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Dealing with A State of Emergency: A Comparative Study Between Indonesia and Malaysia in Government Use for Pharmaceutical Products

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ABSTRACT: The implementation of patents by the government has become a national policy to control the spread of COVID-19 by helping drug supplies in emergencies and urgent situations. The purpose of this research is to analyse patent regulation by the government (Government Use) for pharmaceutical products in the state of emergency in Indonesia by comparing with Government Use in Malaysia. This research is legal research using secondary data with qualitative analysis. The implementation of patents by the government on the Covid-19 drugs remdesivir and favipiravir, whose application in Indonesia has been based on the provisions regulated by TRIPS and the DOHA Declaration. The implementation of this policy is due to a very urgent need in efforts to tackle the COVID-19 pandemic. Malaysia has also implemented the same policy to

address the need to import a generic version of the Hepatitis C drug. It is hoped that the implementation of patents by the Government on the drugs remdesivir and favipiravir can facilitate access for Covid-19 patients who need them and can be an effective strategy to deal with the Covid-19 outbreak.

KEYWORDS: Government Patent Implementation, Covid-19, Remdesivir, Favipiravir

I. INTRODUCTION

Coronavirus is a new type of virus that was initially detected in Wuhan, China, and is known as the Wuhan coronavirus or coronavirus (2019-nCov). The International Committee on Taxonomy of Viruses (ICTV) named this virus "Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2)" and the World Health Organization (WHO) called this disease "Coronavirus Disease 2019", abbreviated as COVID-19. Various strategic policies were continued, community mobility was tightened, such as limiting travel, monitoring a person's transit history, limiting partial movement, to banning entry and exit of local and provincial areas with quarantine. The United States implemented a restriction policy through a social distancing policy, namely banning large events or gatherings, social gatherings, closing schools, closing entertainment venues such as sports venues, cafes, bars, and restaurants. Of course, Indonesia is a country that cannot be excluded from the arrival of this virus. Through the Presidential Decree No. 12 of 2020 concerning Stipulation of Non-Natural Disaster of the Spread of Corona Virus Disease 2019 (COVID-19) as a National Disaster, Indonesia has legally declared that COVID-19 is a state disaster. Indonesia has implemented social restrictions and physical restrictions through the Large-Scale Social Restrictions policy.

Handling COVID-19 as a pandemic is not just about the national policies of countries in parts of the world to contain the spread of the coronavirus in their own territories, but solving this problem must also be carried out with preventive measures so that the pandemic does not recur or reappear. In addition to promoting the Covid-19 vaccine as a solution that will continue to be pursued so that it can be further developed and distributed fairly and evenly to all people, drugs have also been discovered that treat Covid-19 patients with severe symptoms in hospitals, namely Remdesivir and Favipiravir. Remdesivir (GS-5734) is an RdRP inhibitor that inhibits activity against SARS-CoV and Middle East Respiratory Syndrome (MERS-CoV) and is a very promising therapy candidate for COVID-19 because of its ability to inhibit SARS-CoV-2 in vitro. Meanwhile, Favipiravir is a purine nucleic acid analogue and includes (RdRp) inhibitors that inhibit the synthesis of viral RNA proteins[1] and are candidates for the treatment of COVID-19.

Drugs as pharmaceutical inventions are protected by patents in accordance with the scope of intellectual property rights regulated in the TRIPS agreement. Patent protection creates exclusive rights for the patent owner, which gives the patent owner a monopoly right to enforce their patent. On the other hand, patent protection can make drugs more expensive[2], and the availability of essential medicines can be a major problem, especially for poor and underdeveloped countries. As a response to this problem, the TRIPS Agreement inserts

[1] Morteza Arab-Zozani, Soheil Hassanipour, and Djavad Ghoddoosi-Nejad, "Favipiravir for Treating Patients with Novel Coronavirus (COVID-19): Protocol for a Systematic Review and Meta-Analysis of Randomised Clinical Trials," *BMJ Open* 10, no. 7 (2020): 1–3, https://doi.org/10.1136/bmjopen-2020-039730.

