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Accessibility of Pharmaceutical Product Patents for Public Health Through the TRIPs Waiver

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ABSTRACT: The TRIPs waiver is a bilateral or multilateral agreement proposed by member countries as an exception to the TRIPs agreement during the Covid-19 pandemic. The TRIPs waiver aims to urge WTO member countries to exclude and waive the obligation to protect Intellectual Property Rights and patent flexibility in the form of mandatory licenses, implementation of patents by the government, parallel imports, and bolar provision for the prevention, handling, and treatment of Covid-19 during the pandemic. Most of the technology and pharmaceutical products used in handling Covid-19 are objects protected by IPR. This means that anyone is prohibited from producing, selling, importing, and exporting these objects without the permission of the IPR holder. So, this will hinder the access and availability of pharmaceutical products. This normative juridical study aims to examine the importance of the application of the TRIPs waiver in access and availability of pharmaceutical products and examine the policies of WTO member countries towards the proposed implementation of the TRIPs waiver. According to the findings of this article, TRIPs waivers are needed in the Covid-19 pandemic, but many regulations must be regulated for their implementation. It is better to use the patent flexibility regulated in each member country. The implementation of patent flexibility can be adjusted according to the abilities of each member country in terms of access and availability of pharmaceutical products during Covid-19.

KEYWORDS: Patent, Pharmaceutical Products, Public Health, TRIPs Waiver.

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I. INTRODUCTION

Waivers are not an idea that emerged after the Covid-19 pandemic. Waivers have been used several times bilaterally or multilaterally to obtain privileges between countries. The waiver is based on the legal provisions of Article IX (3) and (4) of the World Trade Organization (WTO) Agreement. Composition IX (3) directs that in remarkable circumstances, the Ecclesiastical Conference may choose to forgo a commitment surveyed on part by this understanding or any of the Multilateral Trade Agreements, handed that any similar decision shall be taken by three-fourths of the Members unless else handed for in this paragraph.

Grounded on Composition IX (3) and (4) of the WTO Agreement, a disclaimer is granted because[1] of exceptional circumstances, does not have to be approved by agreement, given to and applies to WTO members who request it, there is a time limit, if valid for further than one time it must be reviewed by the Ministerial Conference every time, can be terminated, modified, or extended depending on whether the exceptional circumstances still live.[2]

Waivers have been implemented in the General Agreement on Tarif and Trade (GATT) and Trade-Related Aspects of Intellectual Property Rights (TRIPs). Examples of waivers in the GATT, namely Article 1 and Article 13 of the GATT, were given to the European Union to provide preferential treatment to Pakistan due to the massive floods that occurred in Pakistan, which harmed millions of people and Pakistan's economy. An example of a waiver in TRIPs is the Decision of the General Council of 30 August 2003.[3] This declaration controls the exception from the commitments set out in sections (f) and (h) of Article 31 of the TRIPs agreement around pharmaceutical items. Article 31 (f) regulates that products with mandatory licenses may not be exported, and Article 31 (h) regulates the obligation to pay adequate royalties to patent holders. The waiver is valid until the amendment of TRIPs Article 31 bis contains provisions regarding how to implement mandatory licensing for both importing countries and drug exporting countries.

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[1] M . Hawin, Indonesia's Interests in the Weiver TRIPs Agreement or Government Use, (Jakarta: Universitas Indonesia).
[2] Ibid.
[3] Ibid.

In 1995, when the WTO surfaced, countries that registered as members agreed that they would misbehave with the passages agreement in exchange for lowering trade walls. This agreement is driven by knowledge-grounded husbandry similar to the United States and chains, ferocious exploration in the pharmaceutical assiduity, and the perpetration of introductory protection for IPR from patents to copyrights.[4] Before this was negotiated, more than 50 countries did not have patent protection for pharmaceutical products. Once patent protection takes effect, this provision is obligatory in all countries except least developed countries. Middle-income countries like India started complying with it in 2005.[5]

At the end of December 2019, a virus appeared that attacked the respiratory tract, spread veritably snappily, and resulted in death. This contagion is named Covid-19 because it is a variant of the coronavirus. Developed and developing countries are trying to find medicines and vaccines for this virus. The vaccine for Covid-19 was first discovered by Sarah Gilbert, videlicet the AstraZeneca vaccine.[6] This vaccine has been exempt from patent protection with the aim that vaccines can save human lives and fulfill the health rights of every citizen around the world. Then several vaccines were discovered, such as Moderna, Pfizer, and Sinovac.[7]

The large demand for vaccines by countries around the world and the limited production capabilities of vaccine manufacturers result in limited access and availability of vaccines. Limited access and availability of pharmaceutical products such as vaccines, drugs, and medical equipment for Covid-19 sufferers led to the idea of implementing the TRIPs waiver through a proposal submitted by the governments of South Africa and India to the WTO. TRIPs are demanded to count pharmaceutical products from patent protection and TRIPs inflexibility in the form of obligatory licenses, patent perpetration by the government, parallel imports, and bolar provision during

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[4] Ibid.

