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Mechanism and Waiver of Covid-19 Vaccine Patent Rights According To *Agremeent on Trade-Related Aspects of Intellectual Property Rights* (*Trips*)

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ABSTRACT: TRIPS' patent policy limits the country's efforts in drug development, especially in the manufacture of generic drugs – drugs made after the patent period has expired. Patents greatly affect prices because they have a monopoly of ownership and require royalties from patent owners, such as rules about the selling price of drugs and the location of their distribution. The purpose of this study is to identify and study the licensing mechanisms necessary to protect public health access rights, COVID-19 vaccine patent filings in emergency situations, and COVID-19 vaccine patent waivers according to the Agremeent on Trade-Related Aspects of Intellectual Property Rights (TRIPs). The results of the study show that in an emergency, the mechanism for filing a patent for a Corona virus drug can be carried out based on the rules of Article 31 of the TRIPs Agreement, which allows the state to apply for a mandatory license or government use, especially in critical situations. This means that patents can be applied without the permission of the patent owner so that the Corona vaccine and drug are immediately made on a mass scale. The Government of Indonesia can use patents based on Patent Law No. 13 of 2016. In emergency situations, the government can patent without the permission of the patent holder. The United States can ignore COVID-19 vaccines as a progressive policy and encourage multilateral cooperation. Thus, developing countries must take advantage of this waiver to push for international reform of patent law to fulfill the right to public health.

KEYWORDS: Patent Rights, Vaccines, Covid-19, TRIPs.

I. INTRODUCTION

The COVID-19 pandemic has caused many problems in various areas, such as work, school, and finance. The government cannot solve everything alone, so many companies in Indonesia are helping. They give money, medicine, and free internet to people in need. This is called Social Responsibility, which means the company helps during difficult times[1].

In an effort to curb the spread of the virus, the COVID-19 pandemic has resulted in social restrictions and communal activities. It can be difficult for pharmacists to serve patients with high-quality services while still adhering to established health protocols because they are healthcare professionals[2].

Vaccine manufacturers in Indonesia face challenges, especially related to patents and global cooperation in developing treatments for the virus. This patent policy could limit the development of generic drugs, which are a cheaper alternative to patent drugs. This can affect how affordable and easy it is for patients to get medicines. The COVID-19 pandemic has caused changes in the way people interact with each other and participate in activities to stay healthy and prevent the spread of the virus. This also has an impact on companies in the pharmaceutical sector in Indonesia that focus on the provision of medicines and medical devices. Several companies, such as PT Kimia Farma Tbk, PT Kalbe Farma Tbk, and PT Indofarma Tbk, also helped by donating resources to fight this pandemic.

Vaccine manufacturers in Indonesia continue to face a number of problems, including patents, despite the importance of international collaboration in the development of drugs to overcome the coronavirus. Vaccine manufacturers face several challenges, especially those from developing countries. First, due to strong coalitions among wealthy countries, access to new vaccination research and development has become limited. Second, patents are subject to restrictions[3].

[1] Helisa Noviarty dan Yuniarsih Edryani, 2021, "Dampak Pandemi iCovid-19 Terhadap Pengungkapan Tanggung Jawab Sosial Pada Sektor Farmasi", *Jurnal Audit dan Akuntansi Fakultas Ekonomi,* Vol. 10 No. 2, 12

[2] Nisa Maria, dkk, 2022, "Pelaksanaan Pelayanan Farmasi Klinik di Apotek Pada Masa Pandemi COVID-19: Suatu Literature Review", *Saintech Farma: Jurnal* i*Ilmu Kefarmasian,* Vol. 15 No.1, 2

[3] Lidya Shery Muis, 2019, "Hak Atas Aksesibilitas Obat Paten Bagi Masyarakat", *Jurnal Pranatam* Vol. 2, No. 1, 37

TRIPS' patent policy limits the country's efforts in drug development, especially in the manufacture of generic drugs – drugs made after the patent period has expired. Patents greatly affect prices because they have a monopoly of ownership and require royalties from patent owners, such as rules about the selling price of drugs and the location of their distribution. Thus, patents can prevent patients from obtaining drugs[4].