[2] Amy Kapczynski and Aaron S. Kesselheim, "'Government Patent Use': A Legal Approach to Reducing Drug Spending," *Health Affairs* 35, no. 5 (2016): 791–97, https://doi.org/10.1377/hlthaff.2015.1120.

a protection clause to enable WTO member countries to develop their own patent regime according to their national needs without conflicting with the TRIPS Agreement. As a WTO member and a member of the TRIPS Agreement, Indonesia is obligated to harmonize its national Intellectual Property Rights laws and regulations with the Intellectual Property Rights provisions in the TRIPS Agreement, including patent provisions.

Patent protection for drugs in the medical industry is an interesting topic of study. Before and after the TRIPS agreement, there was an intense discussion about the relationship between drug patents and drug availability to the public[3]. Many developing countries and non-governmental organizations (NGOs) are waiting for WTO Members to improve access to medicines in poor countries, are losing ground in the fight against public health epidemics such as tuberculosis, malaria, and HIV/AIDS, and are actively campaigning for structural and operational changes within the WTO[4]. After the TRIPS agreement, the Doha Declaration provides provisions that can help developing and least developed countries address the impact of drug patent protection on the health sector stemming from the TRIPS Agreement[5].

Even though the medicine exists, the quality standards are not good because many are counterfeit or produced without credible quality control, which is certainly dangerous. The increasing number of diseases that need continuous treatment makes the availability of

[3] Luqman Hakim, "Implementasi Lisensi Wajib TRIPs Agreement Dalam Produk Farmasi Di Negara Swedia," *Jurnal Hukum Lex Generalis* 4, no. 1 (2023): 28–58, https://doi.org/10.56370/jhlg.v4i1.349.

[4] Bryan C. Mercurio, "TRIPs , Patents , and Access To Life- Saving Drugs in the Developing World," *Marquette Intellectual Property Law Review* 8, no. 2 (2004): 211–53.

[5] Tomi Suryo Utomo, "Doha Declaration in The Perspective of Cheap and Affordable Drug Access: A Complement to the TRIPS" Agreement," *Unisia* 30, no. 64 (2007): 122–32.

drugs very important for public health[6], where we are currently in the process of entering the Omicron variant wave. The availability of COVID-19 drugs is needed to deal with the COVID-19 pandemic in Indonesia. Given the importance of international cooperation in developing drugs to fight the coronavirus, vaccine makers in Indonesia are still facing several obstacles, one of which is patent rights. Vaccine producers, especially those from developing countries, face several obstacles. First, limited access to research and development of new vaccines because developed countries have formed strong coalitions. Second, patent rights are very limited.

Limited patent rights" refers to a term that emphasizes the exclusivity of intellectual property rights, especially patents, where patents have a limited term of protection, namely, twenty years. During the protection period, other people (other than the patent owner) are prohibited from using, making, or selling the patent owner's invention. The term limited in patents also refers to the limitations of claims in patents. Patent rights are also limited to uses such as compulsory licenses, educational interests, research, experiments, or non-commercial analysis.

The WTO Director General's speech stated that each WTO member country has the right to regulatory flexibility regarding pharmaceutical patents. This flexibility is known as compulsory licensing and is intended to overcome the problem of countries that do not have the ability to buy patented drugs or are unable to produce drugs locally[7]. Paragraph 6 of the Doha Declaration on TRIPS and Public Health essentially states that "WTO members with

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[6] Winner Sitorus, "Kepentingan Umum Dalam Perlindungan Paten," *Yuridika* 29, no. 1 (2014): 39–60, https://doi.org/10.20473/ydk.v29i1.357.

[7] Utomo, "Doha Declaration in The Perspective of Cheap and Affordable Drug Access: A Complement to the TRIPS" Agreement."

insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement". This compulsory licensing is the freedom to give rights to developing countries to produce, buy or sell second-class drugs, not patented drugs, for public health purposes[8].

Previous research has discussed legal protection of pharmaceutical product patents for government use in an article entitled "*Pelindungan Hukum Terhadap Paten Produk Farmasi Atas Pelaksanaan Paten Oleh Pemerintah* (Government Use)"[9]. Apart from that, other previous studies discussed public health access right to pharmaceutical product patents in an article entitled "*Hak Akses Kesehatan Masyarakat Terhadap Hak Paten Produk Farmasi*"[10]. Then, there is also previous research on compulsory licenses and patent execution by the government based on the TRIPs Agreement in an article entitled "*Analisis Yuridis Terhadap Lisensi Wajib Dan Pelaksanaan Paten oleh Pemerintah Berdasarkan Perjanjian TRIPs*"[11]. All of these studies show that government patents, especially in the

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[8] Trias Palupi Kurnianingrum, "Pelindungan Hak Paten Atas Pengetahuan Obat Tradisional Melalui Pasal 26 UU No. 13 Tahun 2016 Tentang Paten (Protection of Patent Rights on Traditional Medicine Knowledge Through Article 26 of Law No. 13 of 2016 Concerning Patents)," *Negara Hukum: Membangun Hukum Untuk Keadilan Dan Kesejahteraan* 10, no. 1 (2019): 49–65, https://doi.org/10.22212/jnh.v10i1.1222.

