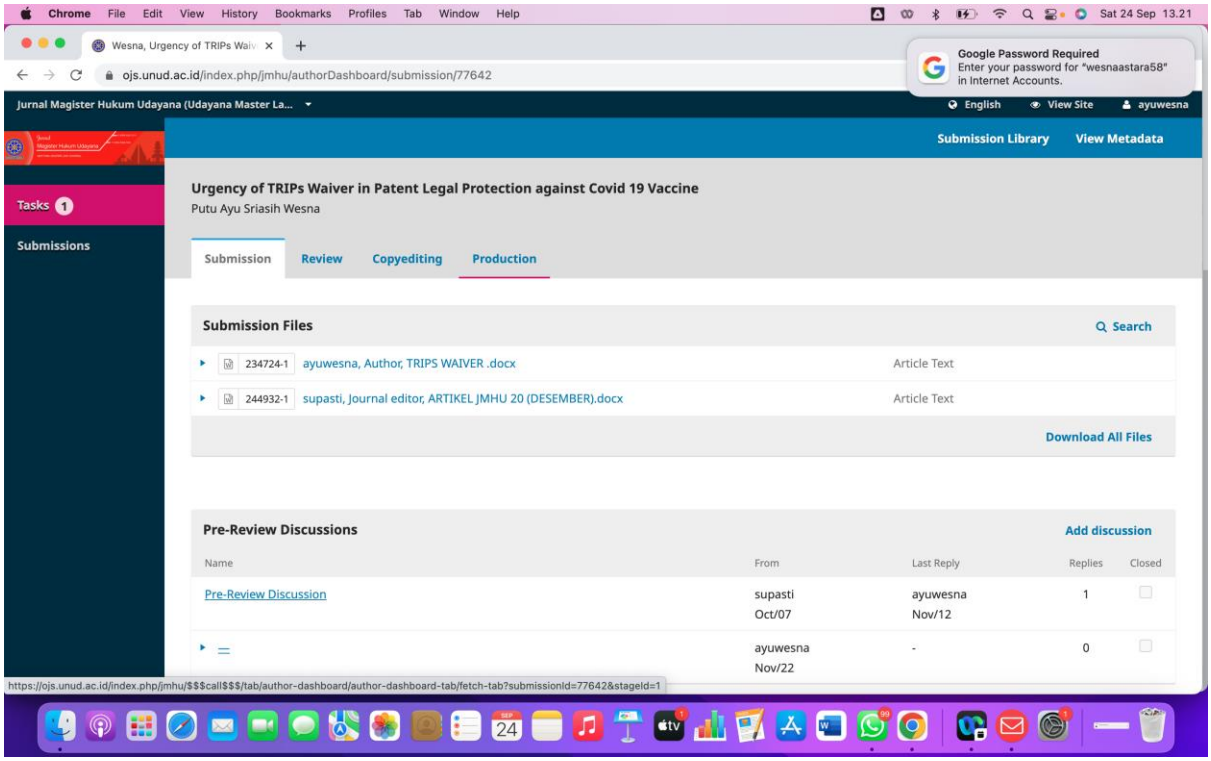
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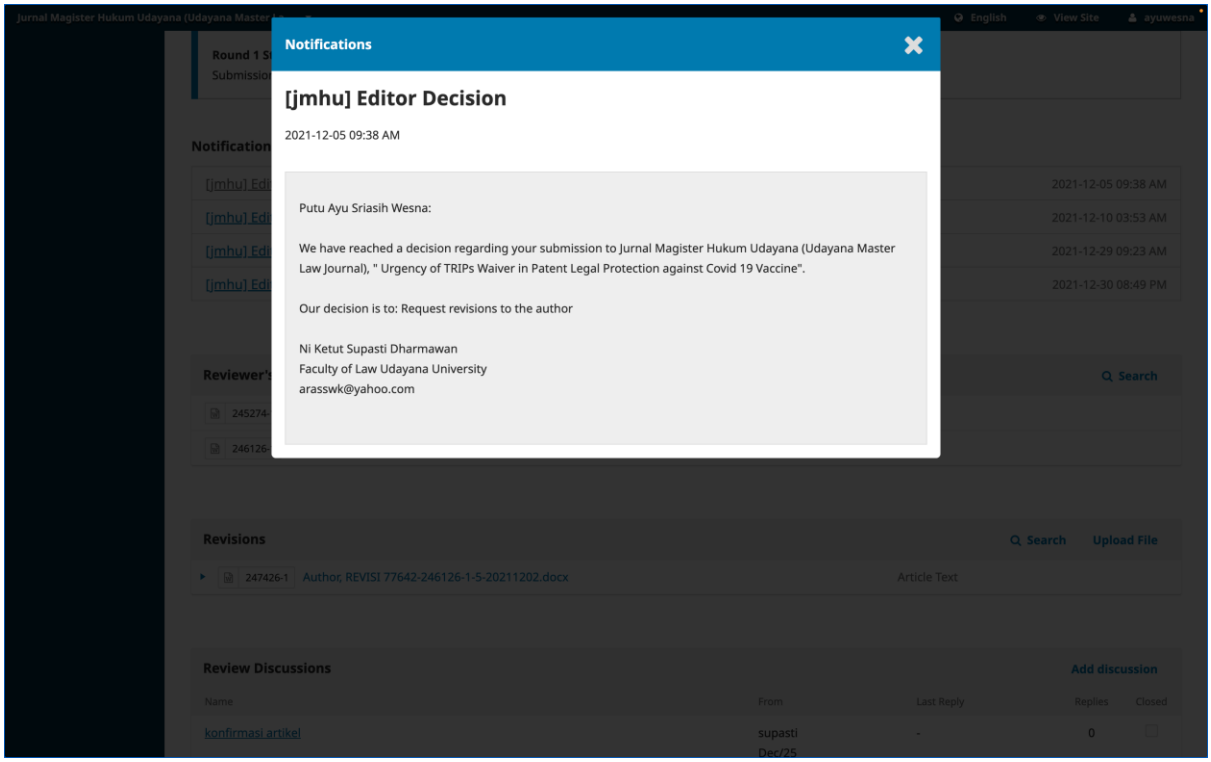
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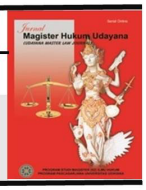

Urgency of TRIPs Waiver in Patent Legal Protection against Covid 19 Vaccine

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Abstract
The emergence of Covid 19 in December 2019 in the city of Wuhan, China which spread throughout the world caused the WHO to finally declare it as a pandemic. This is in line with the emergence of new products that have intellectual property values related to the handling of the COVID-19 pandemic, one of which is vaccines. Intellectual Property protection arrangements can lead to monopolistic practices of knowledge by the pharmaceutical industry in developed countries. This is a form of abuse of intellectual property protection, especially patent protection by corporations that hide under the term exclusive rights in intellectual property protection.
Exclusive rights provide the authority to prevent other people from producing and trading products whose technology is requested for protection in an effort to keep profits in the hands of intellectual property holders. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Waiver proposal promoted by India and South Africa opened the fact that the increase in COVID-19 cases, the emergence of new variants and the global vaccination gap are reminders that countries in the world must work together in dealing with pandemic

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1.Introduction

The TRIPs agreement is one of the 15 issues in the GATT (General Agreement on Tariffs and Trade) Agreement which regulates intellectual property rights issues globally. The final Uruguay Round (GATT) document was approved on 15 December 1993 and ratified on 15 April 1998 in Marrakech. The final document of the Uruguay Round is more than 500 pages long with more than 28 global trade agreements were signed by 125 countries including Indonesia. In general, the TRIPs agreement contains juridical norms that must be complied with and implemented in the field of intellectual property rights, in addition to regulations regarding the prohibition of trading on goods resulting from violations.

