-term production of medical supplies. Efforts should concentrate on fairly redistributing the world's vaccination stockpiles to underprivileged nations in the near future. A well-coordinated worldwide approach that makes use of scientific developments and guarantees accessibility for all is necessary to effectively confront the epidemic. Thus, it is imperative to support current international partnerships and programmes like the COVID-19 Tools Accelerator (ACT-A) and COVID-19 Technology Access Pool (C-TAP) in order to provide fair and equal access to these vital products[18].

(A) TRIPS Waiver Decision: Correct and Necessary

First off, it makes sense for pharmaceutical companies to share in the profits from their products' development when significant public financing goes towards the creation of vaccines or other pharmaceuticals. Although the protection of intellectual property rights (IPRs) has historically been used to stimulate innovation, the public support for COVID-19 medical items greatly reduced the risks involved in the R&D process. Governments in less developed nations ought to receive easier access to vaccines in exchange for their investment.

Second, those who oppose the Waiver fail to acknowledge the significant profits that industry monopolies produce. Pfizer's record-breaking income in 2022 demonstrates how monopolistic methods in the pharmaceutical industry typically result in large profits. The industry would still do better than the great majority of other sectors, even if profits were to slightly decline. Therefore, it would seem that the huge profits that pharmaceutical companies generate more than offset the monetary risks associated with research and development. Apart from legal implications, there is a moral obligation to tackle the inequality that puts millions of lives in jeopardy and the profit-driven incentives that impede their redemption. Furthermore, current quality control systems, including the WHO's COVID-19 prequalification programme, lessen worries about the calibre of vaccines provided under a waiver.[19] Furthermore, programmes such as COVAX will only accept products that fulfil strict quality requirements set by national regulatory bodies, such as the vaccine regulation system in South Africa.[20] Furthermore, giving up patent protection for COVID-19 vaccinations does not mean that patent protection will never exist. Governments that meet the eligibility requirements are still able to approve and support domestic vaccine production without worrying about facing copyright lawsuits. This

[18] Shuwen Xu, To Waive or Not to Waive: The Debate and Analysis of TRIPS Waiver, 18 Asian J. WTO & Int'l Health L & Pol'y 423 (2023).
[19] *Manufacturing ,Safety and Quality Control of Vaccines,* WHO (Dec. 8, 2020), https://www.who.int/news-room/feature-stories/detail/manufacturing-safety-and-quality-control.
[20] *South Africa's Vaccine Regulator Reaches New WHO Level to Ensure Safety, Quality and Effectiveness,* WHO (Oct. 5, 2022), https://www.who.int/news/item/05-10-2022-south-africa-s-vacc ine-regulator-reaches-new-who-level-to-ensure-safety-quality-effectiveness.

system makes it possible for IPR holders to get adequate compensation, and also makes production simpler than it would be if compulsory licencing were implemented in accordance with the TRIPS Agreement.

Last but not least, the "tragedy of the anticommons"—barriers to downstream product development caused by exclusive patent rights—may prevent future innovation. [21]To promote biomedical innovation, policymakers should work to decrease restrictive licencing practices and achieve coherence in patent boundaries. While limiting the duration of patent exclusivity may allay these worries, an IP waiver offers a quicker and more efficient way to rectify unequal access given the urgency of the pandemic response.

(B) The Extension to Diagnostics and Therapeutics Is Necessary As Well

According to the World Intellectual Property Organisation (WIPO), there are a significant number of patents for COVID-19 vaccines and treatments. Even with the availability of different treatments, rich and poor countries continue to have different levels of access. The bulk of COVID-19 treatments are in high-income nations, which exacerbates the discrepancies in access to healthcare around the world. Furthermore, because COVID-19 tests and treatments are expensive, low-income countries, despite making up a sizable fraction of the global population, have limited access to them. In comparison to wealthier nations, low- and middle-income countries have lower immunisation rates while having greater populations. This discrepancy increases their vulnerability to severe COVID-19 and emphasises the need for readily available therapies such as Paxlovid. A number of economically disadvantaged nations have agreements in place with Pfizer and Merck that allow for the cheaper production and distribution of their COVID-19 therapies. Nevertheless, a number of badly impacted nations, like Brazil, Cuba, Iraq, Libya, and Jamaica, are not included in these agreements. Many people in these countries still lack vaccinations, and they desperately need access to cheap medical care.

Reluctance to use TRIPS flexibilities to solve concerns with medical product availability has been exacerbated by past failures of governments seeking to use them during epidemics or public health crises. For example, invoking intellectual property as a human right, Pfizer angrily rejected an application for a compulsory licence on its oral COVID medicine Paxlovid patents in the Dominican Republic. The only developed countries that seem to be moving quickly to implement mandatory licencing during the pandemic are those. Additionally, Merck has licenced Indian manufacturers of generic medications while they are still in the testing

[21] Michael A. Heller & Rebecca S. Eisenberg, *Upstream Patents = Downstream Bottlenecks,* 41(3) L. **QUANDRANGLE** *93,95* (1998).

stage. Even while generic variants of Pfizer's Paxlovid are still being developed, approval is still a long way off. Waiving IPRs for COVID-19 drugs provides a quicker way to make therapies available to people in economically disadvantaged nations, as the permission process is cumbersome.

Moreover, the ongoing discussions over the Waiver extension need to proceed quickly. WTO members delayed their subsequent negotiations for almost twenty months before coming to an agreement on the TRIPS Waiver Decision. As the Waiver is implemented, the industry may be encouraged to engage in additional pricing negotiations and voluntary sharing. For example, Moderna and Pfizer-BioNTech promised more vaccination doses for low- and middle-income nations after President Biden endorsed the IP Waiver. Pfizer has arrangements with regional Chinese businesses for Paxlovid import and distribution in addition to regional production.[22]

V. CONCLUSION

A concerning trend that has surfaced throughout COVID 19 is the prioritisation of economic interests over public health and profit objectives, especially by powerful pharmaceutical firms and wealthy governments. People in underdeveloped and least developed nations are disproportionately affected by this prioritisation, which frequently widens gaps. The problem is made worse by patent protections and other intellectual property rights (IPRs), which pose serious obstacles to many countries' ability to get life-saving diagnostics and drugs. The Doha Declaration, which stipulates that the TRIPS Agreement should not prevent member nations from enacting measures to defend public health interests, has responded to these concerns by reiterating how crucial it is to preserve public health. Although there are some issues with the TRIPS Waiver, which was designed to make medical products more widely accessible, the advantages it offers outweigh any possible negative effects on intellectual property rights in general.

There is a need to review previous attempts to resolve the stark disparities in vaccination and pharmaceutical access around the world as the world moves from short-term crisis management to long-term resilience building and considers the lessons learned. It's important to remember that this problem goes beyond the COVID-19 outbreak. This highlights a more widespread systemic issue that calls for coordinated efforts from wealthy countries, international organisations, and pharmaceutical companies. These parties have a responsibility to step up efforts to ensure that everyone has fair access to vaccines and drugs, especially in countries

[22] Shuwen Xu, To Waive or Not to Waive: The Debate and Analysis of TRIPS Waiver, 18 ASIAN J. WTO & INT'l HEALTH L & POL'y 423 (2023).

with low economic standing. This calls for a combined strategy that includes lowering intellectual property rights obstacles, encouraging international organisations to put in place systems for accessing vital resources.

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