[9] Irawati Irawati Yustisiana Susila Atmaja, Budi Santoso, "Pelindungan Hukum Terhadap Paten Produk Farmasi Atas Pelaksanaan Paten Oleh Pemerintah (Government Use)," *Masalah-Masalah Hukum* 50, no. 2 (2021): 196–208, https://doi.org/https://doi.org/10.14710/mmh.50.2.2021.196-208.

[10] Kholis Roisah Raden Bagoes Prasetyo Raharjo, "Hak Akses Kesehatan Masyarakat Terhadap Hak Paten Produk Farmasi," *USM Law Review* 4, no. 2 (2021): 604–13, https://doi.org/10.14710/mmh.50.2.2021.196-208.

[11] Achmad Amri Ichsan, "Analisis Yuridis Terhadap Lisensi Wajib Dan Pelaksanaan Paten Oleh Pemerintah Berdasarkan Perjanjian TRIP's," *Jurnal Ilmu Hukum Legal Opinion* 2, no. 1 (2014): 1–12.

public health sector, remain an important legal issue that needs to be discussed.

The author's research in this article is novelty compared to several previous studies. The location of this novelty is based on a study that analyses the application of government patents for drugs in emergency situations (Covid-19) related to the TRIPS Agreement, the Doha Declaration, Law No. 13 of 2016 concerning Patents, and Directorate General of Presidential Decree Number 77 of 2020 concerning Procedures for the Use of Patents by the Government as an additional legal basis for the use of patents by the government. In addition, this study describes examples of enforcing government patents on remdesivir and favipiravir as drugs for COVID-19 patients in Indonesia and compares them to patent implementation by governments in other countries, namely Malaysia. Indonesia and Malaysia have similarities regarding patents, including the concept of patented drugs and the challenge of setting relatively high prices for patented drugs compared to generic drugs. Both also have systems that regulate patent validity periods. The purpose of this research is to analyse the Government Use of pharmaceutical products in emergencies in Indonesia and compare it with the Government Use in Malaysia.

II. METHODS

This article is a normative juridical law research, namely research that aims to study the application of the principles or rules of positive law. Normative legal research is legal research that places law as a norm construction. The construction of these norms refers to norms, legal principles, court decisions, agreements and doctrines

(teachings)[12]. In accordance with the normative approach, this study then refers to positive law or the application of legal principles and norms in national regulations, especially those relating to patents, which are then adapted to the current situation. Data was collected through an online literature search. In addition, this study uses secondary data sources consisting of primary legal materials, including the Law No. 13 of 2016 concerning Patents, Presidential Regulation No. 100 of 2021 concerning The Government's Patent Implementation of Remdesivir Drug, Presidential Regulation No. 101 of 2021 concerning Patent Implementation by the Government Regarding Favipiravir Medicine, Presidential Decree No. 11 of 2020 concerning Establishing a Public Health Emergency for Corona Virus Disease 2019, Regulation of the Minister of Health No. 28 of 2020 concerning Implementation of Procurement of Vaccines in the Context of Mitigating the Corona Virus Disease 2019 Pandemic, Malaysia Patents Act 1983, Malaysia Patent (Amendment) Act 2022, and TRIPS Agreement.

III. REGULATIONS FOR GOVERNMENT USE IN THE TRIPS AGREEMENT AND THE DOHA DECLARATION

The World Trade Organization (WTO) uses the words Government Use and Compulsory Licensing, which are contained in the WTO Glossary, to refer to the government's use of patents. The definition of Government Use is the application of patents by the government if the government uses product patents or process patents for the benefit of the government or allows other parties to use them without requiring the patent owner's permission, while

12 Mahmud Peter Marzuki, *Penelitian Hukum: Edisi Revisi*, Revisi (Jakarta: Kencana Prenada Media Grup, 2017).

Compulsory Licensing is the right to grant a patent license to a company or individual other than the patent holder to produce, use, sell or import patented products without the approval of the patent owner in line with the mechanisms and rules in the TRIPS Agreement[13].

