

Policy Of Patent Law On Public Health And Medical Products: Discourse In Indonesia Government's Use Of Intellectual Property

Suyud Margono

University of Mpu Tantular Jakarta

E-mail: suyudmargono@gmail.com

ABSTRACT

The protection of Intellectual Property Rights particularly on Patents Policy is very important because the Intellectual Property System provides limitations on the application of Patent Invention on public health, medical and others pharmaceutical products including vaccines. Learning from the pandemic situation, national policy (especially developing countries, with in unequal positioning because of the arguments of developed countries with large industries due to the provisions of the Trade Related Aspect of Intellectual Property Rights (TRIPs) Agreement. In the other hand Compulsory License as standard instrument that makes intellectual property exclusively but confront with International trade as a legal instrument. The research problems, about of patent policy for pharmaceutical and vaccine products in the Intellectual Property Rights (IPR) protection System in the scope of international trade. Research results show that There is National Protection and government's use Exclusivity of Patent for Inventions in scope of drugs, including others medical and pharmaceutical products. In the scope of Intellectual Property System Patents Policy is an opened option that the mechanism can be applied for Public and Social Interests in the sector of national interest, security and public health. Developing countries with lack of facilities continues to fight for equal access before International Cooperation (both bilateral and multilateral) within the scope of international relations is aimed in strengthening cooperation to solve common problems.

Keywords: Patent Law, Government Use Policy, Intellectual Property, International Trade.

Introduction

1. Background

The provisions in the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement shall make intellectual property protection a part of international trade provision, resulting in significant changes in the discussion of human intellectual works. This International Treaty Instrument is at least the most complete international agreement regarding the protection of Intellectual Property Rights, some parties even say that TRIPs is a breakthrough for cooperation in the field of international trade.¹ Indonesia is a WTO (World Trade Organization)² member country with an obligation to comply with the provisions in the TRIPs (Trade Related Aspects of Intellectual Property Rights) Agreement and has adopted also with two major international conventions in the field of copyrights industrial property rights, namely the Berne Convention and the Paris Convention, which relates to Intellectual Property Rights.

With the TRIPs Agreement, it can reduce restriction in international trade related to intellectual property rights, although in this case there are several conflicting opinions, but the advantage for Indonesia with the TRIPs Agreement in general is to enforce the law related to the protection of intellectual property rights, as well as motivating intellectual work producers to innovate because of the protection of intellectual rights including international protection.³ Indonesia as a signatory country to the TRIPs Agreement has their respective meanings related to Intellectual Property Rights which in principle all refer to what is written meaning in PART II Standards Concerning the Availability, Scope and Use of Intellectual Property Rights, including in the field of Patents for inventions in the field of technology and industry.⁴

¹ TRIPs Agreement - Agreement on Trade-Related Aspects of Intellectual Property Rights Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, Marrakesh, Morocco, 1994. WTO Agreement Art. XVI.6 jo TRIPs Art. 72

² Agreement Establishing the World Trade Organization, Marrakesh, Morocco, 1994

³ Jackson, John H., Legal Problems of International Economic Relations: Cases, Materials and Text on the National and International Regulation of Transnational Economic (American Casebook Series), 290, 314, West Group, 1995, p. 278-280

⁴ Long, Doris Estelle, The Impact of Foreign Investment on Indigenous Culture: An Intellectual Property Perspective, North Carolina Journal of International Law and Commercial Regulation, (Vol. 21, Winter 1998), p. 249

The latest development is that the President of the United States government supports for patent abandonment of the Covid-19 vaccine invention, this effort was taken to support equitable vaccines access for all countries without exception. US Trade Representative Katherine Tai⁵ said, while intellectual property rights for businesses are important, the government of the President of the United States, Washington supports patent waiver of the Covid-19 vaccine to end the pandemic, noting that this is a global health crisis, and the Covid-19 pandemic requires extraordinary action as the exceptional circumstances.

The implementation of patents by the government is one of the policies that can overcome the problem of access to drugs including vaccines during the Covid-19 pandemic. This provision has been regulated in Article 109 paragraph (1) letter b of Law No. 13 of 2016 concerning Patents (Patent Law) which states that the government can independently implement patents in Indonesia based on consideration of very urgent needs and public interests.⁶ A valuable lesson from this is Implementation of national Interests of Developing Countries for the procurement of vaccine and pharmaceutical products and its can be implement an independent policy in the provision of health and medical products, including the provision of vaccines, hereby furthermore the research problem about of patent policy for pharmaceutical and vaccine products in the Intellectual Property Rights (IPR) protection system in the scope of international trade.

2. Research Method

This research method is intended for studies that are scientific works which in essence are a means of infrastructure (scientific) for the development of science and technology, so the applied research methodology is adjusted to the main body of knowledge in the field of law.⁷ This research is also an analysis process of observing and acting logically, methodically and systematically regarding phenomena, events or empirical facts that occur or exist around us to be reconstructed in order

⁵United States Trade Representative. <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-TRIPs-waiver.>, 5 May 2021.

⁶ Provisions regarding Procedures for the Use of Patents by the Government as regulated under Presidential Regulation Number 77 of 2020

⁷ Soerjono Soekanto and Sri Mamudji, Normative Legal Research, (Jakarta: PT Raja Grafindo Persada), 2012, p. 1.

to reveal facts and information that are useful for life,⁸ especially for the Intellectual Property Rights (IPR) protection system for health and medical products, including the provision of vaccines in the scope of international trade provisions.