[5] Ibid.

[6] Chris Melvin, "Covid vaccine pioneer Dame Professor Sarah Gilbert receives honorary degree" University of Bath (18 July 2022), online: <https://www.bath.ac.uk/announcements/covid-vaccine-pioneer-dame-professor-sarah-gilbert-receives-honorary-degree/#:~:text=Professor%20Gilbert%20co%2Ddeveloped%20the,to%20at%20least%20170%20countries.>.

[7] Chiranjib Chakraborty, Manojit Bhattacharya & Kuldeep Dhama, "SARS-CoV-2 Vaccines, Vaccine Development Technologies, and Significant Efforts in Vaccine Development during the Pandemic: The Lessons Learned Might Help to Fight against the Next Pandemic" (2023) 2023 Mar; 11(3): 682. National Library of Medicine.

the Covid-19 pandemic[8] so that countries in the world can pierce the knowledge demanded to fight the pandemic.[9]

Participating in the knowledge behind the creation of a Covid-19 vaccine is crucial to adding products and advancing the vaccines needed to attack the ever-arising variants of Covid-19. No single vaccine manufacturer can produce enough vaccines to meet world demand, and demand for vaccines has far outstripped supply. High-income countries take the lion's share of the reserve dose. The background of this article raises the following question: how important are TRIPs waivers in fulfilling the right to health over pharmaceutical products? Additionally, this paper also observes how member countries respond to the idea of the TRIPS waiver during the Covid-19 pandemic. Fulfilling the right to accessibility of pharmaceutical products for sufferers of Covid-19 is very important, so the theoretical approach used in this article is the right to health as a human right.

Therefore, the TRIPs waiver is an important idea during a pandemic because it relates to the right to health and safety of the lives of the world's population. The TRIPs waiver is one of the efforts made by WTO member countries to gain access to knowledge, information, data, and technology for the availability of sufficient vaccine supplies throughout the world. This vaccine is important because it functions to reduce the transmission rate of Covid-19.

II. METHODS

The accessibility of pharmaceutical product patents through the TRIPs waiver is reviewed using normative juridical research methods. The problem approach used in this research is the statute approach and the comparative approach. The statute approach is the approach taken by examining laws and regulations related to health, human rights, and TRIPs waivers.[10] comparative approach[11] is an activity to compare the laws of a country with the laws of other countries.

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[8] Anthony, "WTO TRIPs Waiver for Covid-19", Johny Hopkins University (10 May 2021), online: <https://publichealth.jhu.edu/2021/wto-trips-waiver-for-covid-19-vaccines> .

[9] M. Hawin, supra note 1.

[10] Introduction to law (Indonesia: Kencana Prenada Media Group, 2008) at 47.

[11] Marzuki, supra note 10.

III. THE IMPORTANCE OF APPLICATION OF THE TRIPS WAIVER IN FULFILLING THE RIGHT TO HEALTH TO PHARMACEUTICAL PRODUCTS

The TRIPs waiver is important in the availability of the Covid-19 vaccine because it is considered the most appropriate and capable step to remove all barriers to vaccine access and availability, especially patent protection for the Covid-19 vaccine. The waiver is anticipated to accelerate the increased emergence of new Covid-19 vaccines where untapped vaccine product capacity still exists and can also encourage vaccine manufacturers to increase their technology transfer works. The main idea of submitting the TRIPs waiver offers by member countries is fulfilling citizens' rights to health.[12]

The significance of health as a human right and as a necessary condition for the fulfillment of other rights has been honored internationally. Where specifically, composition 25 of the Universal Declaration of Human Rights (UDHR) states that "everyone has the right to a standard of living acceptable for the health and welfare of himself and his family...". The right to health is in the form of "gradational consummation," as quested in Article 2 Paragraph (1) of the International Covenant on Economic, Social, and Cultural Rights (ICESCR),[13] indicating that the state can gradationally realize this aspect. International human rights law establishes two rules relating to health, both public and individual rights to health. The first rule states that the protection of public health fairly limits human rights, while the second rule is individual health rights are the government's obligation to provide them.[14] The main idea of health law is to reduce health problems and/or preclude their emergence, as well as evolve the capability of individuals and communities to overcome them.