Based on the notion of Government Use and Compulsory Licensing, both of which can be implemented without the permission of the patent owner in a WTO member country, one of which is Indonesia, it is more compatible with the term patent implementation by the government because compulsory licensing is translated into Indonesian as a mandatory license and can give rise to many interpretations. against the mandatory licensing rules in Law No. 13 of 2016 concerning Patents, which are very different between the two. The TRIPS Agreement does not specifically mention implementation by the government or mandatory licenses, but these provisions are a form of flexibility in patent protection in the patent section of Article 31 (b) of the TRIPS Agreement in relation to other uses without authorization of the right holder or other uses without the consent of the right holder. The provisions of Article 31 (b) of the TRIPS Agreement state that the application of a patent by the state or a third party on behalf of the state, in principle, requires prior efforts to obtain permission from the patent holder, but related permits can be waived if there is a connection with a national emergency or other very serious situations. urgent or non-commercial use[14]. In addition, Article 31(h) of the TRIPS Agreement provides that the patent holder is entitled to fair compensation for

[13] Yustisiana Susila Atmaja, Budi Santoso, and Irawati Irawati, "Pelindungan Hukum Terhadap Paten Produk Farmasi Atas Pelaksanaan Paten Oleh Pemerintah (Government Use)," *Masalah-Masalah Hukum* 50, no. 2 (2021): 196–208, https://doi.org/10.14710/mmh.50.2.2021.196-208.

[14] Sartika Nanda Lestari, "Implementasi Compulsory Licensing Terhadap Obat-Obatan Dalam Bidang Farmasi Di Indonesia," *Diponegoro University* (2012).

implementation of the provisions of Article 31(b) of the TRIPS Agreement.

Through the protection of drug patents, citizens in developing countries, such as WTO members, find it difficult to obtain patented essential medicines because the prices for the drugs sold are too high. Furthermore, in 2001, WTO member countries adopted a declaration explaining the relationship between the TRIPS Agreement and public health, namely the Doha Declaration on the TRIPS Agreement and Public Health, which explains the provisions on compulsory licensing in paragraphs 5 and 6. In addition, the TRIPS General Council issued a General Council Regulation on the Export and Import of Pharmaceutical Products in 2003 to implement paragraph 6 of the Doha Declaration, followed by an amendment in 2005 to add Article 31 bis after Article 31 of the TRIPS Agreement[15].

The essence of the provisions of the TRIPS Agreement is that the other party has the possibility to use the patent without the right holder's consent, but must still notify the right holder. The provisions of Article 31 allow for a request to use a patent without the consent of the right holder on the basis of urgent national interests or other very urgent circumstances or non-commercial use for the public interest. In Urgent National Interests or Other Very Urgent Conditions, right holders must be notified immediately that if the patented technology is to be used for the benefit of the government, the patent holder must be notified as soon as possible. Applying for the use of a patent must go through an evaluation procedure by a certain authority, for example, a government representative. The

[15] Mayas M Eka An Aqimuddin, Iman Sunendar, Frency Siska, Rahmat J. Tanjung, "Tinjauan Pendekatan Hukum Dan Ekonomi Terhadap Model Lisensi Wajib Paten Atas Obat Dalam Wto-Trips Dan Deklarasi Doha 2001," in *Prosiding Seminar Nasional Penelitian Dan PKM Sosial, Ekonomi Dan Humaniora*, 2015, 1–13.

authority should have the power to review the licensing decision to use a patent at any time, and can terminate the license if the basis for granting the license no longer exists[16]. The use of a patent without the consent of the right holder is requested due to a very urgent situation; therefore, the use of said right must be limited to the country of origin of the country concerned.

Articles 1-7 of the DOHA Declaration state that for Compulsory Licensing and Government Use, each member state must comply with the following provisions:

a. There are public health problems that are epidemic in nature, for example, HIV/AIDS, malaria, tuberculosis, or other epidemics that require expensive drugs because they are protected by patents.
b. There is an urgent national crisis. In this regard, each member country is given the freedom to define "national crisis" or "very urgent need" according to the country's national needs.
c. There are problems related to the inability and lack of capacity of member countries to patent drugs.