The research method is adapted to the research topic which is the main problem being researched by the author as part of the legal science research as described above, which is intended for the development of knowledge for society. So the research method in this scientific paper uses legal research methods with qualitative analytical descriptive. This scientific work is written based on the material collected and analyzed based on data according to the topic to be discussed. As we all know that a research is an effort made by humans to find new things and solve a problem,⁹ therefore this written of this scientific paper uses an approach in the perspective of national interests, with a multidisciplinary analysis in accordance with the theoretical framework validity of the Exclusivity of Patent Policy for Health and Pharmaceutical Products in the Intellectual Property Rights (IPR) Protection System.

3. Discussion and Analysis

3. 1. WTO-TRIPs Waiver Provision Patents Law in the scope of International Trade

The international agreement is known as Trade-Related Aspects of Intellectual Property Rights and most countries in the world are members of the WTO so that the provisions contained in the TRIPS Agreement apply¹⁰ as a minimum standard of IPR law in these countries. The patent section of this agreement regulates innovation that can be protected by patents and which cannot be protected, meaning of exclusive rights and restrictions on patent holders rights, invalid use of patents by other people without permission of the patent holder, within patent protection period.

Indonesia is a member of the WTO, since 1994. The WTO is a world trade organization resulting from the Uruguay Round negotiations from 1984-1994. Unlike its predecessor organization, the GATT (General Agreement on Tariffs and

⁸Abdul Kadir Muhammad, Law and Legal Research, (Bandung: PT Citra Aditya Bakti), 2004, p. 2.

⁹ Bambang Sunggono, Method of Legal Research, (Jakarta: PT Raja Grafindo Persada), 2001, p. 27.

¹⁰ This agreement is effective since January 1, 1995

Trade), which only regulates trade in goods, the WTO has a broader agreement, namely trade in goods, trade in services (GATs/General Agreement Trade in Services), trade related aspects -aspects of intellectual property rights known as (TRIPs/trade-related aspects on intellectual property rights), law enforcement and dispute resolution.

Patents are one of the main issues in the protection of Intellectual Property which is a concern in the Paris Convention and the International TRIPs Agreement. Its inclusion in the TRIPS Agreement indicates that legal protection of a patent is very important and strategic within the framework of international trade.¹¹

Innovation as a business strategy basically based on an intellectual work which is an intellectual property¹² that not only needs to be rewarded but also protected. This protection of Intellectual Property cannot be separated from the efforts of the State to ensure that the protection according intellectual property system, but during the Covid-19 pandemic, the WTO has faced calls with public demands in temporarily to remove form intellectual property in particular the Covid-19 vaccine in relation with Patent System.

A waiver of the TRIPs provisions (TRIPs Waiver) as Patent Policy with respect to agreements on Trade-Related aspects of Intellectual Property, although the idea has been strongly opposed by many giants pharmaceutical industry and their host countries also. They insist that patents are not the main barrier to increasing production, and that such TRIPs Waiver a move could hinder innovation.¹³ Currently, Indonesia has negotiated several free trade agreements (Free Trade Agreements/FTAs) with several trading partner countries, such

¹¹Carlos Correa. Trade related aspects of intellectual property rights: a commentary on the TRIPS agreement. (Oxford University Press, 2020),hal. 1-33. Bandingkan dengan Can Huang. "Recent development of the intellectual property rights system in China and challenges ahead." Management and Organization Review, Vol.13, No.1 (2017),page. 39-48.

¹² The acronym IP is a translation of Intellectual Property, previously this understanding was known as Intellectual Property Rights /IPR, in its entirety. And in its development, the acronym IP as a Directorate General of Intellectual Property (DGIP) is under the subscription system of the Indonesian Ministry of Law and Human Rights.

¹³ <https://www.cnbcindonesia.com/news/20210507094616-4-243981/top-biden-down-of-the-mountain-as-agree-to-remove-patent-covid-vaccine> May 7, 2021.

as the European Union and countries in the RCEP (Regional Comprehensive Partnership Agreement). In fact, it has just signed a free trade agreement with the EFTA (European Free Trade Agreement) country.¹⁴

One mechanism that could be used is by granting compulsory licenses or government use of patents, in this situation of which can be applied according to in a national emergency. The World Health Organization (WHO) has a policy called the National Medicines Policy. This National policy is a guideline to help countries adjust their policies to make essential medicines accessible and affordable. Affordable prices are an important prerequisite for providing access to essential medicines both of in the public and private sectors.¹⁵

In the TRIPS Agreement, products from inventions in Patent protection for the health sector, such as pharmaceuticals, including vaccines, are treated the same as other commodities, this background is because the Application of Intellectual Property in the health sector is part of the Pharmaceutical Industry. Various studies show that the TRIPS Agreement can create problems with access to medicines. Prior to the TRIPs period, the state had the right to determine patent arrangements and other IPR protection according to development needs of community, For instance, India as a country already has a patent law which does not provide patent protection for pharmaceutical products. In addition, it also does not provide patents for products (simple patents).