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The provisions of Article 1 paragraph (1) of the GATT 1994 which underlies the WTO agreement as well as Article 3 and Article 4 of TRIPs on non-discrimination, in principle require the application of the same legal standards for all WTO member countries. In fact, social reality is not the same. There is a gulf that separates developed and developing

countries. Inequality and inequality create situations of injustice, one of which is very controversial is the protection of drug patents.[1] This is because the effects of the patent have resulted in very high drug prices so that many people cannot afford to buy them. This condition is experienced by people with diseases that can become epidemic, such as tuberculosis, malaria and AIDS, whose sufferers are generally poor people, while the medicine is very expensive.[2]

Since the beginning of the Corona virus being declared as a Pandemic, obstacles regarding access to drugs, PPE, and treatment are believed to be a serious challenge. Several developing countries at the beginning of the pandemic experienced a shortage of PPE stocks and even now the shortage of ventilators (breathing aids) needed to save people with COVID is still a serious threat. In handling Covid-19, almost everything is related to the issue of protecting intellectual property rights (IPR). That almost all health products in handling Covid-19 such as test kits, diagnostics, masks, medicines, vaccines, and ventilators are protected in patents, trade secrets, and industrial designs. This is what ultimately opens up opportunities for the pharmaceutical industry to take the opportunity in a pandemic situation to extract as much profit as possible from the abuse of IPR protection and encourage monopolistic practices in knowledge, production, prices, and distribution (supply). Pharmaceutical corporations still use a business scheme approach in responding to the needs of handling pandemics in the world.[3]

In October 2020, India and South Africa submitted a proposal for an agreement to waive some of the provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement for the prevention, control and treatment of COVID-19, called the TRIPS waiver. The two countries hope that the TRIPS waiver will facilitate and increase the scale of production of products related to COVID-19, such as PPE, medicines, and vaccines, to prevent, cope with and treat COVID-19. The Indian and South African proposals have the support of more than 100 countries, including Indonesia.

The proposal was initially opposed by a number of parties such as the European Union, Australia, Canada, and Brazil. After the US declared support for the TRIPS waiver in the era of President Joe Biden. In its development several countries began to show a change in attitude. APEC, whose members include Australia and Canada, called for negotiations on the text of the proposed TRIPS waiver agreement. Meanwhile, the BRICS countries (Brazil, Russia, India, China, have expressed their support for the discussion regarding the TRIPS waiver to overcome the COVID-19 pandemic. Although the change in attitude of some of the initial refusals has not indicated the agreement of the TRIPS waiver. Of course, negotiations require a long process considering that some repellent is the basis of pharmaceutical companies that produce COVID-19 vaccines.

2. Research Method

In writing this research using normative legal research methods as a characteristic of legal science is its normative nature. This research started from the existence of a norm vacuum

[1] Ni Ketut Supasti. Dharmawan, "157204-ID-Perlindungan-Hukum-Atas-Karya-Cipta-Prog.Pdf," *Badan Penerbit Universitas Diponegoro, Semarang (2011)*., 2011.
[2] P.A.S. Wesna, "Konstruksi Pengaturan Penetapan Imbalan Atas Pelaksanaan Paten Obat-Obatan Oleh Pemerintah Dalam Dimensi Perbandingan," 2019.
[3] A. Hertanti, H., Prakoso, A. Hertanti, H., Prakoso, "Hentikan Monopoli HAKI Terhadap Covid 19 Laksanakan TRIPs Waiver, J," *Indonesia For Global Justice*, 2021.

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in the TRIPS Agreement where there was no neglect of several provisions in the TRIPs Agreement, which was expected to minimize the gap in access to the Covid 19 vaccine in various countries. This study uses the following approaches: statute approach, conceptual approach, and analytical approach. The technique of tracing legal materials used is using document study techniques, and analysis of studies using qualitative analysis.

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3. Hasil Dan Pembahasan

3. Result and Discussions

3.1. Protection of Public Health Through the Flexibility of TRIPs Before the Covid 19 Pandemic

Technology has a very important role in human life. In the current era of globalization, technology is able to solve problems faced by humans. To produce new discoveries in its development, someone has sacrificed energy, thought, time and also cost. In general, the findings produced have a high economic value. Therefore, it is appropriate to be given legal protection in the form of granting exclusive rights to the inventor for his findings. Inventions in the field of technology are objects of patents, which are included in the legal framework of intellectual property in industrial property rights.[4]

The concept of intellectual property protection originated from developed countries that already have national laws and regulations on intellectual property. Likewise in the international world, these developed countries have begun to agree on the regulation of intellectual property through various international agreements which are also known as conventions governing intellectual property. For example, those relating to industrial rights (patents, trademarks and industrial designs) were initially regulated through the Paris Convention of 1883, then copyright was regulated through the Berne Convention of 1886, the oldest convention governing copyright. In its development, various international conventions related to intellectual property include: Berne Convention, Universal Copyright Convention, Convention Establishing the World Intellectual Property Organization (WIPO), Patent Cooperation Treaty (PCT), The Hague Agreement Concerning the International Deposit of Industrial Designs, Paris Convention, as well as the TRIPs-WTO Agreement.[5]

Intellectual property exists after the concept of intangible objects comes out of the human mind, then is realized in a creation of science, art and literature so that it is in the form of tangible objects. Broadly speaking, the concept of ownership and wealth is related to "rights", then from a legal point of view, there are known rights relating to ownership and rights relating to materials. Basically, material rights also include ownership rights because ownership is always related to certain objects both materially and immaterially.

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Ownership of Intellectual Property is not the result of new human intellectual abilities in the form of certain ideas. Intellectual property rights only exist when the human intellectual ability has formed something that can be seen, heard, read, or used practically. Intellectual property rights are rights that come from the results of creative activities, an ability of the human mind that is expressed to the general public in various forms, which have benefits and are useful in supporting human life, as well as having economic value. From a philosophical point of view, the concept of Intellectual Property began in the 18th century, which was inspired by John Locke and Jean Jacques Rousseau, known as the "Natural Right Theory". Locke's view that, every person naturally has a right to himself, therefore the result of his work (labor) because he has made sacrifices in the form of finding, processing, and adding an element of "personality" to something that has been found, processed: "every". man has a property in his own person. This nobody has any right o but himself. The labor of his body and the work of his hands, we may say are

[4] N.K.S. et al. Dharmawan, "Harmonisasi Hukum Kekayaan Intelektual Indonesia," *Swasta Nulus*, 2018.
[5] *Ibid*, n.d.

properly his".[6] Everyone has property or wealth in his own person. No one has the right but himself. The work of his hands, we can say is his own (private property of the person himself).

All member countries, including Indonesia, are required to comply with the minimum standards of TRIPs in full compliance. This obligation in Indonesia is often known as legal harmonization, meaning that Indonesia is obliged to harmonize legal provisions in the field of intellectual property rights in order to comply with the TRIPs Agreement which has been ratified under Law Number 7 of 1994 concerning Ratification of the Agreement Establishing the World Trade Organization. World Trade).[7] Before the Covid-19 pandemic hit the whole world, the pharmaceutical and health patent fields were areas that were in the spotlight of developing countries. This is because the effects of the patent have resulted in the price of drugs, especially essential drugs, to be very expensive so that many people cannot afford to buy them. This condition is experienced by people with diseases that can become epidemic, such as tuberculosis, malaria and AIDS, whose sufferers are generally poor people, while the medicines as essential medicines are very expensive.

After the launch of the TRIPS agreement, developing and underdeveloped countries increasingly believe that the agreement will provide more benefits to developed countries. The limited access of the poor in developing and underdeveloped countries to essential medicines is evidence that strengthens this belief. Drug price declines will occur if these countries are able to implement and maximize protective provisions (such as parallel imports and compulsory licensing) consistently. Efforts to insert these protective articles into the national legal systems of developing and underdeveloped countries often lead to lawsuits from developed countries. An example is the conflict between the United States and Brazil. The conflict boils down to the provisions of the Brazilian Patent Law which include strict mandatory licensing. The inclusion of these provisions is considered by the United States government to be excessive and has the potential to harm the rights of drug patent holders in the United States. The dispute between multinational pharmaceutical companies and the South African government is another example which proves that the proposed adoption of protective articles (parallel imports and compulsory licensing), which are actually allowed and permitted in the TRIPS agreement often lead to conflicts with developed countries.

Patent protection for drugs automatically prohibits other parties from producing or selling patented drugs. Thus, the owner of a patent on a drug has a monopoly right to determine the price and quantity of production. As a result, drug prices are expensive. An example is the price of the drug Flucanazole for people with HIV/AIDS. In India it costs $55, while in the Philippines it costs $697 and Indonesia $703. This fact occurs because Flucanazole in India is not protected by patents.[8] The legal dispute shows that the articles protecting TRIPS are weak and meaningless articles because the interpretation of these articles more often uses the perspectives and interests of developed countries as producers of Intellectual Property Rights. Since access to cheap essential medicines has become a serious problem in many countries, non-governmental organizations and developing countries have urged the WTO Council (the WTO council) to include the topic of public health in the agenda of the WTO ministerial meeting in Seattle in 1999. Unfortunately, at

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[6] O. Granstrand, "The Economics and Management of Intellectual Property: Towards Intellectual Capitalism," *Cheltenham (UK): Edward Elgar Publishing Limited.*, 1999.