Indonesia regulates the right to health in Article 28H Paragraph (1) of the 1945 Constitution, which regulates that every citizen has the right to live in physical and spiritual substance, to have a place to live, and to get a good and healthy terrain, and has the right to admit health services. The right to health is also regulated in Article 34 Paragraph (3), which states, "the state is responsible for furnishing proper health service establishments." The

[12] M. Hawin, supra note 1.
[13] "Advancing and Defending Economic, Social and Cultural Rights" in (Insist Press, 2003) at 6.
[14] Human Rights in Indonesian Health Law (Surakarta: Universitas Sebelas Maret, 2013) at 1.

fulfillment of human rights involving the right to health is the responsibility of the state, especially the governance, as highlighted in Article 28I Paragraph (4) also the right to health is governed in Law Number 36 of 2009 concerning health. Article 5 stipulates that, first, everyone has the same right to gain access to resources in the health region. Second, everyone has the right to acquire safe, quality, and affordable health services. Third, every person has the right to subsist independently and be accountable in determining the health services challenged for themselves.

The governance's responsibility in the health section is highlighted in Article 7: "The governance is assigned with arranging health works that are fair and accessible to the community." Also, " the governance is responsible for perfecting public health situation." Thus, the governance is responsible for fulfilling the right to health as part of human rights. The perpetration of governance liabilities is not only important but will also come standard in perfecting people's lives as an instantiation of human rights. Examining the country's reactions to this waiver policy is essential for upholding global health responsibility and emphasizing the shared obligation to ensure fair access to healthcare resources globally.

The accessibility of pharmaceutical products through TRIPs waivers to fulfill the right to health is one of the things that is of international concern with access to the Covid-19 vaccine. For now, Indonesia is still giving vaccines free of charge up to the 4th dose. It is feared that patent protection for vaccines will result in high prices, resulting in limitations for the state in fulfilling the need for the Covid-19 vaccine. From a legal perspective, there are two reasons for limited access to vaccines and drugs. Videlicet, the vittles contained in the International Covenant on Economic, Social, and Cultural Rights, redounded in expressive changes to the codification of human rights over health.[15] The second is regarding access to drugs related to whether the medicine must be patented. The amplitude of patents in the health region that has been governed by TRIP broadens the number of patents bonded to the introductory requirements of health and the elaboration of health itself. The connection between the two fields is decreasingly transparent and direct,

[15] OHCHR, “International Covenant on Economic, Social and Cultural Rights”, (16 December 1996), online: United Nations Human Rights <https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic -social-and-cultural-rights>.

taking further consideration of the connection between the right to health and patent protection for pharmaceutical products.[16]

In the private medicine region, pharmaceutical diligence spends more on research and development (R&D) than different diligence. Although elaborating on a new vaccine is a precious process, it is still being done, though it is easier to duplicate a preexisting vaccine.[17] This proves that the pharmaceutical region is promising. Despite the pharmaceutical assiduity's claim for patent protection, several countries limit pharmaceutical produce patents for procedure reasons. Whereas patents on pharmaceutical products have become a growing norm in the pharmaceutical region and have redounded in patents for new vaccines and medicines. Patent protection for vaccines and medicines for certain conditions in elaborating nations is arguable because patents do not inescapably activate further medicine development related to improvished people.[18] The issue of patent protection in the health region raises a conflict of interest between the pharmaceutical assiduity's practice of recovering its investment returns and the government's interest in limiting healthcare costs.[19]

Availability generally refers to the idea that health procedures should advance the accessibility of vaccines and drugs at affordable prices for all those who need them.[20] Consummate governance around humanity has to place severe conditions on the independence of their citizens due to the epidemic to contain the complaint.[21] However, furnishing impulses for the elaboration of new medicines limits access due to the advanced costs of vaccines and medicine. This implies a want for access to vaccines and drugs by the economically disadvantaged. Limited profitable capacity means that not everyone in elaborating nations has health insurance and frequently pays out of funds. Price is a major issue in entering vaccines and drugs, but patents

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[16] Ibid.

[17] "The Conflict Between Parallel Trade and Product Access and Innovation: the Case of Pharmaceuticals" (2008) I:4 Journal of International Economic Law, online: <https://papers.ssrn.com/sol3/papers.cfm?abstract_id= 157027> at 637.

[18] Keith E Maskus, "Integrating Intellectual Property Rights and Development Policy" (2004) 62:1 Journal of International Economics 237–239.

[19] "Intellectual Property Rights and Innovation" in Capital for Our Time: The Economic, Legal and Management Challenges of Intellectual Capital , nicholas imparato ed (Stanford: Hoover Institution Press, 1999) at 132.