This policy has been proven to encourage innovation in generic drug companies. It is claimed that granting pharmaceutical patents will encourage innovation, but it gives patent owners monopoly rights. This right allows pharmaceutical companies to keep drug prices high, at least for

¹⁴ Currently, Indonesia is negotiating several free trade agreements (Free trade agreements/FTAs) with several trading partner countries, such as the European Union and countries in the RCEP (Regional Comprehensive Partnership Agreement). In fact, it has just signed a free trade agreement with the EFTA (European Free Trade Agreement) countries as well as Indonesia and Australia. Not only that, apart from negotiating FTAs with partners from developed countries, Indonesia is also negotiating FTAs with developing countries, Turkey, and PTA (preferential trade agreement) with Iran.

¹⁵ WHO Policy Perspective on Medicines - Equitable access to essential medicines: a framework for collective action, World Health Organization, Geneva, 2004, at 1 Accessed January 2021.

at least 20 years. Implementation of pharmaceutical products in the patent system can prevent the entry of generic drugs at low prices, even though these generic drugs are really needed by the public, especially patients in developing countries.¹⁶ The existence of medicines for the community is aimed at ensuring public health, but in reality vaccines and medicines are still protected in the patent system. The fact is that patent medicines are expensive, and the amount available is not sufficient to guarantee public health, so a government policy is needed that pays attention to and prioritizes public health interests. One way to get an affordable drug because the vaccine or drug is still protected by a patent system is to use a non-voluntary licensing mechanism.¹⁷

Article 28 of the TRIPs Agreement regulates “the patent holder's exclusive rights to prevent third parties from making, using, offering for sale, selling, or importing without approval from the patent holder. Meanwhile, articles 30 and 31 regulate the exclusion of the above exclusive rights. Article 31 of the TRIPS Agreement does not use the term 'compulsory license' but instead uses the term 'use without the permission of the right holder'. This term is used simultaneously to mean compulsory license and government use of patents (compulsory license and government use of patents).¹⁸

Although the TRIPS Agreement regulates the rights and limitations of the exclusive rights of patent holders, it is not easy to use mandatory licensing mechanisms or other mechanisms that reduce the exclusive rights of patent holders, such as parallel imports. Strict restrictions on the application of mandatory licenses in the field of medicine make drugs expensive. The HIV/AIDS epidemic exacerbated these restrictions at that time (in the late 1990s). Antiretroviral drugs are expensive, resulting in many people living with AIDS not being able to access the drugs they need to survive the disease.

¹⁶ Michael Bailey, R. M., & Smith, M. *Fatal Side Effects: Medicine Patents Under the Microscope*. 2010: London. p. 5.

¹⁷ World Health Organization (WTO), *How to Develop and Implement a National Drug Policy* (2nd edn, 2001), at 33 Accessed May 2020. GENEVA: The World Health Organization announced on Friday (May 7) it had approved a COVID-19 vaccine from China's state-owned Sinopharm pharmaceutical industry for emergency use.

¹⁸ Anthony Taubman (eds), ‘A Handbook On The WTO TRIPs Agreement’, Cambridge University Press 2012., p 109. https://www.wto.org/english/res_e/publications_e/handbook_wto/TRIPsag12_e.pdf, October 2020.

As an example, the experience of South Africa faced a big challenge when it wanted to change regulations that pushed down the price and availability of AIDS drugs through a compulsory licensing mechanism and parallel imports, so the United States placed South Africa on Section 301 of the Watch List. - then it is called a country that does not fulfill IPR protection.¹⁹

Indonesia has also gained experience in using patents by the government (government use)., this policy is only applied for antiretroviral drugs. Indonesia already has regulations on the use of patents that are in line with the provisions in the TRIPs Agreement. This provision can be applied when the public health condition is in an emergency. This can happen because the need for drugs is very high because it is not accompanied by the availability of raw materials or the ability of the national industry to produce them, resulting in high prices for these drugs.²⁰

Table 1: Constraint of Law Patent Policy for emergency use of vaccine the WTO-TRIPS Waiver Proposal in Pandemic Situation²¹

General Concept of WTO-TRIPS Waiver	▪ The proposed TRIPS Waiver → provide flexibility to countries in choosing whether or not to apply IPR protection (Patents, Copyrights, Industrial Designs, and Trade Secrets) in trade and handling the Covid-19 pandemic.
---	---

¹⁹ Haochen Sun, 'The Road to Doha and Beyond: Some reflections on the TRIPs Agreement and Public Health', EJIL 15 (2004) p. 123-150. Accessed from: <http://www.ejil.org/pdfs/15/1/335.pdf> January 2021.

²⁰ <https://dgip.go.id/artikel/detail-artikel/Government-Prepare-obat-covid-19-murah?kategori=liputan-humas>. Decree of the Minister of Law and Human Rights of the Republic of Indonesia Number M.H.H-01.KI.05.01 of 2020 concerning the Team for the Preparation of the Draft Presidential Regulation of the Republic of Indonesia concerning the Implementation of Patents by the Government for Favipiravir and Remdesivir Drugs in 2020

²¹ This table is the result of the author's observations by developing various issues regarding the Diplomatic Background of the Covid-19 Pandemic Vaccines in applications submitted on behalf of developing countries for the WTO-TRIPS Waiver Proposal.