[7] N.K.S. Dharmawan, "Relevansi Hak Kekayaan Intelektual Dengan Hak Asasi Manusia Generasi," *Jurnal Dinamika Hukum* 14, no. 3 (2014), https://doi.org/doi:10.20884/1.jdh.2014.14.3.323.

[8] A. O Sykes, "TRIPS, Pharmaceuticals, Developing Countries, and the Doha Solution.," *Chi. J. Int'l L.,* 47, no. 3 (n.d.).

that time not many people paid attention to the problem until the fourth ministerial meeting in Doha was held in 2001.[9]

TRIPs actually regulate some flexibility of patent rights as a protective article to protect the interests of developing countries. The flexibility provisions in general actually aim to provide protection for public health in developing countries. Some of these provisions can be used in order to provide the ability of the poor to buy drugs cheaply. Access to cheap drugs is one of the things related to public health. Flexibility in TRIPs related to patents on drugs consists of; parallel imports, and mandatory licenses. Both models of flexibility provide the possibility of lower drug prices.

The international community's awareness of access to cheap drugs has finally encouraged WTO member countries to make specific arrangements regarding flexibility in TRIPs. In the end, the will of WTO member countries to specifically regulate the flexibility of TRIPs on public health related to access to cheap drugs was followed up by the success of making a Declaration on the TRIPs Agreement and Public Health in 2001 in Doha, Qatar which emphasized and detailed the flexibility of TRIPs.[10] The WTO makes exceptions to import bans for some diseases that endanger health. In the September 2001 Doha meeting, patents were waived specifically for drugs for tuberculosis, malaria and AIDS. This policy allows countries that have the capability and production facilities to make copies of drugs for AIDS, namely ARVs or generic ARVs so that they can be sold at much cheaper prices. Meanwhile, countries that are unable to produce their own products are allowed to import from neighboring countries.[11]

In TRIPs, there are several models of patent flexibility as the TRIPs Safeguard, namely Parallel Import and Compulsory Licensed.Article 28 of TRIPs states that the patent holder has the exclusive right to prohibit third parties without their permission from using, using, selling, including importing products related to the patent. However, there is a note on this provision that prohibiting the import of these products must not conflict with the principle of exhaustion of Intellectual Property Rights.

The provisions of TRIPs show that basically TRIPs does not prohibit the practice of parallel imports. The policy to prohibit or allow parallel imports is left to the national law of each country concerned. In some developed countries the practice of parallel imports is indeed prohibited, this is mainly to protect their industrial interests, for example the United States is one of the countries that strongly oppose parallel imports both in terms of their domestic trade and trade between countries. However, European countries that are members of European Urion enforce a single market between their member countries, and allow parallel imports as long as it is within the scope of their single market. Indonesia as a developing country with a fairly large population should pay attention to this problem, where the prohibition of parallel imports in Indonesian patent law will be able to affect the availability of national medicines.[12]

Compulsory licenses or mandatory licenses are basically unknown in TRIPs, but the basic principles are contained in article 31 regarding "other use without authorization of the right holder". One of the reasons for using this compulsory license is because the party

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[9] B. C. Mercurio, "TRIPs, Patents, and Access To Life-Saving Drugs In The Developing World.," *Intellectual Property L. Rev.,* 8, no. 2 (2004).

[10] M. Aqimuddin, E. A., Sunendar, I., Siska, F., Tanjung, R. J., & Mayas, "Tinjauan Pendekatan Hukum Dan Ekonomi Terhadap Model Lisensi Wajib Paten Atas Obat Dalam WTO-Trips Dan Deklarasi Doha 2001.," in *Prosiding SNaPP: Sosial, Ekonomi Dan Humaniora, 5(1)*., 2015, 1–5.

[11] M. Djumhana, *Perkembangan Doktrin Dan Teori Perlindungan HKI.* (Bandung: PT. Citra Aditya., 2006).

[12] T. Mardiyanto, "Hukum Paten Lndonesia Dalam Perspektif Kepentingan Konsumen Untuk Akses Obat.," *Perencanaan Pembangunan,* 2002.

applying for the license has applied for the license, but was unsuccessful even though his party had submitted a proper offer and the application was submitted within a sufficient period of time.[13]

In addition to these reasons, the provisions of article 31 also open up the possibility of submitting an application for the use of a patent without the permission of the right holder on the grounds that there is an urgent national interest (national emergency) or other very urgent conditions (other circum sences of extreme urgency) or non-commercial use for the public interest (public non-commercial use). In the case of an urgent national interest or other urgent situation, the right holder must be notified as soon as possible. Meanwhile, in the case of non-commercial use for the public interest, where the government or other parties without conducting a patent search know that the patent technology will be used for the benefit of the state, the patent holder must still be notified as soon as possible.

3.2. the urgency of Indonesia's implementation and attitude in the Ignorance of the TRIPs Agreement on the Covid 19 Vaccine

GATT is an international system, forum and institution in the field of trade. The system began to be realized in 1947 and began operating in 1948. The system that was realized was initially only considered an interim system, which could develop pragmatically so that it became something complex and has undergone expansion, both in terms of substantive coverage and in terms of institutions. After the Uruguay Round negotiations (1986-1994) were completed, the GATT member countries also agreed to form a new institution called the World Trade Organization (WTO), as the successor institution to GATT.[14]

Various basic principles that form the basis of GATT as a system based on an integral set of thoughts or conceptions. The components of the basic principles of GATT are of course also embedded in the text of the General Agreement as the main juridical source of GATT. In order for the discussion of the juridical system to be based on a well-founded conceptual systematic, it is deemed necessary to briefly discuss these basic principles. The principles that underlie GATT as a system are the principles contained in the GATT agreement including the Waiver Principle and Emergency Restrictions on Imports. GATT also allows exceptions in the form of waivers and other emergency measures. Among other things, exceptions in the form of waivers that have been permitted are exceptions taken by the United States in carrying out its agricultural policies, which actually violate the GATT, but because they were implemented before the GATT, the steps and policies received a waiver.[15]

2nd October 2020, India and South Africa proposed a waiver of certain articles in the TRIPs or TRIPs waiver. India and South Africa have urged the WTO to temporarily waive obligations to protect intellectual property rights related to the prevention, containment or treatment of COVID-19. This action is expected to be supported by developing countries that are members of the WTO, with the hope that this proposal will provide greater accessibility and affordability of essential medicines and equipment. However, decision-making at the World Trade Organization (WTO) is based on

[13] P.A.S. Wesna, "Doha Declaration Sebagai Perlindungan Masyarakat Atas Akses Obat Esensial Di Negara Berkembang Pasca Trips Agreement," *Jurnal Kertha Wicaksana Sarana Komunikasi Dosen Dan Mahasiswa.* 6 (5AD).

[14] Kartadjoemena. H.S., "Substansi Perjanjian GATT / WTO Dan Mekanisme Penyelesaian Sengketa, System, Kelembagaan,Prosedur, Implementasi, Dan Kepentingan Negara Berkembang.," in *Universitas Indonesia-Press.*, n.d., 1–2.

[15] Suardi., "Pengaturan World Trade Organization Dalam Hukum Internasional Serta Konflik Kepentingan Antar Negara Maju Dan Negara Berkembang," *Jurnal Inspirasi* No. XIII E (2012): 10.

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consensus. Countries must vote for a proposal to be approved. As there is currently no unanimous support for the TRIPS Waiver, proponents of the waiver proposal are campaigning to obtain the (three-fourth) majority of votes required at the TRIPS board meeting for the waiver to materialize. The current situation is very complex with important actors consisting not only of developed and developing countries, but also of various large pharmaceutical companies and non-governmental organizations.

The TRIPS Waiver proposal seeks to waive chapters 1, 4, 5, and 7 of Part II of the TRIPS Agreement, as well as Article 31. The rules set out lengthy procedural requirements for the export and import of pharmaceutical products and restrict access to some countries. The original draft of the October 2 proposal also noted that the waiver would remain in effect for a period undecided by the TRIPS board and could be reviewed by the General Council no later than one year after it was granted. The two proposed clauses are very important because they can provide developing countries with the time that may be needed to procure essential medical products, as well as allow for an annual review of the effectiveness of the waiver.[16]

South Africa and India, as main proponents of the proposal, noted that a large number of patents were filed for anti-viral drugs, making it difficult to increase production of already limited drugs. On January 15, 2021, communications sent by Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe expressed surprise that the other member states on the TRIPS Council were unaware of the supply shortage that was occurring. occur in developing countries regarding the production and distribution of medical supplies. They cite tocilizumab and sarilumab as just two examples of anti-inflammatory drugs that have been used in the treatment of Covid-19 patients. However, patents for both drugs still exist in many developing countries with major patents in at least 55 developing countries.