[20] Globalization and access to drugs : perspectives on the WTO/TRIPS agreement (German: World Health Organization (WHO), 1999) at 3.

[21] Nanik Prasetyoningsih et al, "State Obligation in Fulfilling the Right to Health through the Mandatory COVID-19 Vaccination" (2023) 3:2 Indonesian Journal of Law and Society 195–218.

are not the only factor affecting access, as cheap general medicines may not be affordable for people below the poverty line, In this situation, access can only be assured through public subventions and price regulators. This limited availability of pharmaceutical products is a conclusive reason to apply for TRIPs waivers in this pandemic. Because, during a pandemic, generic vaccines claim to decrease transmission, and generic medicines claim to reduce conditions caused by Covid- 19.

IV. WTO MEMBER STATE POLICIES AGAINST IDEAS OF THE TRIPS WAIVER

The differences in interests between developed countries, developing countries, and improvished countries regarding access and availability of Covid-19 vaccines and medicines have resulted in the idea of implementing the TRIPs waiver. This idea has received various responses from WTO member countries. Some agree with the conditions, and others oppose it. Within the proposition put forward by India, South Africa, and 60 co-sponsors broadly related to well-being items and advances for the anticipation, treatment, and treatment of Covid-19, TRIPs individuals will be exempted for at slightest three a long time from TRIPs commitments to ensure licenses, copyrights, mechanical plans, and exchange privileged insights for each demonstrative, restorative, antibody, therapeutic gadget, and individual defensive gear utilized to anticipate, contain, and treat Covid-19. It moreover incorporates materials, components, and strategies of fabrication. Thereexamined proposition does not differ significantly from the first proposition, recommending that the WTO part reaction remains isolated on the waiver issue.[22]

Indonesia underpins the TRIPs waiver proposition at the WTO. President Joko Widodo expressed that Indonesia had chosen to be one of the co-sponsor nations for the TRIPS waiver proposition.[23] This proposition will create openings to postpone IPR security rules for medications, demonstrative tests, immunizations, and other advances related to taking care of Covid-19 while the pandemic is still progressing or until worldwide

[22] European Commission, Opening Statement by Executive Vice-President Valdis Dombrovskis at the European Parliament plenary debate on the Global COVID-19 (European Commission, 2021).

[23] Sapto Andika Candra, "Jokowi Desak Negara G20 Dukung TRIPs Waiver" Republika (22 May 2021), online: <https://news.republika.co.id/berita/qthcfu384/jokowi-desak-negara-g20-dukung-trips-waiver>.

insusceptibility is accomplished.[24] This proposition permits each nation to collaborate in terms of inquiry about and R&D improvement to extend the generation capacity of Covid-19 immunization. Moreover, Jokowi emphasized Indonesia's readiness to become a Covid-19 antibody generation center within the Southeast Asian locale since Indonesia has PT Bio Farma with the capacity to create up to 25 million measurements of Covid-19 antibodies per month.[25]

This is intended so that rich countries do not block the TRIPs waiver and agree on behalf of humanity. This urge aims to eliminate inequality in access to vaccines for poor and developing countries in the world due to Intellectual Property Rights (IPR) monopolistic practices by large pharmaceutical companies, as well as vaccine nationalism practices by rich countries. The TRIPs waiver will open even more massive vaccine production space. This is because the demand for the Covid-19 vaccine is much higher than the supply. This supply confinement is caused by generation and dispersion control carried out by massive pharmaceutical companies through the IPR monopoly.[26] What is required presently is to nullify the IPR restraining infrastructure and not a compromise arrangement that still opens space for pharmaceutical companies to work out control over the generation and dispersion of antibodies within the title of benefit. This permitting hone by pharmaceutical companies has restricted fabricating generation capacity by as it were selecting only which producers and in which nations can create immunizations.[27]

In a report issued by the Organization of Specialists Without Borders, it was specified that this select hone was carried out by AstraZeneca, which constrained the giving of its permit to the Serum Institute of India (SII). Besides , SII is precluded from providing upper-middle-income and high-income nations, AstraZeneca's most profitable markets. AstraZeneca has entered into more innovation transfer agreements with immunization producers in low and middle-income nations based on adenovirus vector innovation, which is simpler to fabricate and disseminate. The cost of the

[24] Ibid.
[25] Ibid .
[26] Rachmi Hertanti, “WTO Must Immediately Pass TRIPS Waiver For Access to Equitable Vaccines” (10 March 2021), online: <https://igj.or.id/wto-harus-segera-loloskan-trips-waiver-for-access- vaccine-fair/>.
[27] Ibid.