	▪ Note: medicines, vaccines, and various medical equipment that are used are mostly protected by IPR and anyone is prohibited from producing, selling, importing and exporting without owner's permission (IPR Holders)
Proposal TRIPs Waiver	TRIPs Waiver proposal proposed by India, South Africa (2 October 2020), <u>Purpose</u>: to challenge WTO member countries, especially developed countries that have an international pharmaceutical industry, to waive (neglect) the obligation to protect Intellectual Property Rights (IPR) related to prevention during the Covid-19 pandemic.
TRIPs Waiver Working Mechanism (Proposal)	TRIPs Waiver proposal proposed at WTO → Important ▪ Providing Flexibility (to the state) will not enforce IPR protection (Patents, Copyrights, Industrial Designs and Trade Secrets) ▪ Ensuring access, drugs, vaccines, and various medical equipment in all WTO member countries
TRIPs Waiver Working Mechanism (Consent)	If the WTO member countries agree to approve the TRIPs Waiver Proposal, production, sale, export-import of drugs, vaccines and medical equipment related to Covid-19 can be carried out, so that the availability, affordability and access of drugs, vaccines and medical equipment can be increased (reproduced) quickly during the Covid-19 pandemic.

Regarding the TRIPs Waiver Proposal²² (waiver of the provisions of the TRIPs Agreement on Patent for emergency use In the WTO-TRIPS Waiver Proposal - in table 1) in the WTO, as the TRIPs Waiver Proposal. This is very important in order to provide policy space that is wide enough for all countries, especially developing countries, for research, local manufacturing, supply, and others context in public health handling pandemic Covid-19. Indonesia has agreed, but in the discussion process there is still very strong tension between countries that support and those that do not support. Even though Indonesia supports the TRIPs Waiver proposal, the Ministry of Foreign Affairs itself will still see to what extent the dynamics of the TRIPs Waiver proposal will have an impact in the future whether the Waiver as a whole or there will be more bargains in the future, so that Indonesia's position is more to find a middle point, because, if this proposal is too extreme and will be difficult to accept politically.

3.2. Government Use Policy for Inventions of Patent

Indonesia is a country that has a wealth of genetic resources and traditional knowledge which are often utilized by domestic and foreign inventors to produce new inventions. however, there is substance to legal developments, both national and international according to standards in the Agreement on Trade-Related Aspects of Intellectual Property Rights, hereinafter referred to as the TRIPs agreement.²³

Basic Constitution Article 28C paragraph (1), the 1945 Constitution of the Republic of Indonesia stipulated:

"Everyone has the right to develop himself through meeting his basic needs, has the right to receive education and to benefit from science and technology, arts and culture, in order to improve his quality of life and for the welfare of mankind."

In addition to the theory of State Sovereignty, which can be applied in this research there is also the Theory of Sovereignty of Law: "Law has and is the highest authority in a country. The state that creates laws. Law is an embodiment of

²² TRIPs Waiver Proposal was proposed on 2 October 2020 by India and South Africa at the WTO to allow all countries not to provide or not to enforce IPR rules related to the handling of Covid-19 both for drugs , test kits, vaccines, or other technologies during the pandemic until global immunity is achieved.

²³ General Explanation of Law Number 13 of 2016 concerning Patents

the will or will of the state.” The rule of law is one of the functions of the human soul which reacts to human actions in relation to other humans in society. Dynamics of the Sovereign of Law Theory (Recht Souvereiniteit)²⁴, which also experienced the development of the theory of People's Sovereignty,²⁵ that shall be applied in the discussion of this article. The national economic system is run through the principle of kinship, giving authority to the state to manage the Indonesian economic system, by making economic democracy as its basis, which is also followed by the principles of togetherness, efficiency with justice, sustainability, environmental insight, independence, and maintaining balance development and national economic unity.²⁶

The stipulation approach in the Patent Law is not only a policy to protect technological innovations but also in order to maintain the balance of the national economy, in the form of as follows:

- Optimizing the state's presence in the government's best services in the field of intellectual property;
- Alignment with the interests of Indonesia without violating international principles;
- Realizing economic independence by driving strategic sectors of the domestic economy by encouraging National inventions in the field of technology to realize strengthening technology;
- Building a National Patent base through a systemic approach to pragmatic legal realism

²⁴ Jeffrey Goldsworth., *Legislative Sovereignty and the Rule of Law in Sceptical Essays on Human Rights*, (Tom Campbell, Keith D. Ewing, Adam Tomkins eds. Oxford University Press 2001) page 69. Rule of law stands in contrast to the idea that the sovereign is above the law (rex lex), a feature of Roman Law and other legal systems.

²⁵ Menurut JJ Rousseau stating that it is the people who have the authority to make a law, his argues that sovereignty (or the power to make the laws) should be in the hands of the people, he also makes a sharp distinction between the sovereign and the government. The government is composed of magistrates, charged with implementing and enforcing the general will. The "sovereign" is the rule of law, ideally decided on by direct democracy in an assembly. Under a monarchy, however, the real sovereign is still the law. See Entry, "Rousseau" in the *Routelege Encyclopedia of Philosophy*, Edward Craig, editor, Volume Eight, p. 371.