In the Global Health Summit Forum which was attended by G20 member countries which was held on May 21, 2021, Indonesia has decided to become one of the co-sponsors of the TRIPS Waiver proposal. Indonesia hopes that other G20 member countries can provide the same support. During the meeting, Indonesia emphasized the importance of increasing the production capacity of the Covid-19 vaccine. Indonesia sees a clear gap in vaccine distribution, between developed countries and developing and poor countries. The achievement of the world's economic recovery is also very dependent on the resolution of the pandemic. Indonesia also urges G20 member countries to provide support for increased production and equal access to vaccines for all countries. In this regard, Indonesia supports the TRIPS Waiver proposal for the prevention and treatment of COVID-19, including for vaccines. During the meeting, Indonesia through the Head of State, President Joko Widodo, stated that Indonesia was ready to become a hub for the production of Covid-19 vaccines in the Southeast Asian region. This is because Indonesia has PT Bio Farma, a state-owned company which is the largest vaccine producer in Southeast Asia with the ability to produce Covid-19 vaccines of up to 25 million doses per month.

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In addition to Indonesia's stance in the Global Health Summit which was attended by G20 member countries, the Minister of Foreign Affairs of the Republic of Indonesia and the Minister of Foreign Affairs of Russia, jointly chaired the ASEAN-Russia Special Ministerial Meeting which was held virtually on July 6, 2021. During the meeting two agendas were discussed. related to the implementation of the TRIPS waiver. First, regarding cooperation in handling the pandemic. The Minister of Foreign Affairs of the

[16] Annie Zhu, "Situasi Terkini Pada TRIPS," 2020, 1–4, https://igj.or.id/situasi-terkini-pada-trips-waiver/.

Republic of Indonesia encourages Russia to support the fulfillment of vaccine needs in the region through dose-sharing, prioritizing ASEAN countries as recipients of Russian vaccines and exploring the possibility of joint-production with ASEAN Member States. Second, related to regional architecture. The Indonesian Foreign Minister saw the similarities in the principles of the Russian Vision regarding regional architecture and the ASEAN Outlook on the Indo Pacific (AOIP), which became increasingly relevant during the pandemic. The meeting, which was held to encourage Russia's commitment and active role in the Southeast Asian region, has produced an outcome document in the form of a Co-chairs Summary which in essence agreed to accelerate the post-pandemic recovery process, including suppressing socio-economic impacts, restoring macroeconomic and financial stability, supply chain, connectivity and strengthen environmental resilience.[17]

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4. Conclusion

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Patent protection for drugs automatically prohibits other parties from producing or selling patented drugs. The international community's awareness of access to cheap drugs has finally encouraged WTO member countries to make specific arrangements regarding flexibility in TRIPs. The will of WTO member countries to specifically regulate the flexibility of TRIPs on public health related to access to cheap drugs was followed up by the success of making a Declaration on the TRIPs Agreement and Public Health in 2001 in Doha, Qatar which emphasized and detailed the flexibility of TRIPs. The WTO makes exceptions to import bans for some diseases that endanger health. In the September 2001 Doha meeting, patents were waived specifically for drugs for tuberculosis, malaria and AIDS. This policy allows countries that have the capability and production facilities to make copies of drugs for AIDS, namely ARVs or generic ARVs so that they can be sold at much cheaper prices. Meanwhile, countries that are unable to produce their own products are allowed to import from neighboring countries.

The patent system does help protect intellectual property rights, but these rights should not be considered as the nation's top priority. Continuing support for current TRIPS provisions creates barriers to essential medicines and equipment, triggering a Health crisis through pharmaceutical monopolies on R&D and medical supplies, as well as Article 31 restrictions. Access to safe and affordable medicines should be considered a human right. The TRIPS Waiver proposal seeks to waive chapters 1, 4, 5, and 7 of Part II of the TRIPS Agreement, as well as Article 31. The rules set out lengthy procedural requirements for the export and import of pharmaceutical products and restrict access to some countries. Through the waiver of TRIPS, it is hoped that every country can collaborate in terms of research and development in order to increase the production capacity of the Covid-19 vaccine. After global immunity is achieved, the award for the result of intellectual ability is returned to the situation before the TRIPs waiver was implemented, which can be granted a patent for 20 years.

During the current global pandemic, the urgency of the TRIPS Waiver is expected to open up opportunities for overriding intellectual property protection rules for medicines, diagnostic tests, vaccines, and other technologies related to the handling of Covid-19 while the pandemic is still ongoing or until global immunity is achieved. This proposal allows each country to collaborate in research and development to increase the production capacity of the Covid-19 vaccine. After global immunity is achieved, the

[17] "Pimpin Pertemuan Menlu ASEAN-Rusia, Menlu RI Dorong Kerja Sama Produksi Vaksin," accessed November 8, 2021, https://setkab.go.id/pimpin-pertemuan-menlu-asean-rusia-menlu-ri-dorong-kerja-sama-produksi-vaksin/?utm_source=rss&utm_medium=rss&utm_campaign=pimpin-pertemuan-menlu-asean-rusia-menlu-ri-dorong-kerja-sama-produksi-vaksin.

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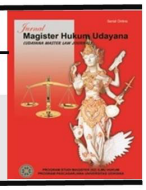

Urgency of TRIPs Waiver in Patent Legal Protection against Covid 19 Vaccine

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Abstract

The emergence of Covid 19 in December 2019 in the city of Wuhan, China which spread throughout the world caused the WHO to finally declare it a pandemic. This is in line with the emergence of new products that have intellectual property values related to the handling of the COVID-19 pandemic, one of which is vaccines which are very essential. Intellectual Property protection provisions can lead to monopolistic practices of knowledge by the pharmaceutical industry in developed countries. This is a form of abuse of intellectual property protection, especially patent protection by corporations that hide behind exclusive rights in intellectual property protection.

Exclusive rights provide the authority to prevent other people from producing and trading products whose technology is requested for protection in an effort to keep profits in the hands of intellectual property holders. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Waiver proposal promoted by India and South Africa opened the world's eyes that the increase in COVID-19 cases, the emergence of new variants and the global vaccination gap are reminders that countries in the world must work together in dealing with pandemic

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1.Introduction

The TRIPs agreement is one of the 15 issues in the GATT (General Agreement on Tariffs and Trade) Agreement which regulates intellectual property rights issues globally. The final Uruguay Round (GATT) document was approved on 15 December 1993 and ratified on 15 April 1998 in Marrakech. The final document of the Uruguay Round is more than 500 pages long with more than 28 global trade agreements signed by 125 countries including Indonesia. In general, the TRIPs agreement contains juridical norms that must be complied with and implemented in the field of intellectual property rights, in addition to regulations regarding the prohibition of trading on goods resulting from violations.

The provisions of Article 1 paragraph (1) of the GATT 1994 which underlies the WTO agreement as well as Article 3 and Article 4 of TRIPs on non-discrimination, in principle require the application of the same legal standards for all WTO member countries. In fact, social reality is not the same. There is a gulf that separates developed and developing countries. Inequality and inequality create situations of injustice, one of which is very

controversial is the protection of drug patents.[1] This is because the effects of the patent have resulted in very high drug prices so that many people cannot afford to buy them. This condition is experienced by people with diseases that can become epidemic, such as tuberculosis, malaria and AIDS, whose sufferers are generally poor people, while the medicine is very expensive.[2]

Since the beginning of the Corona virus being designated as a Pandemic, obstacles regarding access to drugs, PPE, and treatment are believed to be a serious challenge. Several developing countries at the beginning of the pandemic experienced a shortage of PPE stocks and even now the shortage of ventilators (breathing aids) needed to save people with COVID is still a serious threat. In handling Covid-19, almost everything is related to the issue of protecting intellectual property rights (IPR). That almost all health products in handling Covid-19 such as test kits, diagnostics, masks, medicines, vaccines, and ventilators are protected in patents, trade secrets, and industrial designs. This is what ultimately opens up opportunities for the pharmaceutical industry to take the opportunity in a pandemic situation to extract as much profit as possible from the abuse of IPR protection and encourage monopolistic practices in knowledge, production, prices, and distribution (supply). Pharmaceutical corporations still use a business scheme approach in responding to the needs of handling pandemics in the world.[3]

In October 2020, India and South Africa submitted a proposal for an agreement to waive some of the provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement for the prevention, control and treatment of COVID-19, called the TRIPS waiver. The two countries hope that the TRIPS waiver will facilitate and increase the scale of production of products related to COVID-19, such as PPE, medicines, and vaccines, to prevent, cope with and treat COVID-19. The Indian and South African proposals have the support of more than 100 countries, including Indonesia.