Pharmaceutical products, such as medicines, vaccines, and others, are products resulting from new inventions resulting from research and/or technological development. Patent holders can have the right to protect pharmaceutical products by providing them with the legal protection of Intellectual Property Rights (IPR), as the principle of an IPR based on the protection of trade secrets or also known as undisclosed information[5].In this regard, in general, the protection of patent rights is very important because the price of patent products tends to increase, which can hinder the development of the industry. Law Number 13 of 2016 concerning Patents, or the Patent Law, has given the government the authority to carry out the use of patents by the government to meet the needs of pharmaceutical and biotechnology products. This is related to the provision of very urgent needs for the benefit of public health[6].

Criticism of pharmaceutical products, particularly in the context of patents and accessibility, focuses on a few key issues that are often considered to be contrary to the public's interest in accessing affordable and effective health care. Based on the background, this paper will explore a legal review of the provisions of the Covid-19 vaccine patent based on the provisions of TRIPs. Therefore, the researcher formulated the title of this paper, namely "Mechanism and Waiver of Covid-19 Vaccine Patent Rights According to Agremeent on Trade-Related Aspects Of Intellectual Property Rights (TRIPs)".

II. RESEARCH QUESTION

1. How compulsory licensing is for the protection of public health access rights?
2. What is the mechanism for filing a Covid-19 vaccine patent in an emergency?
3. How is the waiver of the patent rights of the Covid-19 vaccine according to *Agremeent on Trade- Related Aspects of Intellectual Property Rights* (*TRIPs*)?

III. RESEARCH METHOD

Research this research uses normative juridical research (legal research), which is research that uses materials from written regulations or other normative legal materials. Another name for this research is library research, because it is focused on the collection of documents and library data[6]. Normative juridical law research is research on socially formed legal doctrines and principles contained in literature and legal science[7]. This research uses a legislative approach (statue approach) and a conceptual approach.

In this study, the author uses legal materials based on documents. The secondary data that the researcher uses is in the form of materials sourced from documents rather than from sources as the main legal material, as is the nature of normative research[8].The sources of legal materials used, namely primary and secondary legal materials. The primary legal materials that will be used by the researcher in this study are Patent Law No. 13 of 2016 and Agremeent On Trade-Related Aspects Of Intellectual Property Rights (TRIPs). Meanwhile, secondary legal materials are in the form of draft laws, books, journals, and opinions of experts in the legal field[9].The collection of legal materials through data collection data collection using a bibliography study. Meanwhile, data analysis adopts a qualitative analytical descriptive method using a deductive logic approach.

IV. RESULT AND DISCUSSION

Mandatory License For Protection Of Public Health Access Rights.

Some of the thoughts offered by TRIPs Agremeent are mandatory licenses, which are used to mitigate the negative effects of applying patent protection. So far, the implementation of patent protection for pharmaceutical products, especially essential drugs, is considered to only protect the manufacturer, usually. Multi-National Corporations, (MNCs) that come from developed countries, rather than protecting the general public who need cheap or affordable essential medicines that usually come from developing or

[4] Raden Bagoes Prasetyo Raharjo dan Kholis Roisah, 2021, "Hak Akses Kesehatan Masyarakat Terhadap Hak Paten Produk Farmasi", *Jurnal USM Law Review*, Vol. 4 No. 2, 605

[5] Yuliana Maulidda Hafsar, 2021, "Hak Atas Kekayaan Intelektual, Hak Merek, Rahasia Dagang, Dan Pelanggaran Hak Merek Dan Rahasia Dagang Serta Hak Patent", *Jurnal Dinasti Review*, Vol.2 No.6, hlm.734 [6] Yustisiana Susila Atmaja, dkk, 2021, "Pelindungan Hukum Terhadap Paten Produk Farmasi Atas Pelaksanaan Paten Oleh Pemerintah (*Government Use*)",
Jurnal Masalah-Masalah Hukum, Jilid 50 No. 2, 197

[6] Soerjono Soekanto, 2006. *Pengantar Penelitian Hukum*, Jakarta : UI Press, 34

[7] Zainuddin Ali. 2016. *Metode Penelitian Hukum*, Jakarta: Sinar Grafika, 17

[8] Suteki. 2022. *Metode Penelitian Hukum*, Depok: Raja Grafindo, 266

[9] Muhaimin. 2020. *Metode Penelitian Hukum*, Mataram: Mataram University Press, 60

backward countries. Therefore, during the Uruguay Round of Negotiations, the Protective Articles – also known as Alien TRIPs – were granted to protect the interests of the Right to Public Health Access[10].