²⁶ Kompas.com., "Contents of Article 33 of the 1945 Constitution and its meaning", <https://www.kompas.com/skola/read/2021/07/05/132235369/isi-pasal-33-uud-1945-dan-maknanya?> News 5 July 2021

The Theoretical framework used in this study regarding the implementation of patents by the State (Government Use) for the public health particularly in product or process of invention to support access to medical, food, drugs in Strengthening National Defense which is related to the Intellectual Property Rights Protection system is also related to the theory of State Sovereignty (Staats-souvereiniteit) put forward by Jean Bodin and George Jelinek within the framework of protecting the wealth of traditional communities. According to the theory of state sovereignty: "The highest power lies with the state and the state regulates the lives of its members of society. A sovereign state protects its community members, especially the weak members of society."²⁷

The development of the issue of IPR ownership and its protection is the result of pressure from developed countries²⁸ therefore for a developing country (i.e Indonesia, the most difficult problem is adjusting and implementing agreements)²⁹ has 5 (five) year transition period is too short a period for the level of capability of the existing official administration, moreover Indonesia is a net importer products and technology transfer, so that to perform intellectual property (IP) standards is still difficult for business entities from developing countries and material standards are still focused on the interests of IP owners and Licensee, such as multinational pharmaceutical industries, which are dominated by multinational companies with large capitalization supported by developed countries.

The national environmental impact on specific patent protection standards for invention medical use product for WTO member countries including Indonesia which have complied with the TRIPS Agreement provisions is one of the international harmonizations that can be followed up with policies and supervision from the World Intellectual Property

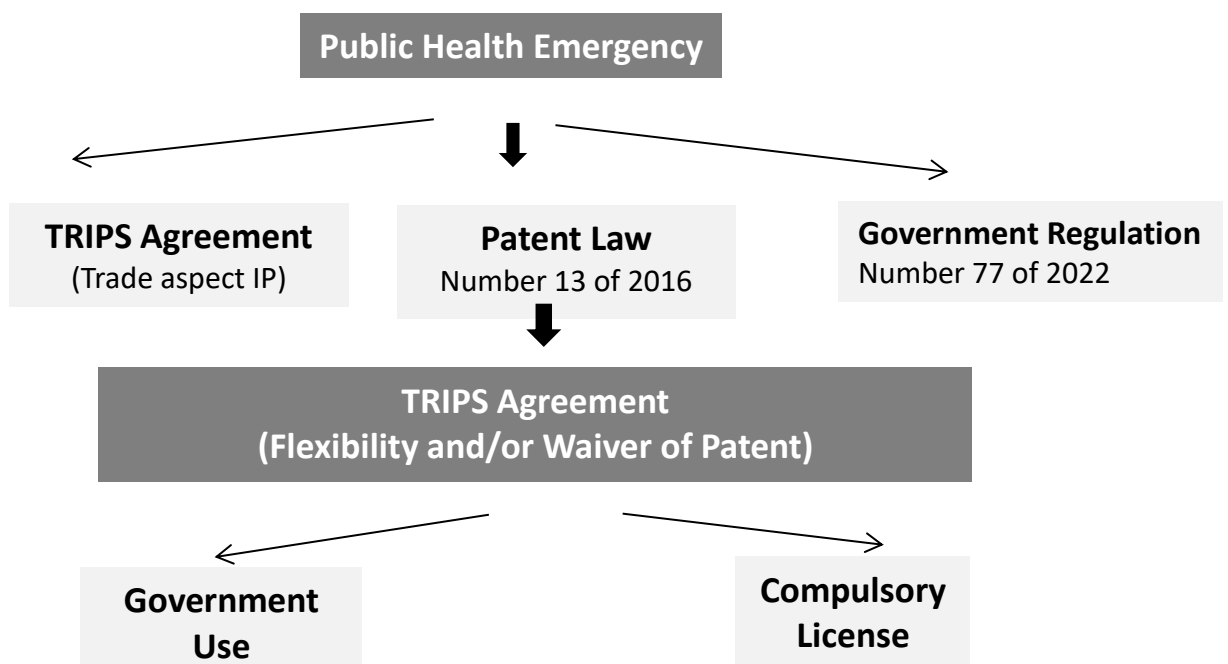
²⁷ Jimly Asshiddiqie, *The Idea of People's Sovereignty in the Constitution and Its Implementation in Indonesia*, Jakarta: PT Ichtiar Baru, 1994. p. 121.

²⁸ H.S. Kartadjoemena., *GATT, WTO and the Main Results of the Uruguay Round*. UI Press. Jakarta (Kartadjoemena) 1997.,page. 16.

²⁹ The agreement allows countries to vary the time of the transition period to implement its rules. The transition, for developed and developing countries respectively in 1996 and 2000. Meanwhile for members of the least developed countries or LDC (least developed countries), until 1 July 2021 in response to a request from the LDC group, or before 2021 if the country is no longer categorized as a lagging country

Organization/WIPO (World Intellectual Property Organization) which aims to further harmonization of the patent system, which could replace the TRIPs Agreement. In addition, bilateral or regional trade and investment agreements between developed and developing countries often include the application of IP regimes that go beyond the TRIPs or TRIPs Plus standards. Thus there is continuous pressure on developing countries to increase the level of IP protection, based on standards in developed countries.