The Doha Declaration presupposes rules that can provide assistance to developing countries to address the health sector effects of TRIPS drug patent protection, such as: Bolar regulation, parallel imports, mandatory licensing, and implementation of patents by the state. However, the credibility of the Doha Declaration is still questionable because it cannot be classified as an official interpretation based on Article IX 2 of the Marrakesh Agreement Establishing the WTO. Developed countries believe that the Doha Declaration cannot be used to interpret the TRIPS Agreement.

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[16] Puguh Toko Arisanto & Adi Wibawa, "Implementasi Developmental State India Dalam Menghadapi Paten Trips Dan Strategi Ranbaxy Lab. Dalam Persaingan Global," *Jurnal Transborder* 3, no. 1 (2019): 43–58.

Article IX 2 of the Marrakesh Agreement states:

The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements. In the case of an interpretation of a Multilateral Trade Agreement in Annex 1, they shall exercise their authority on the basis of a recommendation by the Council overseeing the functioning of that Agreement. The decision to adopt an interpretation shall be taken by a three-fourths majority of the Members. This paragraph shall not be used in a manner that would undermine the amendment provisions in Article X.

Therefore, this declaration does not have legal force as a means of interpreting an international treaty[17]. In this regard, it is necessary to issue an executive regulation at the level of state government to technically define a model of flexibility in the application of patents by the government that is adapted to the interests of the domestic community, particularly in Indonesia. The use of domestic regulations can regulate in detail the use of government patent implementation models[18]. The regulatory model that is formed can consider using economic analysis and a human rights approach so that the results benefit society and the pharmaceutical industry.

IV. MECHANISMS FOR GOVERNMENT USE OF PHARMACEUTICAL PRODUCTS IN THE STATE OF EMERGENCY IN INDONESIA

17 Evi Darma Pertiwi, "Pelindungan Hak Akses Kesehatan Atas Perubahan Ketentuan Lisensi-Wajib Dalam Undang-Undang Cipta Kerja," *Jurnal Lex Renaissance* 7, no. 1 (2022): 100–113, https://doi.org/10.20885/jlr.vol7.iss1.art8.

18 Lidya Shery Muis, "Hak Atas Aksesibilitas Obat Paten Bagi Masyarakat," *Widya Pranata Hukum : Jurnal Kajian Dan Penelitian Hukum* 1, no. 1 (2019): 36–64, https://doi.org/10.37631/widyapranata.v1i1.259.

The implementation of patents by the Indonesian government is one step that can address the issue of drug availability during the COVID-19 pandemic. This provision is stipulated in Article 109 (1) (b) of Law of the Republic of Indonesia Number 13 of 2016 concerning Patents, which stipulates that the government can independently utilize patents in Indonesia, given the urgent need for public interest. In the context of the COVID-19 pandemic, the Indonesian government has the right to grant patent utilization permits related to COVID-19 medical products to the government without negotiating with patent holders. This is because the COVID-19 pandemic clearly constitutes a national emergency, and such permits can be granted for non-commercial public use to protect public health.

During this pandemic, several countries have issued mandatory licenses and Government Patents related to COVID-19, such as Hungary and Russia for Remdesivir, and Israel for Lopinavir/Ritonavir[19], as well as revising their laws regarding mandatory licences, such as Australia, Brazil, Canada, Germany, Indonesia, and Russia[20].

Director of Patents, Integrated Circuit Layout Design, and Trade Secrets, Dede Mia Yusanti, announced that the implementation of patents by her government for medicines during this pandemic was because the conditions for implementing this policy were very suitable during this pandemic. This is in accordance with Article 109 (1) (b) of the Patent Law No. 13 of 2016 (Patent Law), which states

[19] Katrina Perehudoff, Ellen Thoen, and Pascale Boulet, "Overriding Drug and Medical Technology Patents for Pandemic Recovery: A Legitimate Move for High-Income Countries, Too," *BMJ Global Health* 6, no. 4 (2021): 10–13, https://doi.org/10.1136/bmjgh-2021-005518.