The proposal was initially opposed by a number of parties such as the European Union, Australia, Canada, and Brazil. After the US declared support for the TRIPS waiver in the era of President Joe Biden. In its development several countries began to show a change in attitude. APEC, whose members include Australia and Canada, called for negotiations on the text of the proposed TRIPS waiver agreement. Meanwhile, the BRICS countries (Brazil, Russia, India, China, have expressed their support for the discussion regarding the TRIPS waiver to overcome the COVID-19 pandemic. Although the change in attitude of some of the initial refusals has not indicated the agreement of the TRIPS waiver. Of course, negotiations require a long process considering that some repellent is the basis of pharmaceutical companies that produce COVID-19 vaccines.

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2. Research Method

In writing this research using normative legal research methods as a characteristic of legal science is its normative nature. This research started from the existence of a norm vacuum in the TRIPS Agreement where there was no neglect of several provisions in the TRIPs

[1] Ni Ketut Supasti. Dharmawan, "157204-ID-Perlindungan-Hukum-Atas-Karya-Cipta-Prog.Pdf," *Badan Penerbit Universitas Diponegoro, Semarang (2011)*., 2011.
[2] P.A.S. Wesna, "Konstruksi Pengaturan Penetapan Imbalan Atas Pelaksanaan Paten Obat-Obatan Oleh Pemerintah Dalam Dimensi Perbandingan," 2019.
[3] A. Hertanti, H., Prakoso, A. Hertanti, H., Prakoso, "Hentikan Monopoli HAKI Terhadap Covid 19 Laksanakan TRIPs Waiver, J," *Indonesia For Global Justice*, 2021.

Agreement, which was expected to minimize the gap in access to the Covid 19 vaccine in various countries. This study uses the following approaches: statute approach, conceptual approach, and analytical approach. The technique of tracing legal materials used is using document study techniques, and analysis of studies using qualitative analysis.

3. Hasil Dan Pembahasan

3. Result and Discussions

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3.1. Protection of Public Health Through the Flexibility of TRIPs Before the Covid 19 Pandemic

Technology has a very important role in human life. In the current era of globalization, technology is able to solve problems faced by humans. To produce new discoveries in its development, someone has sacrificed energy, thought, time and also cost. In general, the findings produced have a high economic value. Therefore, it is appropriate to be given legal protection in the form of granting exclusive rights to the inventor for his findings. Inventions in the field of technology are objects of patents, which are included in the legal framework of intellectual property in industrial property rights.[4]

The concept of intellectual property protection originated from developed countries that already have national laws and regulations on intellectual property. Likewise in the international world, these developed countries have begun to agree on the regulation of intellectual property through various international agreements which are also known as conventions governing intellectual property. For example, those relating to industrial rights (patents, trademarks and industrial designs) were initially regulated through the Paris Convention of 1883, then copyright was regulated through the Berne Convention of 1886, the oldest convention governing copyright. In its development, various international conventions related to intellectual property include: Berne Convention, Universal Copyright Convention, Convention Establishing the World Intellectual Property Organization (WIPO), Patent Cooperation Treaty (PCT), The Hague Agreement Concerning the International Deposit of Industrial Designs, Paris Convention, as well as the TRIPs-WTO Agreement.[5]

Intellectual property exists after the concept of intangible objects comes out of the human mind, then is realized in a creation of science, art and literature so that it is in the form of tangible objects. Broadly speaking, the concept of ownership and wealth is related to "rights", then from a legal point of view, there are known rights relating to ownership and rights relating to materials. Basically, material rights also include ownership rights because ownership is always related to certain objects both materially and immaterially.

Ownership of Intellectual Property is not the result of new human intellectual abilities in the form of certain ideas. Intellectual property rights only exist when the human intellectual ability has formed something that can be seen, heard, read, or used practically. Intellectual property rights are rights that come from the results of creative activities, an ability of the human mind that is expressed to the general public in various forms, which have benefits and are useful in supporting human life, as well as having economic value.

From a philosophical point of view, the concept of Intellectual Property began in the 18th century, which was inspired by John Locke and Jean Jacques Rousseau, known as the "Natural Right Theory". Locke's view that, every person naturally has a right to himself, therefore the result of his work (labor) because he has made sacrifices in the form of finding, processing, and adding an element of "personality" to something that has been

[4] N.K.S. et al. Dharmawan, "Harmonisasi Hukum Kekayaan Intelektual Indonesia," *Swasta Nulus*, 2018.
[5] *Ibid*, n.d.

found, processed: "every". man has a property in his own person. This nobody has any right o but himself. The labor of his body and the work of his hands, we may say are properly his".[6] Everyone has property or wealth in his own person. No one has the right but himself. The work of his hands, we can say is his own (private property of the person himself).

All member countries, including Indonesia, are required to comply with the minimum standards of TRIPs in full compliance. This obligation in Indonesia is often known as legal harmonization, meaning that Indonesia is obliged to harmonize legal provisions in the field of intellectual property rights in order to comply with the TRIPs Agreement which has been ratified under Law Number 7 of 1994 concerning Ratification of the Agreement Establishing the World Trade Organization. World Trade).[7] Before the Covid-19 pandemic hit the whole world, the pharmaceutical and health patent fields were areas that were in the spotlight of developing countries. This is because the effects of the patent have resulted in the price of drugs, especially essential drugs, to be very expensive so that many people cannot afford to buy them. This condition is experienced by people with diseases that can become epidemic, such as tuberculosis, malaria and AIDS, whose sufferers are generally poor people, while the medicines as essential medicines are very expensive.

After the launch of the TRIPS agreement, developing and underdeveloped countries increasingly believe that the agreement will provide more benefits to developed countries. The limited access of the poor in developing and underdeveloped countries to essential medicines is evidence that strengthens this belief. Drug price declines will occur if these countries are able to implement and maximize protective provisions (such as parallel imports and compulsory licensing) consistently. Efforts to insert these protective articles into the national legal systems of developing and underdeveloped countries often lead to lawsuits from developed countries. An example is the conflict between the United States and Brazil. The conflict boils down to the provisions of the Brazilian Patent Law which include strict mandatory licensing. The inclusion of these provisions is considered by the United States government to be excessive and has the potential to harm the rights of drug patent holders in the United States. The dispute between multinational pharmaceutical companies and the South African government is another example which proves that the proposed adoption of protective articles (parallel imports and compulsory licensing), which are actually allowed and permitted in the TRIPS agreement often lead to conflicts with developed countries.

Patent protection for drugs automatically prohibits other parties from producing or selling patented drugs. Thus, the owner of a patent on a drug has a monopoly right to determine the price and quantity of production. As a result, drug prices are expensive. An example is the price of the drug Flucanazole for people with HIV/AIDS. In India it costs $55, while in the Philippines it costs $697 and Indonesia $703. This fact occurs because Flucanazole in India is not protected by patents.[8] The legal dispute shows that the articles protecting TRIPS are weak and meaningless articles because the interpretation of these articles more often uses the perspectives and interests of developed countries as producers of Intellectual Property Rights. Since access to cheap essential medicines has become a serious problem in many countries, non-governmental organizations and developing

[6] O. Granstrand, "The Economics and Management of Intellectual Property: Towards Intellectual Capitalism," *Cheltenham (UK): Edward Elgar Publishing Limited.*, 1999.
[7] N.K.S. Dharmawan, "Relevansi Hak Kekayaan Intelektual Dengan Hak Asasi Manusia Generasi," *Jurnal Dinamika Hukum* 14, no. 3 (2014), https://doi.org/doi:10.20884/1.jdh.2014.14.3.323.
[8] A. O Sykes, "TRIPS, Pharmaceuticals, Developing Countries, and the Doha Solution.," *Chi. J. Int'l L.,* 47, no. 3 (n.d.).

countries have urged the WTO Council (the WTO council) to include the topic of public health in the agenda of the WTO ministerial meeting in Seattle in 1999. Unfortunately, at that time not many people paid attention to the problem until the fourth ministerial meeting in Doha was held in 2001.[9]

TRIPs actually regulate some flexibility of patent rights as a protective article to protect the interests of developing countries. The flexibility provisions in general actually aim to provide protection for public health in developing countries. Some of these provisions can be used in order to provide the ability of the poor to buy drugs cheaply. Access to cheap drugs is one of the things related to public health. Flexibility in TRIPs related to patents on drugs consists of; parallel imports, and mandatory licenses. Both models of flexibility provide the possibility of lower drug prices.