Figure 1: Flowchart of Public Health Emergencies (Based on Law No. 13 of 2016)³⁰



The TRIPS Agreement rules offer some flexibility that can be utilized by WTO member countries, especially developing countries. Some of them are determining the criteria for inventive steps. This opens up the opportunity for

³⁰ Processed by the author by making a Public Health Emergency Flowchart (Based on Indonesian Law No. 13 of 2016 concerning Patent).

third parties to challenge patent applications. Once a patent has been granted, that right can be used to issue compulsory licenses, and parallel imports. In 2001, driven by African countries and several developing countries, the WTO agreed to the Doha Declaration on TRIPs and Public Health and Argumentation of Group of Countries Against the Implementation of the TRIPS Agreement Waiver Proposal (see Table-2).

The Doha declaration is a response to concerns over strengthening IP protection, which is considered to reduce access to medicines, especially in developing and poor countries. The contents of the declaration included member countries agreeing that the TRIPS agreement does not, and should not, prevent member countries from protecting public health. This declaration is a reaffirmation that the TRIPS agreement must be interpreted and implemented in a way that supports the rights of states to protect public health, in particular promoting access to medicines for all.

Several countries have decided to apply for compulsory licenses or government use patents to protect the public from diseases that endanger the public. It is not easy to apply for a mandatory license or use of a patent by the government. In practice, the state's wishes are opposed by patent-owning pharmaceutical companies. Apart from South Africa, several developing countries India and Thailand have also faced challenges when establishing mandatory licensing policies to manufacture certain medicines in their countries. From 2006 to 2008 the Thai government implemented TRIPS Flexibility by using a government use license mechanism using antiretroviral drugs (AIDS), heart disease, and generic forms of anti-cancer medicines.³¹

Figure 3: Flow on Compulsory License Implementation (In Patent System) ³²



³¹ Adun Mohara et al., 'Impact of the Introduction of Government Use Licenses on the Drug Expenditure on Seven Medicines in Thailand', *Value in Health* 15, no. 1 SUPPL. (2012): S95 – S99 [https://www.valueinhealthjournal.com/article/S1098-3015\(11\)03553](https://www.valueinhealthjournal.com/article/S1098-3015(11)03553)

³² Processed by the Author by making the Application of a Compulsory License in the Patent System (With a Compulsory License Based on Article 116 of Law No. 13 of 2016 concerning Patent).

Article 116 Law no. 13 of 2016 concerning Patents juncto Article 14 PP No. 77 of 2020, determined:

In the event that the government cannot implement the patent itself, the government may appoint a third party to implement it under conditions

- a. Must have facilities and be able to apply for a patent
- b. Do not transfer the implementation of the patent granted to another party
- c. Have good production methods, distribution, and supervision in accordance with statutory provisions.



compensation on behalf of the Government in a Compulsory License is carried out by an appointed third party.

(Based on Article 116 paragraph (3) Law no. 13 of 2016 concerning Patents)

**Compensation
(Royalty Fee)**

Therefore, the ideal choice for developing countries³³ for instance Indonesia is if the TRIPs Waiver proposal can be agreed so that we can have a policy by producing vaccines locally. TRIPs Waiver in handling pandemic Covid-19 if it can be accepted and implemented in its member countries it will be able to overcome IP barriers to ensure fair distribution, policy regulation, including efforts to reduce prices to accelerate production development and equitable access for medical use and public health products.³⁴

In the global era of relations in international trade has given birth to new rules and rules of the game which tend to provide limitations for developing countries, including Indonesia, which is a follower of developed countries in various fields. Likewise the rules of the game in today's world free trade which are embodied through the WTO (world trade organization) which also involves trade activities with the protection of all aspects on protecting intellectual property rights under the TRIPs Agreement which is more an instrument for the state developed countries in dominating and occupying a higher bargaining position than developing countries.

³³ Vaccine diplomacy carried out by the government towards vaccines emphasizes humanitarian diplomacy by Ministry of Foreign Affairs Republic Indonesia. Collaborative efforts have also been made through the Access to Patent Tools (APT) Accelerator, (Covid test kits, treatments and vaccines)

³⁴ There are several parties involved, including: WHO, Gavi, CEF, Unitaid, Bill & Melinda Gates Foundation, Wellcome, World Bank, The Global Fund, dan Find.

This pressure or pressure is clearly not beneficial for developing countries, including Indonesia, which still desperately needs the influx of foreign investment in the framework of economic and industrial development. Developing countries reluctantly accepted and signed the agreement.³⁵ Various statements of legitimacy and justification were then issued by the governments of developing countries to accommodate this interest in the form of ratification or drafting of legislation in the field of Patent and Technology Transfer.

International trade issues and become an important icon in the discussion of human intellectual work. This TRIPS Agreement is an international agreement that is generally complete with regard to the protection of IP,³⁶ some parties even discussed that TRIPs Agreement is a breakthrough in cooperation in the field of international trade.³⁷ For developed countries, protection of IPR has become one of the important requirements to protect products from an act of unfair competition, counterfeiting and in order to increase investment.³⁸ When developing countries do not provide protection for IP, investors from developed countries are reluctant to bring their knowledge and technological innovations and invest their capital in developing countries. As mentioned above, TRIPs Agreement was born as a result of pressure from developed countries to protect their commercial interests in the field of Intellectual Property.³⁹

4. Conclusion

Patent Law Policy should be applied Public and Social Interests in the sector of public Health and medical Products. Discourse constraint of the Patent exclusivity under Intellectual Property system may not applied either Licensing and/ or compulsory

³⁵ H. S. Kartadjoemena., Op Cit, p. 531.