[20] Médecins Sans. Frontieres, "Compulsory Licenses, the TRIPS Waiver, and Access to COVID-19 Medical Technologies," 2021.

that the government can independently implement patents in Indonesia if very urgent public interest needs are considered. Furthermore, considering Article 116 (1) of the Patent Law, which states that if the Government cannot use a patent according to Article 109 (1), the Government can hire a third party to carry it out. The appointment of a third party is subject to conditions, including that the appointed party is not allowed to transfer the patent to another person, and compensation on behalf of the State will only be paid to the appointed third party.

The definition of government use is that the implementation of a patent by the government is intended when the government uses or allows another party to use the rights to a product patent or process patent for the benefit of the government without needing to obtain permission from the patent holder, while mandatory licensing is the authority that grants a license to a company or individual other than the patent holder to use the patent rights, namely making, using, selling or importing patented products without permission from the patent holder if it is in accordance with the procedures and provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights[21]. The definition of government use is that the implementation of a patent by the government is intended when the government uses or allows another party to use the rights to a product patent or process patent for government purposes without needing to obtain permission from the patent holder, while mandatory licensing is the authority that grants a license to a company or individual other than the patent holder to use the patent rights, namely making, using, selling or importing patented products without permission from the patent holder if in

[21] Atmaja, Santoso, and Irawati, "Pelindungan Hukum Terhadap Paten Produk Farmasi Atas Pelaksanaan Paten Oleh Pemerintah (Government Use)."

accordance with the procedures and provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights. The legal basis for government use in Indonesia is contained in Presidential Regulation No. 77 of 2020 concerning Procedures for Patent Implementation by the Government.

The implementation of Government Use in Indonesia is different from the provisions of a mandatory license. This is because in Indonesia, there are two forms of Compulsory Licensing, namely the mandatory license in Law No. 14 of 2001 concerning Patents articles 74-78, and the second is the implementation of patents by the government as stipulated in Law No. 14 of 2001 concerning Patents articles 99-103. There is a fundamental difference between a compulsory license and a government patent, both in the rationale and in the application process. Usually, the reason for applying for a compulsory license tends to be financial reasons, while the government's reason for applying for a patent is for the national interest and the wider community. As for the application, a mandatory license begins with a request from a third party and approval from the Directorate General of Intellectual Property Rights for granting it, it is different in the procedure for implementing patents by the government, namely with a presidential decree after hearing the opinion of the Minister of Health. Considering that the acquisition of medicines must be done to serve the interests of society and the state, Indonesia uses compulsory licensing in efforts to implement patents by the government [22].

The Indonesian government has introduced a mechanism for

[22] Samariadi, "Implementation of Compulsory Licensing of Pharmaceutical Patents in Indonesia Is Associated With DOHA Declaration on The TRIPs Agreement and Public Health," *De Lega Lata* I, no. Juli-Desember 2016 (2016): 448–65.

implementing patents by the government for remdesivir and favipiravir, which are drugs to meet the needs of COVID-19 patients in Indonesia. The government can independently apply for patents in Indonesia based on Article 109 paragraph 1 of Law No. 13 of 2016 concerning Patents if it is related to national defense and security or to meet very urgent needs for the interests of its people. In addition, Article 111 of Law No. 13 of 2016 concerning Patents states that medical products intended for a global public health emergency include products that can be patented by governments. If this regulation is related to this pandemic situation, then the Covid-19 drug meets the patent requirements set by the government because it is a drug to fight Covid-19, which is, of course, very much needed in this pandemic situation. This is in line with Presidential Decree Number 11 of 2019 concerning the Establishment of a Public Health Emergency for the 2020 Coronavirus Disease, which stipulates the COVID-19 epidemic as a public health emergency due to the high number of victims and extraordinary effects. The most pressing issue for the government is the introduction of patents for COVID-19 drugs.

Through this patent application procedure by the government, the economic rights of inventors are still granted by providing proper compensation to the patent owner. In a pandemic situation like this, the appropriate compensation will be measured by taking into account the financial benefits that will be received by potential Covid-19 drug patent holders from the state's ability to provide payments based on Article 115 of Law No. 13 of 2016 concerning Patents. So that the economic rights of vaccine inventors can be adjusted through the government patent mechanism. Compensation is not specifically regulated, but it is governed by private law through a separate agreement with the government.