The international community's awareness of access to cheap drugs has finally encouraged WTO member countries to make specific arrangements regarding flexibility in TRIPs. In the end, the will of WTO member countries to specifically regulate the flexibility of TRIPs on public health related to access to cheap drugs was followed up by the success of making a Declaration on the TRIPs Agreement and Public Health in 2001 in Doha, Qatar which emphasized and detailed the flexibility of TRIPs.[10] The WTO makes exceptions to import bans for some diseases that endanger health. In the September 2001 Doha meeting, patents were waived specifically for drugs for tuberculosis, malaria and AIDS. This policy allows countries that have the capability and production facilities to make copies of drugs for AIDS, namely ARVs or generic ARVs so that they can be sold at much cheaper prices. Meanwhile, countries that are unable to produce their own products are allowed to import from neighboring countries.[11]

In TRIPs, there are several models of patent flexibility as the TRIPs Safeguard, namely Parallel Import and Compulsory Licensed.Article 28 of TRIPs states that the patent holder has the exclusive right to prohibit third parties without their permission from using, using, selling, including importing products related to the patent. However, there is a note on this provision that prohibiting the import of these products must not conflict with the principle of exhaustion of Intellectual Property Rights.

The provisions of TRIPs show that basically TRIPs does not prohibit the practice of parallel imports. The policy to prohibit or allow parallel imports is left to the national law of each country concerned. In some developed countries the practice of parallel imports is indeed prohibited, this is mainly to protect their industrial interests, for example the United States is one of the countries that strongly oppose parallel imports both in terms of their domestic trade and trade between countries. However, European countries that are members of European Urion enforce a single market between their member countries, and allow parallel imports as long as it is within the scope of their single market. Indonesia as a developing country with a fairly large population should pay attention to this problem, where the prohibition of parallel imports in Indonesian patent law will be able to affect the availability of national medicines.[12]

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[9] B. C. Mercurio, "TRIPs, Patents, and Access To Life-Saving Drugs In The Developing World.," *Intellectual Property L. Rev.,* 8, no. 2 (2004).

[10] M. Aqimuddin, E. A., Sunendar, I., Siska, F., Tanjung, R. J., & Mayas, "Tinjauan Pendekatan Hukum Dan Ekonomi Terhadap Model Lisensi Wajib Paten Atas Obat Dalam WTO-Trips Dan Deklarasi Doha 2001.," in *Prosiding SNaPP: Sosial, Ekonomi Dan Humaniora, 5(1)*., 2015, 1–5.

[11] M. Djumhana, *Perkembangan Doktrin Dan Teori Perlindungan HKI.* (Bandung: PT. Citra Aditya., 2006).

[12] T. Mardiyanto, "Hukum Paten Lndonesia Dalam Perspektif Kepentingan Konsumen Untuk Akses Obat.," *Perencanaan Pembangunan,* 2002.

Compulsory licenses or mandatory licenses are basically unknown in TRIPs, but the basic principles are contained in article 31 regarding "other use without authorization of the right holder". One of the reasons for using this compulsory license is because the party applying for the license has applied for the license, but was unsuccessful even though his party had submitted a proper offer and the application was submitted within a sufficient period of time.[13]

In addition to these reasons, the provisions of article 31 also open up the possibility of submitting an application for the use of a patent without the permission of the right holder on the grounds that there is an urgent national interest (national emergency) or other very urgent conditions (other circum sences of extreme urgency) or non-commercial use. for the public interest (public non-commercial use). In the case of an urgent national interest or other urgent situation, the right holder must be notified as soon as possible. Meanwhile, in the case of non-commercial use for the public interest, where the government or other parties without conducting a patent search know that the patent technology will be used for the benefit of the state, the patent holder must still be notified as soon as possible.

3.2. the urgency of Indonesia's implementation and attitude in the Ignorance of the TRIPs Agreement on the Covid 19 Vaccine

GATT is an international system, forum and institution in the field of trade. The system began to be realized in 1947 and began operating in 1948. The system that was realized was initially only considered an interim system, which could develop pragmatically so that it became something complex and has undergone expansion, both in terms of substantive coverage and in terms of institutions. After the Uruguay Round negotiations (1986-1994) were completed, the GATT member countries also agreed to form a new institution called the World Trade Organization (WTO), as the successor institution to GATT.[14]

Various basic principles that form the basis of GATT as a system based on an integral set of thoughts or conceptions. The components of the basic principles of GATT are of course also embedded in the text of the General Agreement as the main juridical source of GATT. In order for the discussion of the juridical system to be based on a well-founded conceptual systematic, it is deemed necessary to briefly discuss these basic principles. The principles that underlie GATT as a system are the principles contained in the GATT agreement including the Waiver Principle and Emergency Restrictions on Imports. GATT also allows exceptions in the form of waivers and other emergency measures. Among other things, exceptions in the form of waivers that have been permitted are exceptions taken by the United States in carrying out its agricultural policies, which actually violate the GATT, but because they were implemented before the GATT, the steps and policies received a waiver.[15]

2nd October 2020, India and South Africa proposed a waiver of certain articles in the TRIPs or TRIPs waiver. India and South Africa have urged the WTO to temporarily waive obligations to protect intellectual property rights related to the prevention, containment or treatment of COVID-19. This action is expected to be supported by

[13] P.A.S. Wesna, "Doha Declaration Sebagai Perlindungan Masyarakat Atas Akses Obat Esensial Di Negara Berkembang Pasca Trips Agreement," *Jurnal Kertha Wicaksana Sarana Komunikasi Dosen Dan Mahasiswa.* 6 (5AD).

[14] Kartadjoemena. H.S., "Substansi Perjanjian GATT / WTO Dan Mekanisme Penyelesaian Sengketa, System, Kelembagaan,Prosedur, Implementasi, Dan Kepentingan Negara Berkembang.," in *Universitas Indonesia-Press.*, n.d., 1–2.

[15] Suardi., "Pengaturan World Trade Organization Dalam Hukum Internasional Serta Konflik Kepentingan Antar Negara Maju Dan Negara Berkembang," *Jurnal Inspirasi* No. XIII E (2012): 10.

developing countries that are members of the WTO, with the hope that this proposal will provide greater accessibility and affordability of essential medicines and equipment. However, decision-making at the World Trade Organization (WTO) is based on consensus. Countries must vote for a proposal to be approved. As there is currently no unanimous support for the TRIPS Waiver, proponents of the waiver proposal are campaigning to obtain the (three-fourth) majority of votes required at the TRIPS board meeting for the waiver to materialize. The current situation is very complex with important actors consisting not only of developed and developing countries, but also of various large pharmaceutical companies and non-governmental organizations.

The TRIPS Waiver proposal seeks to waive chapters 1, 4, 5, and 7 of Part II of the TRIPS Agreement, as well as Article 31. The rules set out lengthy procedural requirements for the export and import of pharmaceutical products and restrict access to some countries. The original draft of the October 2 proposal also noted that the waiver would remain in effect for a period undecided by the TRIPS board and could be reviewed by the General Council no later than one year after it was granted. The two proposed clauses are very important because they can provide developing countries with the time that may be needed to procure essential medical products, as well as allow for an annual review of the effectiveness of the waiver.[16]

South Africa and India, as main proponents of the proposal, noted that a large number of patents were filed for anti-viral drugs, making it difficult to increase production of already limited drugs. On January 15, 2021, communications sent by Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe expressed surprise that the other member states on the TRIPS Council were unaware of the supply shortage that was occurring. occur in developing countries regarding the production and distribution of medical supplies. They cite tocilizumab and sarilumab as just two examples of anti-inflammatory drugs that have been used in the treatment of Covid-19 patients. However, patents for both drugs still exist in many developing countries with major patents in at least 55 developing countries.