antibody at $3 per dosage is less than half the cost of the Pfizer/ BioNTech antibody within the African Union.[28]

The European Union has called for a third-way alternative that incorporates:

a. Exchange assistance and teaching on trade confinements;
b. bolstering for generation extension counting through voluntary licensing agreements;
c. clarifying and streamlining the utilizatione of obligatory licenses beneath TRIPs amid times of emergency.[29]

The United States Trade Representative (USTR) supports the TRIPs waiver. However, the United States has only expressed support for a much narrower coverage waiver than current sponsorship proposals and third-way alternative proposals that waive TRIPs waivers. The third-way alternative can be used to provide access and availability of medicinal vaccines without the TRIPs waiver. This means that countries producing Covid-19 vaccines and medicines can protect their products with patents and provide access to products through voluntary licensing.

United States legislation has been proposed in Congress to restrain USTR's control to favor TRIPs waivers, for illustration by looking for Congressional endorsement of any waivers or forbidding the utilization of government reserves to bolster waivers.[30] TRIPs, whereas the waiver requires agreement from the 164 WTO member nations, any text-based transactions that happen are likely to proceed for a few months or more. The jump for the TRIPs waiver lies within the necessity that all 164 WTO member nations concur to the content of the waiver as it were in certain parts.[31]

Most WTO members support TRIPs since they do not accept their Covid-19 open well-being needs will be met by maintaining patent assurance. Pfizer has asked the government to put state resources such as government bank saving, government office buildings, or military bases as collateral to balance the costs of future lawful cases.[32] On the off chance that

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[28] Jason Mast, "As fears mount over J&J and AstraZeneca, Novavax enters a shaky spotlight" End Point News (21 April 2021), online: <https://endpts.com/as-fears-mount-over-jj-and- astrazeneca-novavax-enters-a-shaky-spotlight/>.

[29] European Commission, supra note 22.

[30] Govtrack,"HR3236, 117th Cong", online: <https://www.govtrack.us/congress/bills/117/hr3236/cosponsors>.

[31] European Commission, supra note 22.

[32] Master, supra note 23.

TRIPs waivers of a few scopes are passed at the WTO after text-based arrangements, obstacles will remain for compelling usage. The TRIPs waiver will not alter the IPR assurance in drive in WTO member nations and each member nation must choose how to alter their residential laws inside the scope allowed by the TRIPs waiver. It is improbable that approaches coming about from conflicting IPR assurance will encourage the assisted development of antibody generation, particularly on the off chance that deliberate exchange of innovation from existing producers remains basic to making a secure immunization.[33]

Modern drug manufacturers, such as Novartis and Roche, mostly come from wealthy countries. Meanwhile, most patients come from improvished countries in Asia, Latin America, and Africa. When a complicated patent system with all its restrictions is enforced, what occurs is an injustice for these countries. Patients in destitute nations are burdened with the costs of patented drugs they regularly cannot manage. Affirmed waiver by a few member nations does not mean that all WTO member nations do not give IPR security for well-being items related to Covid-19. Countries that oppose the TRIPs waiver will continue to provide IPR protection with the aim that inventors will apply for patents for inventions related to traditional knowledge in these countries. For example, Bolivia has considered using the flexibility of Article 31 TRIPs in the form of a mandatory license to import the Johnson & Johnson Covid-19 immunization from the Canadian company Biolyse Pharma.

Commodity-producing nations continue their endeavors to extend worldwide generation and conveyance of Covid-19 antibodies and treatments, with an accentuation on growing to developing nations. To illustrate, Pfizer dispatched two billion doses to developing nations over 18 months.[34] It is assessed that by the conclusion of 2021, the worldwide generation of Covid-19 immunizations could exceed 11 billion doses, the sum that is possibly adequate to realize worldwide crowd insusceptibility.[35] In early 2022, 3.5 million doses were dispersed to Indonesia.

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[33] Govtrack, supra note 30.

[34] Jared S Hopkins, "Pfizer, BioNTech to Deliver 2 Billion Covid-19 Vaccine Doses to Developing Countries" Wall Street Journal (21 May 2021), online: <https://www.wsj.com/livecoverage/covid-2021-05 -21/card/GsPYoFscRppTzYYt0l4f>.

[35] Simon J Evenett & Matt Linley, "How Much Vaccine Will Be Produced This Year ? " Airfinity (20 May 2021), Online: <Https://Www.Airfinity.Com/Articles/How-Much-Vaccine-Will-Be-Produced-This-Year>.