The flexibility contained in TRIPs Agremeent includes compulsory ilicense, government iuse, parallel import, and Bolar Provision. A mandatory license is the authority granted by an Intellectual Property institution or administrative authority to a third party to use a patented invention without the approval of the Patent Holder on the basis of public interest (unenforced patents, public health, monopolistic practices, emergencies, and national defense).

In Article 31 of the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights), which is part of the agreement agreed within the scope of the World Trade Organization (WTO). TRIPS is an agreement that regulates various aspects of intellectual property rights at the international level. Article 31 of TRIPS deals with mandatory use (compulsory license) in the context of patents. The following are some general provisions contained in Article 31 of TRIPS:

a. Obligation to Grant Compulsory License: Article 31 provides that WTO members may permit the compulsory use of patents by other parties without the permission of the patent owner in certain situations.
b. Mandatory Terms of Use: TRIPS regulates the conditions that must be met by the party who will use the mandatory license, including the payment of reasonable royalties to the patent owner.
c. Purpose of Mandatory Use: Article 31 provides guidance on the purpose of mandatory use, including to ensure that such use does not detract from fair and reasonable patent protection for the owner.
d. Limitations on Compulsory Use: Article 31 also contains limitations on compulsory use, including restrictions related to production quantity, time, and territory.
e. Notice to the Patent Owner: TRIPS needs to provide notice to the patent owner before using the mandatory license, except in exceptional emergencies.
f. Obligation to Make Meaningful Business: TRIPS affirms that the party using the compulsory license must make a meaningful business to meet its own domestic needs, and that such use must not or is unreasonably disruptive to normal trade.

One way to address the protective effect of drug patents on access to cheap drugs is to provide mandatory licensing, from a public health perspective. Naomi A. Bass found in her research that Compulsory licenses for medicines are a legal mechanism that allows the government to grant permission to third parties to manufacture, use, or sell a patented product without the consent of the patent holder. This practice is regulated in an international context by the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) which is under the auspices of the World Trade Organization (WTO). Mandatory licensing is often considered an essential tool in public health emergencies or when the price of patented drugs is too high to be affordable for a large portion of the population. The pharmaceutical industry, which is mostly multinational companies from developed countries, opposes mandatory licensing because they believe that it will only limit technological innovation and reduce the desire of pharmaceutical companies to develop new drugs. However, it is an opportunity for developing or underdeveloped countries to obtain medicines at lower prices, allowing them to meet the medicinal needs of their citizens.

The right to access public health is included in human rights and is a basic human right. In Indonesia, the public's right to access health is protected by Law No. 39 of 1999 concerning Human Rights, Law No. 36 of 2009 concerning Health, and Law No. 13 of 2016 concerning Patents. In addition, the Indonesia government has ratified several international legal instruments, including the Universal Declaration of Human Rights.

Mekanisme Pengajuan Hak Paten Vaksin Covid-19 dalam Keadaan Darurat.

The government reserves the right to establish the necessary patent policies to ensure that patent holders act in accordance with the public interest. Although exclusive rights to patents are granted to patent holders in a limited way, states can intervene to make regulations that are restrictive in nature[11].To ensure fairness, exclusive rights must be balanced by patent holders and the interests of the community. On the other hand, patents are created to promote and encourage new creations by granting patent holders an almost monopolistic exclusive right. Conversely, patents can hinder public access to health services and medicines.

The purpose of patent enforcement by the government in the context of pharmaceutical products, particularly in mechanisms such as compulsory licensing, aims to ensure the availability, affordability, and access to pharmaceutical products that are important for public health. This is often done in situations where public health interests and urgent community needs are priorities. In Indonesia, Law No. 13 of 2016 concerning Patents, or Law No. 13 of 2016, and Presidential Regulation No. 77 of 2020 concerning Procedures for the Implementation of Patents by the Government, or Presidential Regulation No. 77 of 2020, is a law that regulates the implementation of patents by the government. In accordance with Article 109 paragraph (1) letter b of Law Number 13 of 2016

[10] Achmad Zen Purba, 2004, "*TRIPs* dan Negara-Negara Berkembang", *Jurnal Hukum Internasional,* Vol. 1 No. 2, 247.