In the Global Health Summit Forum which was attended by G20 member countries which was held on May 21, 2021, Indonesia has decided to become one of the co-sponsors of the TRIPS Waiver proposal. Indonesia hopes that other G20 member countries can provide the same support. During the meeting, Indonesia emphasized the importance of increasing the production capacity of the Covid-19 vaccine. Indonesia sees a clear gap in vaccine distribution, between developed countries and developing and poor countries. The achievement of the world's economic recovery is also very dependent on the resolution of the pandemic. Indonesia also urges G20 member countries to provide support for increased production and equal access to vaccines for all countries. In this regard, Indonesia supports the TRIPS Waiver proposal for the prevention and treatment of COVID-19, including for vaccines. During the meeting, Indonesia through the Head of State, President Joko Widodo, stated that Indonesia was ready to become a hub for the production of Covid-19 vaccines in the Southeast Asian region. This is because Indonesia has PT Bio Farma, a state-owned company which is the largest vaccine producer in Southeast Asia with the ability to produce Covid-19 vaccines of up to 25 million doses per month.

In addition to Indonesia's stance in the Global Health Summit which was attended by G20 member countries, the Minister of Foreign Affairs of the Republic of Indonesia and the Minister of Foreign Affairs of Russia, jointly chaired the ASEAN-Russia Special

[16] Annie Zhu, "Situasi Terkini Pada TRIPS," 2020, 1–4, https://igj.or.id/situasi-terkini-pada-trips-waiver/.

Ministerial Meeting which was held virtually on July 6, 2021. During the meeting two agendas were discussed. related to the implementation of the TRIPS waiver. First, regarding cooperation in handling the pandemic. The Minister of Foreign Affairs of the Republic of Indonesia encourages Russia to support the fulfillment of vaccine needs in the region through dose-sharing, prioritizing ASEAN countries as recipients of Russian vaccines and exploring the possibility of joint-production with ASEAN Member States. Second, related to regional architecture. The Indonesian Foreign Minister saw the similarities in the principles of the Russian Vision regarding regional architecture and the ASEAN Outlook on the Indo Pacific (AOIP), which became increasingly relevant during the pandemic. The meeting, which was held to encourage Russia's commitment and active role in the Southeast Asian region, has produced an outcome document in the form of a Co-chairs Summary which in essence agreed to accelerate the post-pandemic recovery process, including suppressing socio-economic impacts, restoring macroeconomic and financial stability. , supply chain, connectivity and strengthen environmental resilience.[17]

4. Conclusion

Patent protection for drugs automatically prohibits other parties from producing or selling patented drugs. The international community's awareness of access to cheap drugs has finally encouraged WTO member countries to make specific arrangements regarding flexibility in TRIPs. The will of WTO member countries to specifically regulate the flexibility of TRIPs on public health related to access to cheap drugs was followed up by the success of making a Declaration on the TRIPs Agreement and Public Health in 2001 in Doha, Qatar which emphasized and detailed the flexibility of TRIPs. The WTO makes exceptions to import bans for some diseases that endanger health. In the September 2001 Doha meeting, patents were waived specifically for drugs for tuberculosis, malaria and AIDS. This policy allows countries that have the capability and production facilities to make copies of drugs for AIDS, namely ARVs or generic ARVs so that they can be sold at much cheaper prices. Meanwhile, countries that are unable to produce their own products are allowed to import from neighboring countries.

The patent system does help protect intellectual property rights, but these rights should not be considered as the nation's top priority. Continuing support for current TRIPS provisions creates barriers to essential medicines and equipment, triggering a Health crisis through pharmaceutical monopolies on R&D and medical supplies, as well as Article 31 restrictions. Access to safe and affordable medicines should be considered a human right. The TRIPS Waiver proposal seeks to waive chapters 1, 4, 5, and 7 of Part II of the TRIPS Agreement, as well as Article 31. The rules set out lengthy procedural requirements for the export and import of pharmaceutical products and restrict access to some countries. Through the waiver of TRIPS, it is hoped that every country can collaborate in terms of research and development in order to increase the production capacity of the Covid-19 vaccine. After global immunity is achieved, the award for the result of intellectual ability is returned to the situation before the TRIPs waiver was implemented, which can be granted a patent for 20 years.

During the current global pandemic, the urgency of the TRIPS Waiver is expected to open up opportunities for overriding intellectual property protection rules for medicines, diagnostic tests, vaccines, and other technologies related to the handling of

[17] "Pimpin Pertemuan Menlu ASEAN-Rusia, Menlu RI Dorong Kerja Sama Produksi Vaksin," accessed November 8, 2021, https://setkab.go.id/pimpin-pertemuan-menlu-asean-rusia-menlu-ri-dorong-kerja-sama-produksi-vaksin/?utm_source=rss&utm_medium=rss&utm_campaign=pimpin-pertemuan-menlu-asean-rusia-menlu-ri-dorong-kerja-sama-produksi-vaksin.

Covid-19 while the pandemic is still ongoing or until global immunity is achieved. This proposal allows each country to collaborate in research and development to increase the production capacity of the Covid-19 vaccine. After global immunity is achieved, the award for the result of intellectual ability is returned to the situation before the TRIPs waiver was implemented, which can be granted a patent for 20 years.