In November 2021, President Joko Widodo granted state patents for the drugs remdesivir and favipiravir, the purpose of which is to meet the medical needs of COVID-19 patients in order to eradicate the pandemic. This is regulated in Presidential Regulation No. 100 of 2021 concerning the Implementation of Patents by the Government for Remdesivir, which regulates patent applications for remdesivir, and Presidential Regulation No. 101 of 2021 concerning Implementation of Patents by the Government for Favipiravir, which regulates patent applications for the drug favipiravir. The target period for patent implementation is 3 (three) years from the entry into force of the two Presidential Decrees; after that, it can be extended if the pandemic has not yet ended, until the Government announces the expiration of the patent validity period. pandemic. Similar to the enforcement of HIV/AIDS and hepatitis B drug patents by the government, remdesivir and favipiravir patent holders are also given reasonable compensation, namely 1% of the net sales value of the drugs they produce every year. Regarding HIV/AIDS drugs and COVID-19 drugs, they have similarities in that both are drugs that are greatly needed by humans, and the disease has caused many deaths.

Although Article 112 (2) of the Patent Law states that the patent owner's rights are not reduced or limited, it can be assumed that the profit obtained by the patent owner from using or exploiting his rights is reduced. In addition, the government takes a case-by-case approach to patent implementation, which requires the government to independently determine in detail which products will be patented and when. This is quite a challenge in a pandemic situation, because the government is obliged to take care of various administrative matters, even though pandemic countermeasures must be carried out as soon as possible.

If we take a deeper look at the pandemic situation, then in order to achieve balance, the realization of the government's Covid-19 drug patents not only fulfills public health rights, but also the rights of inventors, especially in terms of the economic rights of inventors. If it turns out that the inventor is not given royalties or full wages, the inventor can at least continue to enjoy his economic rights with appropriate compensation based on Article 115 of Law No. 13 of 2016 concerning Patents. In this case, appropriate compensation can be measured by considering the financial benefits that can be received by the discoverers of the COVID-19 drug from the government's ability to pay for it. For an exchange to be fair and considered a fair exchange, an achievement must be balanced with a contra-achievement. Through adequate remuneration assistance, is expected to be a driving force for inventors to develop technology in a better direction in return. For domestic use only, not for commercial use[23]. This criterion is implemented according to Article 109 (2) of Law No. 13 of 2016 concerning Patents. If associated with the principle of fair use of the copyright system, patents by the government can be used as long as they are not for commercial purposes. In addition, the patents applied by the government for the Covid-19 vaccine drug are not for commercial purposes, including export activities, and are only carried out to fulfill the health rights of the Indonesian people.

Aspects that must be considered in implementing mandatory licensing and patent implementation in Indonesia:

a) Only applies to medicines whose patents are registered

[23] Cindawati, "Prinsip Good Faith(Itikad Baik) Dalam Hukum Kontrak Bisnis Internasional," *Mimbar Hukum - Fakultas Hukum Universitas Gadjah Mada* 26, no. 2 (2014): 181, https://doi.org/10.22146/jmh.16038.

Law No. 13 of 2016 concerning Patents stipulates that mandatory licenses and use of patents can only be applied to registered patents. This is regulated in Article 93 of Law No. 13 of 2016 concerning Patents, which states that "The Minister may grant mandatory permits to produce patented pharmaceutical products in Indonesia for the treatment of diseases in humans". There is also Article 112 paragraph (2) stipulating "In that case the use of a patent by the Government for an urgent need in the interests of the public ... does not reduce the rights of the Patent Holder ..." Article 1 paragraph (6) of Law No. 13 of 2016 concerning Patents stipulates that the Patent Holder is the owner of the patent which have been registered in Indonesia. If a patent is not registered in Indonesia, then it does not require a mandatory license or use of the patent by the government.

b) The effect on the investment climate

Although Law No. 13 of 2016 concerning Patents allows for mandatory licensing and use of patents by the government, it is also necessary to consider the impact on the investment climate in Indonesia. According to Dede Mia Yusanti, the issue of mandatory licenses is a pending issue for bilateral negotiations. The government's patent application for HIV/AIDS and hepatitis drugs in 2012, for example, received sharp protests, especially from pharmaceutical investors and international pharmaceutical alliances.

c) Complexity of Article 20 of Law No. 13 of 2016 concerning Patents

Many investors oppose the provisions of the Patent Law, which permit mandatory licenses and the use of patents by the government if patent-holding investors in Indonesia do not build factories or manufacture their products in Indonesia. The obligations of Article 20 of Law No. 13 of 2016 concerning Patents are known as Local

Employment Patent Requirements. Article 20 of Law No. 13 of 2016 concerning Patents then became a national polemic. There are those who suggest cancelling Article 20, but there are also those who suggest maintaining this provision. For example, several legal experts criticized the plan to abolish Article 20 of Law No. 13 of 2016 concerning Patents in Law No. 11 of 2020 concerning Job Creation[24].