[11] Masnun, M. A dan Roszana, 2019, "Persoalan Pengaturan Kewajiban Pemegang Paten untuk Membuat Produk atau Menggunakan Proses di Indonesia", *Jurnal Hukum Ius Quia Iustum,* Vol. 26 No. 2, 332

and Article 2 letter b of Presidential Regulation Number 77 of 2020, pharmaceutical product inventions must first obtain patent protection in Indonesia.

In Law Number 13 of 2016 concerning Patents in Indonesia, the criteria for pharmaceutical product patents are regulated to ensure that innovations in the pharmaceutical sector receive adequate protection while still paying attention to the interests of the community. Based on Article 111 letter a of the Law, the criteria used by the government in the implementation of pharmaceutical product patents can be categorized in several aspects, although in a more specific context there are three main criteria that are often taken into consideration, namely:

1. Novelty: The product must have new features that have never been disclosed or known to the public before. This means that the product must not be part of a public technology or have been published in any form prior to the date of filing the patent.
2. Inventive Step (Invention Step or Invention Level): The product must demonstrate the presence of an inventive step that is not obvious to someone skilled in the relevant engineering field. In other words, the product should not be obvious to experts in the field after considering the existing technology.
3. Industrial Application (Industrial Application): The product must be applicable in industry or must be able to be manufactured or used in industry anywhere. This ensures that the granted patents are not only theoretical, but also have practical applications within the relevant industries.

The procedure for implementing pharmaceutical product patents by the government further refers to Presidential Regulation Number 77 of 2020. Based on Articles 16 to 18 of Presidential Regulation Number 77 of 2020 regulates the mechanism for submitting applications for patent implementation by the government. The submission of an application for the implementation of a pharmaceutical product patent is submitted by the minister of health to the Minister in charge of government affairs in the legal field (Minister of Law and Human Rights) in writing by fulfilling the application requirements as stated in Article 16 paragraph (2) of Presidential Regulation Number 77 of 2020. Then, the Minister conducts an administrative examination in the form of the completeness of the application and the examination of the legal status of patent protection of pharmaceutical products according to the application that has been submitted.

In the event that the application is declared incomplete, the minister of health is given a maximum period of 14 (fourteen) days from the date of return to complete the application. If the pharmaceutical product submitted is not protected by a patent in Indonesia and/or the completeness of the application is not completed by the applicant, then the application is rejected. Then, the Minister notifies the patent holder of pharmaceutical products of the submission of an application for patent implementation by the government within a maximum period of 5 (five) days from the time the application is declared to have met the administrative requirements and legal status of patent protection.

In order for the Corona vaccine or drug to be made in mass as soon as possible, patents can go through mandatory licenses or patent applications by the government. Based on the rules of the TRIPs Agreement Article 31, it is possible for a country to make a mandatory license application or government use, especially in critical conditions so that there is a possibility of patent application without permission from the patent owner. In international conventions, the patent protection system in national law has been approved as the basis for support for the protection system. The support is an adjustment of national law with international conventions. So that there will be the same legal protection between countries that have signed international conventions related to IPR.

In accordance with Articles 19 and 20 of Presidential Regulation Number 77 of 2020, the Minister establishes a team from various elements, including ministries in charge of government affairs in the legal field, the ministry of health, ministries in charge of government affairs in the financial sector, ministries in charge of government affairs in the field of state secretariat, and experts through the Ministerial Decree to provide consideration and determine the amount of rewards in the a maximum period of 90 (ninety) days from the enactment of the Ministerial Decree. Then, the results of the implementation of the duties carried out by the Team are submitted to the Minister and in the event that the Minister gives approval, the Minister will convey the results of the implementation of the duties to the President within a maximum period of 15 (fifteen) days from the time the Minister gives approval to be stipulated by the Presidential Regulation. The Minister submits a copy of the Presidential Regulation to the patent holder of the pharmaceutical product.