³⁶ Ibid, See Doris Estelle Long, Loc Cit, p. 269.

³⁷ Meetali Jain, "global Trade and The New Millennium : defining the Scope of Intellectual Property Protection of Plant Genetic Resources and Traditional Knowledge in India", Hasting International & Comparative Law Review, (Vol. 22, No. 1, Fall 1998), p. 780.

³⁸ William C. Revelos, "Paten Enforcement Difficulties in Japan: Are There Any Satisfactory Solution for The United States", George Washington Journal of International Law and Economy, (Vol. 29, 1995), page. 529.

³⁹ H.S. Kartadjoemena, GATT, WTO and Results of the Uruguay Round Agreement, UI Press, Jakarta. 1997.p. 252-253.

License for Inventions of pharmaceutical products shall be an option of government intervention. Several countries have decided to apply for compulsory licenses or government use patents to protect the public from diseases that endanger the public. Developing countries with lack of facilities continues to fight for equal access before International Cooperation (both bilateral and multilateral) within the scope of international relations is aimed in strengthening cooperation to solve common problems including to apply for a mandatory license or use of a patent by the government for medicines, drugs including vaccines eventhough there is contradicting between Intellectual Property Protection with the Public used with the Government's authority for Patent under TRIPs Agreement.

International trade has given new rules of the game for developing countries, WTO (world trade organization) which also involves trade activities with the protection of aspects of protecting intellectual property rights under the umbrella of TRIPs (Trade Related aspects on Intellectual Property Rights) Agreement which is more an instrument for the state - developed countries in dominating and occupying a higher bargaining position than developing countries. A waiver of the TRIPs provisions (TRIPs Waiver) with respect to agreements on Trade-Related aspects of Intellectual Property may increase national resilience is a belief in one's own abilities and strengths with tenacity which contains the principle based on national identity, integrity in establishing mutually beneficial cooperation in global development.

REFERENCES

Books and Journals

- Adun Mohara et al. (2012), 'Impact of the Introduction of Government Use Licenses on the Drug Expenditure on Seven Medicines in Thailand', *Value in Health* 15, no. 1 SUPPL. (2012): S95 – S99
[https://www.valueinhealthjournal.com/article/S1098-3015\(11\)03553](https://www.valueinhealthjournal.com/article/S1098-3015(11)03553)
- Alfons, Maria. (2018), "Implementation of intellectual property rights in a rule of law perspective" *Journal of Indonesian Legislation*, Vol. 14, No. 3.
- Asshiddiqie, Jimly., (1994) *The Idea of People's Sovereignty in the Constitution and Its Implementation in Indonesia*, Jakarta: PT Ichtiar Baru van Hoeve.
- BAPPENAS (National Development Planning Agency/ BAPPENAS), (2019)., *Health Sector Study on the Provision of Drugs*,

- Vaccines and Medical Devices, Directorate of Public Health and Nutrition., Deputy for Human, Community and Cultural Development Ministry of National Development Planning / National Development Planning Agency BAPPENAS, 2019 Accessed from https://www.bappenas.go.id/files/8015/9339/2165/FA_Preview_HSR_Book06.pdf,
- Bailey, Michael, R. M., & Smith, M. (2010)., *Fatal Side Effects: Medicine Patents Under the Microscope*: London.
- Correa, Carlos (2020). *Trade related aspects of intellectual property rights: a commentary on the TRIPS agreement*. Oxford University Press.
- Goldsworth, Jeffrey, (2001)., *Legislative Sovereignty and the Rule of Law in Skeptical Essays on Human Rights*, (Tom Campbell, Keith D. Ewing, Adam Tomkins eds. Oxford University Press.
- Huang, Can. (2017), "Recent development of the intellectual property rights system in China and challenges ahead", *Management and Organization Review* 13.1, Peking: (2017).
- Jackson, John H. (1995), *Legal Problems of International Economic Relations: Cases, Materials and Text on the National and International Regulations of Transnational Economics* (American Casebook Series), West Group.
- Jain, Meetali (1998), "Global Trade and The New Millennium : defining the Scope of Intellectual Property Protection of Plant Genetic Resources and Traditional Knowledge in India", *Hasting International & Comparative Law Review*, (Vol. 22, No. 1, Fall 1998).
- Kartadjoemena, H.S. (1997), *GATT, WTO and Uruguay Round Results*, UI Press, Jakarta.
- Lemhannas RI (2021) *Main Materials in the Field of National Defense Studies.*, Publisher of the National Defense Institute of the Republic of Indonesia, Jakarta.
- Long, Doris Estelle. (1998), *The Impact of Foreign Investment on Indigenous Culture: An Intellectual Property Perspective*, *North Carolina Journal of International Law and Commercial Regulation*, (Vol. 21, Winter 1998),
- Margono, Suyud, (2019) *Provisions on Trade Related Aspect Intellectual Property Rights-(TRIPs) Plus in FTA: Threatening Impact on Access to Community Rights to Health and Medicine*, Research, Faculty of Law, Tarumagara University, Even Semester 2019/2020.
- Muhammad, Abdul Kadir, (2004)., *Law and Legal Research*, (Bandung: PT Citra Aditya Bakti), Indonesia.
- Peter Drabos, Peter, (1996)., *A Philosophy of Intellectual Property.*, Burlington: Ashgate.
- Revelos, William C, (1995) "Patent Enforcement Difficulties in Japan: Are There Any Satisfactory Solution for The United States", *George Washington Journal of International Law and Economy*, (Vol. 29, 1995).