A few pharmaceutical industry groups have proposed a five-step arrangement to rapidly develop Covid-19 correspondence. It begins with expanding the sharing of doses between nations through Covax and other instruments. Second, optimizing immunization generation and crude materials. Third, expel boundaries to exchange imperative crude materials. Fourth, bolster the country's preparation to execute the immunization program. Fifth, energize and assist development.[36] In the months following the official declaration of the pandemic, more vaccines were developed and disseminated, providing high levels of protection against COVID-19.[37] Producers collaborate with other companies to extend worldwide generation. For this case, Moderna engaged Samsung Biologics to supply, fill, and wrap up fabricating for Moderna's antibody. Companies such as Merck and Gilead are also becoming deliberate, authorizing programs with producers in India to create the antiviral specialists Covid-19 molnupiravir and remdesivir.[38] Moderna's Covid-19 vaccine has promised not to apply for patent protection against Covid-19 vaccines during the pandemic. In any case, the fabrication of Moderna's immunization is likely to include gear and forms licensed by other companies, making it an exception patent security on one portion of the method and may not aid another company in constructing the complete formula.[39]

Indonesia underpins the TRIPs waiver while typically being contradicted by scholastics and analysts of pharmaceutical items in Indonesia. If the TRIPs waiver applies to national IPR, it will have a negative effect on R&D in Indonesia, where innovators must be persistently persuaded. The TRIPs waiver is not an arrangement to these imperatives. It can hurt Indonesia since the Merah Putih antibody, created by the Indonesian government, will be secured by licenses within the trust. However, giving licenses to the government can deliver constraining infrastructure by the patent proprietor. The government can take advantage of the flexibility of TRIPs. For example, Indonesia can use the flexibility of patent

[36] IPFMA, "Five Steps To Urgently Advance COVID-19 Vaccine Equity" IPFMA (19 May 2021), online: <https://www.ifpma.org/resource-centre/five-steps-to-urgently-advance-covid- 19-vaccine-equity/>.

[37] Jacques Bughin et al, "Vaccination or NPI? A conjoint analysis of German citizens' preferences in the context of the COVID-19 pandemic" (2023) 24:1 Eur J Health Econ 39–52.

[38] Noah Higgins-Dun, "Gilead, Merck step in to help India's Drug Manufacturers Fight Surging covid-19 Outbreak" Fierce Pharma (27 April 2021), online: <https://www.fiercepharma.com/pharma/gilead-merck- plan-production-boosts-for-covid-19-drugs-india-amid-surging-outbreak>.

[39] Anthony, supernote 5.

implementation by the government for the availability of the Covid-19 vaccine. This strategy has also been utilized by Indonesia three times to stockpile HIV/AIDS drugs. However, in the context of Covid-19 vaccine accessibility, the use of TRIPs waivers has a positive impact because pandemic mitigation can be more accessible and comprehensive to all Indonesian people. In addition, mitigating this pandemic is an obligation to fulfill the right to health for the Indonesian people. This right is recognized and ensured by Article 28H section (1) of the 1945 Constitution. By granting a patent for the Merah Putih vaccine, it is hoped that herd immunity can be achieved soon.[40]

In contrast to Indonesia, wealthy countries, including Germany, Australia, Canada, and Japan, rejected calls to support the TRIPs waiver because they needed further evidence that TRIPs flexibility was insufficient to provide access to and availability of a safe and affordable Covid vaccine.[41] The considerations of member countries against the TRIPs waiver are:[42]

a. Unfair business can occur. Companies can take advantage of the sale of their production without regard to the interests of the IPR owner. This can happen in Indonesia;
b. the waiver only applies to the proposing country and the sponsoring country;
c. countries that oppose will not be waived;
d. waivers are different from suspensions;

They view TRIPs waivers as a potential negative, not accommodating to current endeavors to extend the worldwide generation of Covid-19 immunizations and therapeutics. For illustration, growing antibody generation to unlicensed producers seems to encourage compound supply chain issues and excesive requests for restricted crude materials. This has also prevented official vaccine manufacturers from increasing production in recent months.[43] Additionally, TRIPs waivers may also prevent current

[40] Haris, "Unair Faculty of Law Researcher in ICLGG 2021: Exploring Patent Rights Discourse for Red and White Covid-19 Vaccine - Faculty of Law, Airlangga University" (9 November 2021), online: <https://fh.unair.ac.id/en/ researcher-fh-unair-in-iclgg-2021-digging-discuss-patent-rights-for-red-white-covid-19 vaccine/>.

[41] Tirta Citradi, "Proof of Injustice, Corona Vaccine for Developed Countries!" 13 November 2020.