The government, in this case the Ministry of Health, can take various policies to provide the needs of domestic pharmaceutical products, such as medicines by:

1. Importation of pharmaceutical products, that the government can import generic versions of pharmaceutical products or patented drugs from other countries that do not provide patent protection for such pharmaceutical products;
2. Local production that the government can grant permission to the public or private pharmaceutical industry to locally produce pharmaceutical products that are patented generic versions or otherwise known as second-quality drugs.

Based on Article 116 of Law Number 13 of 2016 and Article 14 of Presidential Regulation Number 77 of 2020 regulating the executor of patents by the government, the Ministry of Health, represented by the Minister of Health, plays the role of executor of pharmaceutical product patents. The health minister can appoint a third party to execute the patent on behalf of the government if

the government is unable to enforce the patent itself. In determining a third party, the minister of health is required to pay attention to the requirements of the third party, including: (a) having facilities and being able to carry out patents; (b) does not transfer the exercise of the patent to another party; (c) have good production methods, circulation, and supervision in accordance with the provisions of laws and regulations. In this case, the Ministry of Health is obliged to carry out periodic supervision and control during the implementation of pharmaceutical product patents by third parties on behalf of the government.

The implementation of patents by the government cannot be carried out exclusively as the patent holder can continue to use the patent rights for the duration of the patent protection granted. The government's right to enforce pharmaceutical product patents must be limited only based on the purpose of its implementation, namely to meet urgent needs for public health interests while still subject to applicable laws and regulations. When the government decides to exercise its rights, the government also has the responsibility to ensure that the implementation of patents carried out by itself can be carried out effectively and on target by looking at the scope and duration of patent implementation by the government. Therefore, the government should be able to make maximum efforts in implementing patents to ensure the availability of easier and more affordable access to pharmaceutical products for the public during a predetermined period of time.

Pharmaceutical product patent holders are entitled to obtain legal protection during the implementation of patents by the government and have been guaranteed in the applicable laws and regulations. The existence of legal protection can be said to be a concrete form that the implementation of pharmaceutical product patents by the government does not limit or hinder the interests of patent holders related to the fulfillment of exclusive rights that have been granted by the state during the patent protection period. Exclusive rights are property rights that have economic value (economic rights) in exchange for the sacrifice of time, energy, thoughts, and costs incurred to produce an invention. Patent holders not only have exclusive rights, but their patents implemented by the government have also given rise to special rights for patent holders implied in Law Number 13 of 2016 and Presidential Regulation Number 77 of 2020.

Concept Although the implementation of a pharmaceutical product patent by the government is likened to forcibly taking a pharmaceutical product patent, the government is still responsible for notifying in writing to the pharmaceutical product patent holder regarding the implementation of the patent by the government in accordance with the provisions of Article 114 paragraph (1) of Law Number 13 of 2016. In accordance with Article 114 paragraph (2) of Law Number 13 of 2016 and Article 20 of Presidential Regulation Number 77 of 2020, the Minister submits a copy of the Presidential Regulation regarding the determination of the implementation of pharmaceutical product patents to patent holders as a form of written notification. With this notification, pharmaceutical product patent holders can find out the process of implementing patents by the government submitted by the minister of health and the stipulation of Presidential Regulations regarding the determination of patent implementation by the government.

The granting of patent protection is carried out after the patent is deregistered, the grant of this patent is according to the application. Based on the rules of the law, each IPR must be registered. Registration in accordance with the requirements of the law as a recognition of justification for IPR shown by a registration certificate so that it receives legal protection[12]. IPR protection due to the obligation of registration is called a constitutive system. Based on the constitutional system, individual IPRs receive recognition and protection from the law if registered. Not registered means that it is not protected and recognized. The constitutive system is embraced by Law No. 13 of 2016[13].

Patent Law No. 13 of 2016 is the application of patents for the government of Indonesia. The government can patent without permission from the patent holder in an emergency. Such as in making pharmaceutical or biotechnology products at high prices or needed in dealing with diseases that can cause sudden death in large numbers, causing significant defects and as KKMMD.

Drug inventors still get their economic rights and their inventions are protected. Dede Mia Yusanti as an official of the Ministry of Law and Human Rights who serves as the Director of Patents, DTLST and Trade Secrets, revealed that patent registration must be in accordance with the process enforced. Each applicant must comply with the existing requirements and processes, namely formality checks, announcements, and substantive checks must be carried out. He emphasized that patent protection starts from the time the patent applicant gets the date of acceptance, even though the grant of the patent will be realized after the process. The applicant may request an acceleration of the announcement so that the process from submission to the end of the examination can take place faster, this is based on the applicable law. But the rule is applied to the public, not limited to emergency conditions.