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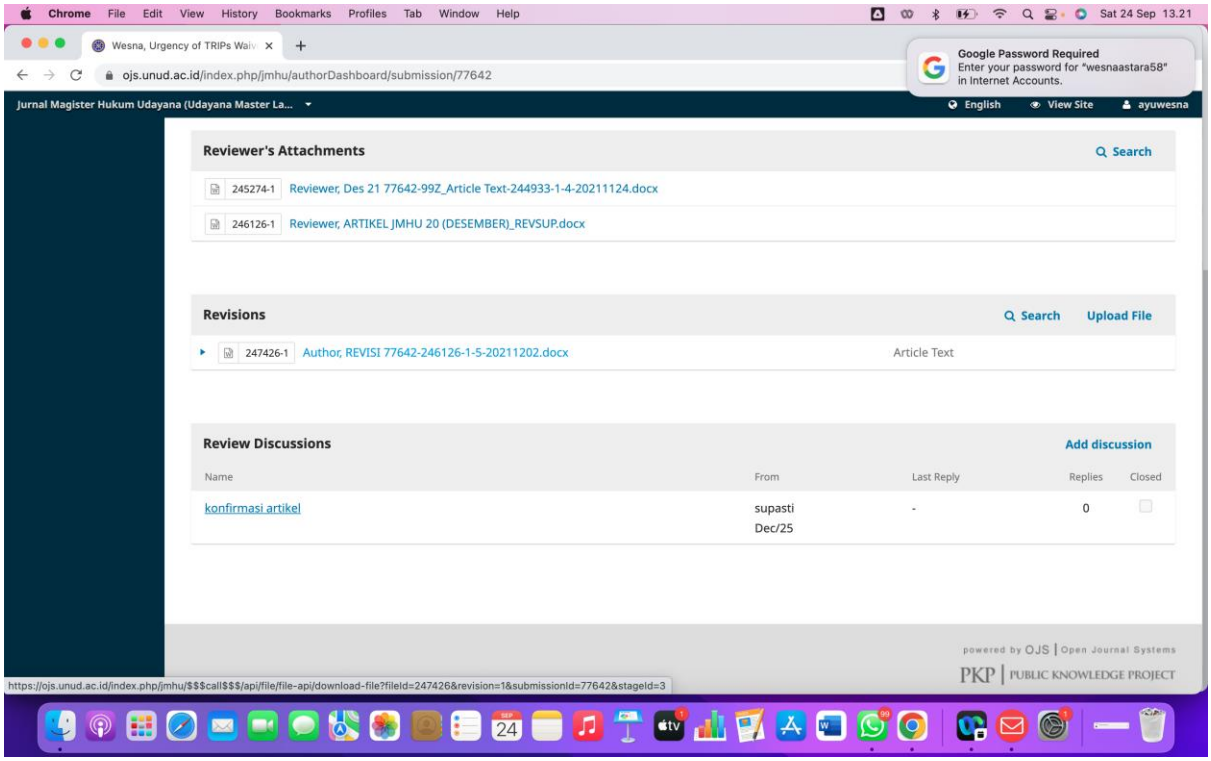
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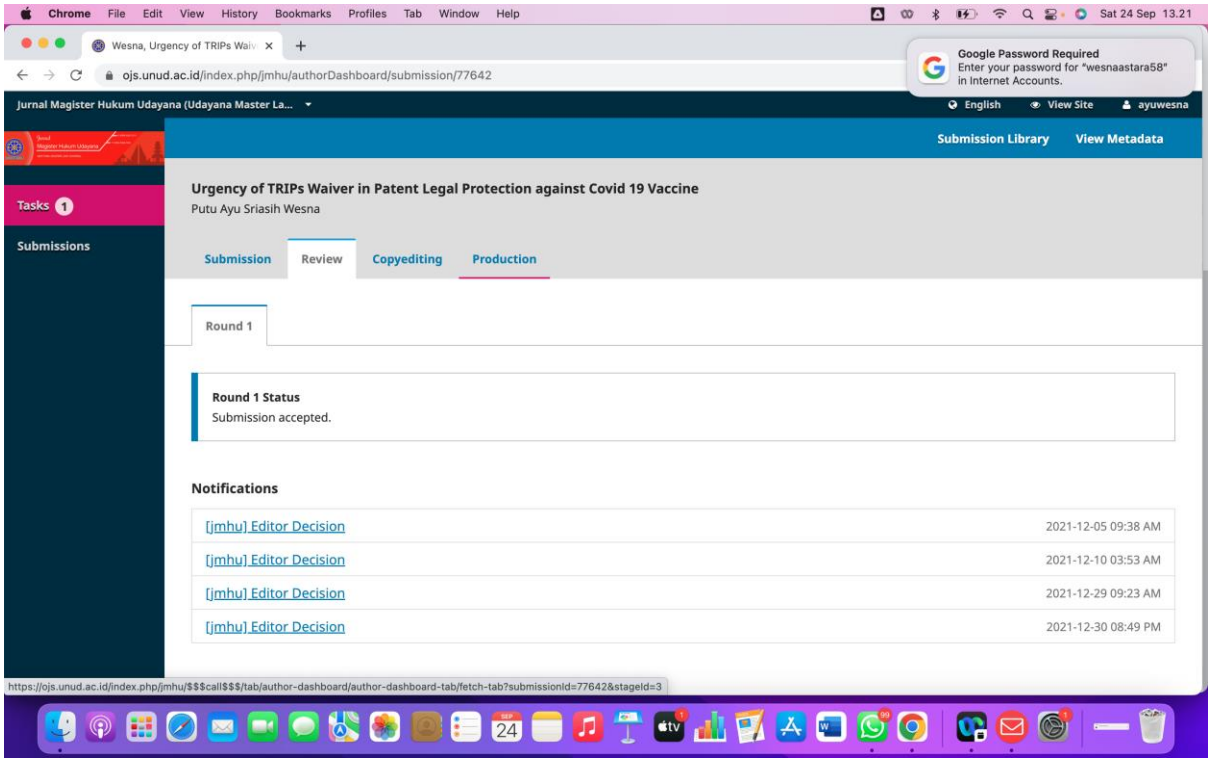
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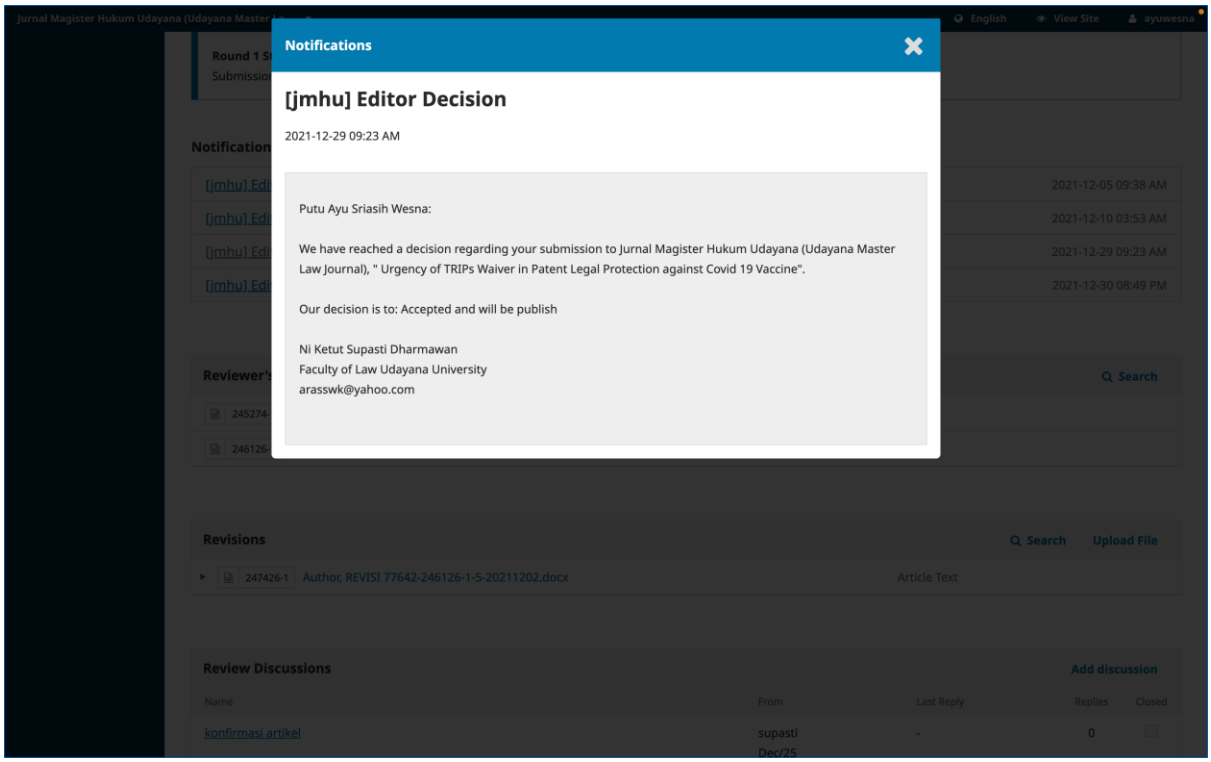
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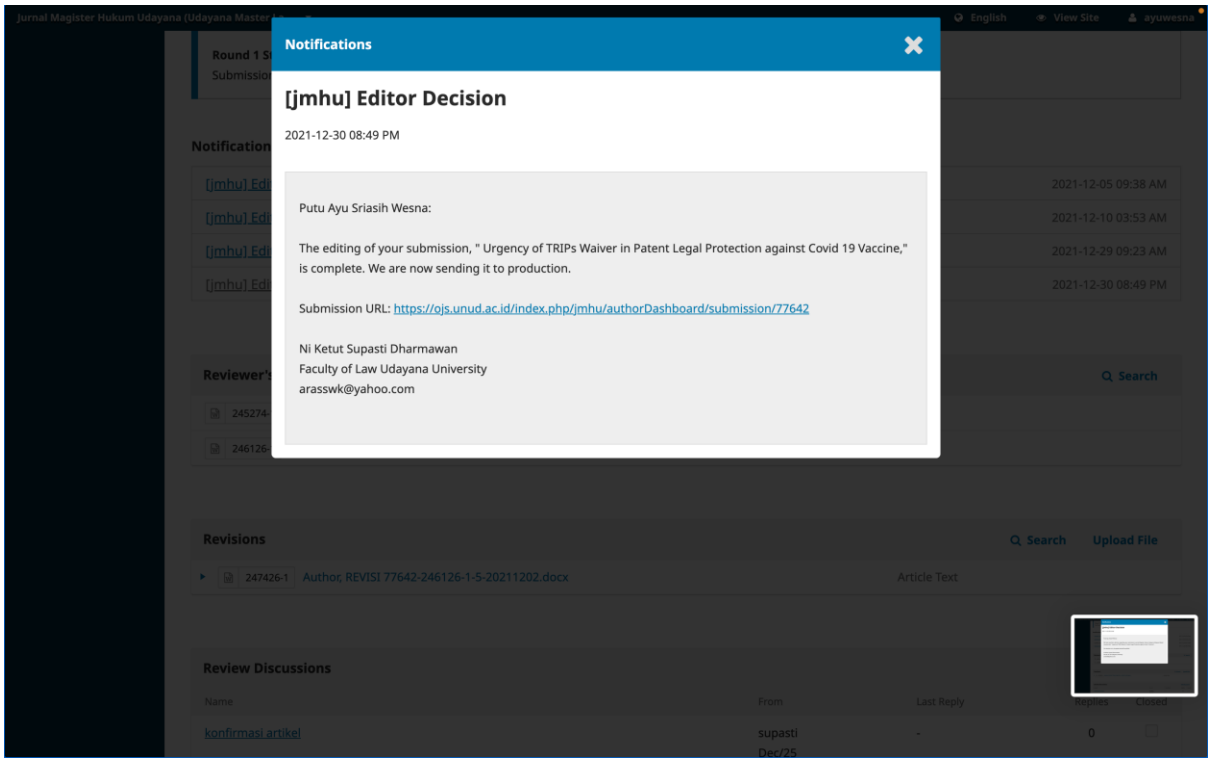
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