- Soekanto, Soerjono, Sri Mamudji, (2012) Normative Legal Research, (Jakarta: PT Raja Grafindo Persada), Indonesia.
- Strauss, Leo and Joseph Cropsey, (1987) Immanuel Kant, History of Political Philosophy, University of Chicago Press, Chicago and London.
- Sun, Haochen (2004), 'The Road to Doha and Beyond: Some reflections on the TRIPs Agreement and Public Health', EJIL 15. Accessed from: <http://www.ejil.org/pdfs/15/1/335.pdf> January 2021.
- Sunggono, Bambang., Method of Legal Research, (Jakarta: PT Raja Grafindo Persada), 2001, Indonesia.
- Taubman, Anthony (eds), (2012) 'A Handbook On The WTO TRIPs Agreement', Cambridge University Press., https://www.wto.org/english/res_e/publications_e/handbook_wtoTRIPsag12_e.pdf, October 2020.
- TRIPs Agreement - Agreement on Trade-Related Aspects of Intellectual Property Rights Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, Marrakesh, Morocco, 1994.WTO Agreement.
- World Health Organization (2004) WHO Policy Perspective on Medicines - Equitable access to essential medicines: a framework for collective action, World Health Organization, Geneva
- World Health Organization (2001), How to Develop and Implement a National Drug Policy (2nd Ed).
- World Health Organization (2020), How to Develop and Implement a National Drug Policy (2nd Ed, 2001), at 33 Accessed May 2020. GENEVA: The World Health Organization announced on Friday (May 7) it had approved a COVID-19 vaccine from China's state-owned drug industry Sinopharm for emergency use.
- World Health Organization (2021)., WHO Policy Perspective on Medicines - Equitable access to essential medicines: a framework for collective action, World Health Organization, Geneva, 2004, at 1 Accessed January 2021.

Website (Internet Link):

- DGIP, 2021, Government Prepares Cheap Covid 19 Drugs., <https://dgip.go.id/article/detail-article/government-prepare-cheap-covid-19-drugs-category=coverage-public-relations>. News January 13, 2021
- Gavi (The Vaccine Alliance), 2021., <https://www.gavi.org/tag/covid19>., Gavi is co-leading COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator. This involves coordinating the COVAX Facility, a global risk-sharing mechanism for pooled procurement and equitable distribution of COVID-19 vaccine.

- Indonesia for Global Justice (IGJ) 2020., Indonesia's Covid-19 Vaccine Diplomacy: "Challenges to Public Access to Vaccines and Equitable Health Services <https://igj.or.id/diplomacy-vaccine-covid-19-indonesia-challenge-access-public-on-vaccine-and-equitable-health-services/>, News 17 December 2020
- Kompas.com., "Contents to Article 33 of the 1945 Constitution and its meaning", <https://www.kompas.com/skola/read/2021/07/05/132235369/isi-article-33-uud-1945-and-its-meaning>. News 5 July 2021
- Kontan.co.id., Priority of Indonesian Vaccine Diplomacy., <https://analysis.kontan.co.id/news/priority-diplomacy-vaccine-Indonesia>, 11 May 2021
- The Third World Networks Indonesia, research results released in https://www.indopremier.com/ipotku/newsDetail.php?jdl=World_Struggle_Vaccines_Covid_19_Time_to_Behave_More_Fair_To_Vaccines_From_Russia_dan_China&news_id
- <https://www.wartaonomi.co.id/read282516/> the shifting of the patterns of relation-internasional-states-states-world-in-middle-pandemic-corona. Shifting Patterns of International Relations of World Countries Amid the Corona Outbreak, 23 April 2020,
- <https://news.detik.com/berita/d-5630844/still-bad-case-corona-ri-4-july-add-27233-mortality-record-555>, News 4 July 2020.
- <https://kompas.com/sains/read/2021/03/02/193000223/ayear-pandemi-covid-19-ini-6-related-virus-corona-yang-still-become?page=all>. , March 2, 2021.
- <https://www.cnbcindonesia.com/news/20210507094616-4-243981/top-biden-down-mountain-as-agree-delete-patent-vaccine-covid>., 7 May 2021.
- United States Trade Representative., 2021 <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-TRIPs-waiver>., Release 5 May 2021.
- <https://katadata.co.id/febrinaiskana/berita/5fcbb6ba0f184/terawan-enacted-6-types-vaccine-covid-19-which-will-be-used-in-ri>., 5 December 2020.
- <https://www.presidentri.go.id/foto/president-ri-sdelivered-pidato-virtual-pada-ktt-kesehatan-global-2021/> virtual speech at the Global Health Summit (Summit) on Global Health, 21 May 2021
- World Health Organization (2003), 'WHO Policy Perspectives on Medicines: How to develop and implement a National Drug Policy' (2003) <<https://www.who.int/management/background>

Legislations:

Indonesian Law Number 13 of 2016 concerning Patents
Presidential Regulation Number 77 of 2020 concerning provisions for
procedures for patent applications by the government
Decree of the Minister of Health Number 189/Menkes/SK/III/2006
concerning National Drug Policy