Until now, there has been no patent for the Corona drug or vaccine registered in Indonesia. However, a patent for an ingredient from the BCL formula that can be declared to prevent Corona has been issued at the DJKI. However, this does not mean that the formula can be used to treat people with COVID-19. Any formulation of the drug that differs from the previous formula must be approved for use by the relevant authorities. The DJKI only protects patents according to the patentability criteria. However, in order for the patent to be used publicly, it needs to be evaluated by BPOM. The services of the Directorate General of Intellectual Property, www.dgip.go.id , serve patent and intellectual property registration during the Corona pandemic.

[12] Zaeni Asyhadie, 2012, *Hukum Bisnis Prinsip dan Pelaksanaannya*, PT RajaGrafindo Persada, Jakarta, 12

[13] Valentino M Demmassabu, 2017, "Penghapusan Lisensi Paten Oleh Pemegang Hak Paten Menurut UndangUndang Nomor 13 Tahun 2016 Tentang Paten," *Jurnal Lex Privatum*, Vol. 5 No. 2

Mechanism and Waiver of Covid-19 Vaccine Patent Rights According To Agremeent on Trade-Related Aspects of Intellectual Property Rights (Trips)

Exemption of Covid-19 Vaccine Patent Rights According to *Agreement On Trade-Related Aspects of Intellectual Property Rights* (*TRIPs*)

The conditions for patentable goods with Covid-19 vaccines are outlined below based on the details and meanings of article 27 of the TRIPs. First and foremost, it must be an "invention". COVID-19 vaccines have been shown to help stop the global pandemic. Until now, there is no specific drug that can cure the COVID-19 virus, so people who are infected can only resign themselves to the high risk of death. The COVID-19 vaccine breaks the chain of disappointment and gives vaccine recipients immunity, which allows them to fight viruses that attack the inner body. So, the COVID-19 vaccine is an "invention".

In addition, the patent must contain "technology", i.e. the skill to solve problems with a specific scientific method. To ensure the quality, effectiveness, and safety of the Covid-19 vaccine in humans, vaccine manufacturing requires various stages of research and clinical trials, which take time, even years. This clinical trial was carried out by comparing the effects of the vaccine with a placebo. This is aimed at ensuring the quality, effectiveness, and safety of the Covid-19 Vaccine in humans. Clinical trials for COVID-19 vaccines, such as clinical trials for other vaccines or drugs, must follow strict procedures to ensure the safety and efficacy of the product. This process involves several stages of trials conducted on humans, after a series of preclinical tests have been conducted first on animal models. The following are the steps or procedures of clinical trials that are commonly carried out in vaccine development, including the COVID-19 vaccine:

1. Pre-Clinical Trials

   Prior to clinical trials in humans, the vaccine was tested on animal models to assess its safety and ability to induce an immune response. This test includes an evaluation of possible side effects and the optimal dose to be used.
2. Phase I

   Clinical trials begin with Phase I, where the vaccine is administered to a small number of healthy people, usually between 20 and 100 volunteers. The main objectives of this phase are to assess the safety of the vaccine and to determine the safe dose and observe the resulting immune response.
3. Phase II

   In Phase II, the vaccine is given to a larger group (hundreds of people) to test its effectiveness and learn more about safety. Participants in this phase may include a broader demographic (age, ethnicity, gender). This phase also helps researchers collect data on the exact dose and schedule of vaccine administration.
4. Phase III

   Phase III is a large-scale clinical trial that includes thousands to tens of thousands of licenses. This phase is critical to confirming the effectiveness of the vaccine and maintaining rare side effects that may not have been detected in smallerscale clinical trials. Typically, this phase also includes a control group that receives a placebo or an alternative vaccine for comparison.
5. Submission for regulatory approval.