[42] M. Hawin, supra note 1.

[43] Katie Rogers & Sheryl Gay Stolberg, "US to Send Virus-Ravaged India Materials for Vaccines - The New York Times" (28 April 2021), online: <https://www.nytimes.com/2021/04/25 /us/politics/india-us-coronavirus. html>.

vaccine producers from assisting intentional permitting understandings with accomplices in other nations. In line with the USTR declaration, advocates of the TRIPs waiver have moved to open discourse from patents to exchange insider facts and innovation exchange, recognizingthat giving up patents will not be adequate to grow a worldwide generation of a secure and successful Covid-19 vaccine.[44]

Within the nonattendance of voluntary licensing agreements, there is no clear component for nations to constrain unique vaccine producers to unveil or exchange privileged insights or give innovation exchange back to unlicensed parties. In the event that pharmaceutical companies feel that the exchange of their innovation to deliberate licensees may cause licensee nations to spread their competitively delicate information, they may defer the intentional licenses.[45] Some proponents of the TRIPs waiver have called on the United States to force technology transfers from US-based vaccine manufacturers. But current United States law, to a great extent, forbids the Food and Drug Administration (FDA) and other administrative offices from freely unveiling or exchanging mystery data submitted for administrative endorsement purposes. Indeed, in the case allowed by future law, the fifth revision recovery clause would likely forbid the United States government from uncovering exchange mystery data submitted beneath the security of current laws and controls without reasonable recompense.[46]

Worldwide pharmaceutical advancement endures genuine misfortunes if WTO individuals utilize TRIPs waivers to uncover and exchange privileged insights of immunization producers submitted amid administrative surveys. This data, TRIPs, for the most part, secures from divulgence and unjustifiable commercial utilizatione by unauthorized parties.[47] In the event that pharmaceutical companies feel that being subject to administrative surveys in certain nations implies losing assurance for protected fabricating forms and other competitively delicate exchange mystery data, they may consider bypassing these nations when considering where to create, fabricate, offer, or permit their items.[48] Companies will be

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[44] Kiran Stacey, "Biden urged to oblige US vaccine makers to share technology", Financial Times (15 May 2021), online: <https://www.ft.com/content/9408223f-0a6c-43b7-9f67-c7e4697005c2>.

[45] Ibid.

[46] "Chrysler Corp. v. Brown, 441 US 281 (1979)", (18 April 1979), online: Justia Law <https://supreme.justia.com/cases/federal/us/441/281/>.

[47] Ibid.

[48] Ibid.

hesitant to contribute to modern advances if they feel they cannot benefit monetarily from their innovations. When Covid-19 initially hit, R&D for a widespread antibody was, to a great extent, ignored by the private segment and required open financing. Many primary Covid-19 vaccines to hit the market depended on cash charge to facilitate effective production.[49]

One of the key perspectives of creating an effective Covid-19 vaccine is the method of stabilizing a potential spike in Covid-19. This development depends immensely on open financing, and all immunizations in the market currentlydepend on this innovation. But whereas they all advantage from freely financed IPR, no vaccine company has ventured forward to connect the worldwide exertion to intentionally share its information through the Covid-19 Technology Acces Pool, propelled by WHO with backing from Costa Rica and 40 other member nations. co-sponsoring.[50]

In a market made almost entirely of open segment buys of antibodies for the widespread, Pfizer produced $3.5 billion in Covid-19 vaccine income the beginning of the 2021 quarter, with an evaluated benefit edge of around 20%, and by far its highest income. Pfizer accomplice BioNTech receives up-front open financing from both the German government and the European Union Investment Bank, whereas Pfizer alone has so far secured $6 billion from the United States government in guarantees to purchase its Covid-19 vaccine.[51]

Wealthy countries representing 13% of the world's population already buy almost 51% of the global vaccine supply. In fact, despite having received public funding to develop Remdesivir, the pharmaceutical company Gilead has entered into secret bilateral agreements with a select few of its generic companies that exclude nearly half of the world's population from its license area.[52] The pharmaceutical industry also believes that TRIPs waivers will not speed up the development of the Covid-19 vaccine. This argument reflects the fact that production processes are very complex and difficult to develop without extensive support from existing manufacturers. This exacerbates inequalities in access to safe and affordable vaccinations. Finally, the TRIPs waiver will have a negative impact on the continued development of the Covid-19 vaccine. There are more than 60 additional vaccines under

[49] IPFMA, supra note 40.
[50] Katie Rogers & Gay Stolberg, supra note 47.
[51] S. Hopkins, supra note 38.
[52] Ibid.