   After the data from the third phase of the clinical trial is collected and analyzed, the vaccine manufacturer submits a complete data package to regulatory bodies (such as the FDA in the United States, the EMA in Europe) for emergency use approval or full approval.
6. Phase IV

   Once the vaccine has been approved, phase IV begins, which involves post-marketing monitoring. This phase aims to combine the long-term side effects that may arise and to ensure the vaccine remains effective and safe when used in a larger and more diverse population.

This clinical trial procedure is designed to ensure that the vaccine developed is not only effective in preventing disease, but also safe for use by the public. Every step in this process is closely monitored by various regulations and guidelines set by global and national health authorities.

The spread of COVID-19 vaccines and rising global health concerns are driving the abandonment of TRIPs, which began in October 2020 by India and Africa. The important thing about the proposal is that COVID-19 vaccine patents are ignored during the pandemic, so that vaccine distribution can be carried out quickly and massively. This is because the COVID-19 pandemic has claimed many lives in a short period of time, increasing the death rate worldwide. Crises that have occurred in South Africa include the HIV (HIV) crisis, the 2004 H5N1 bird flu outbreak, and the 2009 H1N1 bird flu outbreak, all of which pose a problem for developing countries to get a cure.

Because the Covid-19 waiver has not been agreed, developed countries that are the homebase of vaccines, where vaccines are created, can only be purchased by countries with high incomes. The vaccine that is happening now is a difference in vaccine delivery / vaccine apartheid, where rich countries buy almost all of the supply so that other countries do not get their share equally.

Neglect of Covid-19 Vaccines is more focused on the country where the Vaccine originated. For example, the Pfizer vaccine made in the United States. If the U.S. agrees to a waiver of the Covid-19 Vaccine, it means that other countries can freely request the vaccine formula for use such as being produced independently domestically. However, if the United States does not agree with

the waiver of the Covid-19 vaccine, it means that other countries must carry out procedures to ask for legality permission to be able to obtain vaccine data through a license. The WTO does not have the power to determine this, so the neglect of something is the full authority of a sovereign state.

The granting of Patent Rights to the Covid-19 Vaccine gives monopoly rights to the inventor of the Vaccine, so that it can obtain economic rights to the results of its findings. But on the other hand, the waiver of the Covid-19 Vaccine Patent will not provide economic rights for inventors, but can provide easy access for the global community to be able to recover, gain immunity from the Corona Virus, and accelerate the end of the Covid-19 pandemic.

Despite the debate over the TRIPs Waiver, some agree and some disagree, but the filing of a Patent by the inventor is still the authority of the country where it is registered. The WTO cannot revoke an inventor's patent because the WTO is not a patent registration body. The WTO is more of a space consisting of various countries to discuss so that an agreement can be reached jointly.

The country that grants the patent will not grant the inventor's economic rights and monopoly on the product. Instead, the inventors were satisfied with the findings of their research that helped human survival. This renunciation does not last forever; it only lasts until the COVID-19 pandemic ends. Once the pandemic is over, inventors can return to exercising their rights if they want to sign up for the COVID-19 vaccine. Since this is entirely the right of a particular individual, group, or body, there is no other risk that will affect, other than the cost, time, and thought spent. In general, the waiver or waiver of these TRIPs has been in accordance with applicable international rules and conventions approved by countries around the world.

CONCLUSIONS

The right to access public health is included in the basic human rights. In Indonesia, the public's right to access health is protected by the 1945 Law, Law No. 39 of 1999 on Human Rights, Law No. 36 of 2009 on Health, and Law No. 13 of 2016 on Patents. In addition, the Indonesia government has ratified several international legal instruments, including the Universal Declaration of Human Rights.

Taking into account Law No. 13 of 2016 and Presidential Regulation No. 77 of 2020, the government can establish patents for pharmaceutical products for the public interest. Rule Article 31 of the TRIPs Treaty allows countries to apply for patents for Coronavirus drugs in an emergency. This allows countries to apply for mandatory licenses or government use, especially in critical situations, so that patents can be applied without the permission of the patent owner to facilitate the manufacture of vaccines and Corona drugs in bulk quantities. Law No. The Government of Indonesia established a patent in 2016. In emergency situations, the government can issue a patent without the permission of the patent holder.

The United States can ignore COVID-19 vaccines as a progressive policy and encourage multilateral cooperation. Therefore, developing countries should take advantage of this waiver to push for patent law reform globally to fulfill public health rights.

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