development around the world. The investment of time and money is based on the potential to license a vaccine or partner with a larger manufacturer to produce it. Setting aside prospective IPR protection for vaccines under development is likely to undermine continued investment and research, a proposition that is increasingly worrying given the possibility of a new and distinct strain of Covid-19.[53]

IPR is exceptionally imperative for the advancement of unused drugs and vaccines. The Waiver of IPR within the TRIPs waiver proposition has not, however, gotten the correct reaction and arrangement to bargain with Covid-19. International forums should focus on the adaptability concurred upon within the TRIPS understanding. Article 31 TRIPs give a few flexibilities. First, compulsory licensing requires that the licensee has unsuccessfully attempted to get a license on sensible terms and that utilization of the protected advancement is within the open intrigue. Second, the implementation of a patent by the government is stipulated by Presidential Decree, constrained to assembly domestic needs, non-commercial in nature, within a certain period of time, and can be expanded with the thought of the relevant Minister. Third, parallel imports are patent items that have been marketed by the patent holder in one nation and then imported by another country without the endorsement and consent of the patent holder to purchase drugs at a lower cost in their own domestic. Fourth, thebolar provision could allow generic drug producers to utilize patented innovations to create and provide data required by law without the authorization of the patent proprietor before the patent protection period ends. Generic producers can then, at that point, introduce generic forms after the patent lapses.

This flexibility allows the state to take policies to safeguard public health while still protecting patents, which allows member countries to use patents without permission from the right holder under certain conditions set by the state Mandatory licenses, use of patents by the government, parallel imports, and bolar provisions can be provided for flexibility in the event of national crises or extreme direness for non-commercial utilizatione and for a restricted time.[54]

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[53] Katie Rogers & Gay Stolberg, supra note 47.
[54] Nurul Barizah, "Equitable Access to Covid-19 Vaccines", Jawa Pos (August 2021).

The Covid-19 pandemic is a worldwide and national health emergency. This may be the most effective defense for patent flexibility. Nations that implement flexibilities must provide adequate compensation. Nations that do not have fabricating capacity are moreover permitted to carry out parallel imports from other nations utilizing a required permit based on the exhaustion principle of IPR. In order to ensure public health and improved access to drugs, nations must maximize the flexibility of TRIPs and their ease of use.[55]

The flexibility of the TRIPs Agreement and Doha Declaration has been regulated in Law number 13/2016 concerning Patents and Presidential Decree number 7/2020 concerning Procedures for the Implementation of Patents by the Government. Indonesia needs health products that are adequate, low-cost, and fast. To meet the public's need for vaccines and medicines during the current Covid-19 emergency and to procure imports of patented drugs, the government can use the flexibility of a Compulsory License and Patent by Government (Government Use).

The utilization of patents by the government has been used for the avoidance of HIV/AIDS and hepatitis B in Indonesia to encourage access to these imperative medications. This component is regulated by most laws around the world. The WTO TRIPs Agreement, as reaffirmed by the Doha Declaration on TRIPs and public health, recognizes the right of WTO Individuals to allow compulsory licenses and patents by governments and their flexibility to decide the reasons for giving licenses.[56] Government patents can be applied to processes and products for the Covid-19 vaccine that have been patented in Indonesia. As for vaccine processes and products that are not or have not been patented in Indonesia, national pharmaceutical companies can directly imitate them. The key is manufacturing capacity, namely production capability and availability of raw materials. If this can be implemented for Covid-19, then this flexibility must be utilized.[57]

V. CONCLUSION

This article moreover concludes that the idea of the TRIPs waiver is not widely acknowledged by all WTO member nations. Responses from

[55] Ibid at 4.
[56] Barizah, supra note 58.
[57] Ibid .

member countries varied, namely those who agreed, conditionally agreed, and rejected this idea. Countries that agree believe that the TRIPs waiver is the easiest way to access vaccines and medicines and is one way to access all data and information used to produce Covid-19 vaccines and essential medicines. Countries that agree with the conditions think that the use of the TRIPs waiver policy must still be known to obtain permission from the patent holder. Meanwhile, countries that disagreed thought that the TRIPs waiver was not easy to implement because it had to go through a lengthy process and significant costs. The application of the TRIPs waiver requires clear regulations for its implementation.

Until now, WTO member countries have not decided whether to accept or reject the TRIPs waiver idea. This article suggests that WTO member countries should use policies that already exist and have been agreed upon through the TRIPs agreement and the Doha Declaration, namely TRIPs flexibility. WTO member countries can use mandatory licenses and use of patents by the government, which from the start was intended to exempt patents in emergencies that concern the resilience and security of the state.

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