V. MECHANISM OF PATENT EXECUTION BY THE GOVERNMENT OF MALAYSIA

Malaysia is a member of the Paris Convention and the TRIPS Agreement. In Malaysia, patent rights are regulated by the Patent Act 1983, which grants patent owners exclusive rights with respect to their inventions. Malaysia is indeed a member country that complies with the TRIPS Agreement and has prepared a good legal protection mechanism for the enforcement of intellectual property rights.

The Malaysian government has identified innovation as a key economic driver in the transition to a high-income country in 2020[25]. Malaysia views intellectual property as an important asset in the economy. Although Malaysia greatly respects and promotes the security of intellectual property, it has always strived to strike a fair balance between owners of intellectual property rights and the wider public interest, particularly with respect to laws relating to patents. The balance requirements for these patents are enshrined in Article 5(A) of the Paris Convention: this provision gives member

[24] Andrieansjah Andrieansjah, "The Impact of Covid-19 on Intellectual Property Legal System Related To Public Health in Connection With Trips Flexibilities in Indonesia," *Indonesian Law Journal* 13, no. 2 (2020): 165–91, https://doi.org/10.33331/ilj.v13i2.31.

[25] Ida Madieha Azmi, "Intellectual Property Policy and Academic Patenting in Malaysia: Challenges and Prospects," *Pertanika Journal of Social Science and Humanities* 22, no. January (2014): 1–20.

states the right to take measures to prevent the abuse of patent rights, such as through compulsory licensing, to protect public health.

Malaysia gained international attention when it provided Malaysians with easy access to medicines when the country was faced with public health problems in 2004 and 2017, signaling Malaysia's approach to balance of rights while protecting intellectual property rights through the application of the ROG (Rights of Government) mechanism, or Patent enforcement by the government is in accordance with Section 84 of the Patent Law. Malaysia should fully support the new Article 31bis, especially to support LDCs (Least Developed Countries), by incorporating provisions into the Patent Act to address the issues therein[26].

In 2017, Malaysia issued a government-use license for sofosbuvir to increase access to treatment for more than 400,000 people living with Hepatitis C in Malaysia. The decision was made after attempts by the Ministry of Health to be included in voluntary licensing and price negotiations with patent holders were unsuccessful. Compulsory Licensing and Government Use removes patent barriers. The price of sofosbuvir fell 99.7%, from RM360,000 for the entire treatment with the proprietary drug to RM1,248 for the generic version, increasing the availability of Hepatitis C treatment in public hospitals across the country.

Patents are not absolute monopoly rights and are subject to mandatory licensing on the basis of non-use and interdependence of patents and government use under the Malaysian Patent Act

[26] Mohsin Hingun and Rahamatthunnisa Mohamed Nizamuddin, "Amending Section 84 Patents Act 1983 To Encompass the Health Flexibilities Leverage Accorded By Article 31Bis Trips Agreement," *UUM Journal of Legal Studies* 11, no. 2 (2020): 1–26, https://doi.org/10.32890/uumjls.11.2.2020.8052.

1983. Malaysia was the first country in the world to rely on government use rights to create access to affordable medicines following the adoption of the Doha Declaration on TRIPS and Public Health in 2001 by member countries of the WTO.

In September 2017, Malaysia exercised its right to exploit Gilead's patented drug, Sofosbuvir, used to treat Hepatitis C, without Gilead's permission. The Malaysian government continued to exercise its right even though Gilead had announced the extension of its voluntary licensing scheme to supply licensed generic Sofosbuvir to Malaysia. This was the second time Malaysia had exercised its government's right to exploit a patented invention without the rights holder's permission. The first time occurred in 2003, when the government exercised its right to supply affordable HIV/AIDS drugs patented by GlaxoSmithKline and Bristol-Myers Squibb after lengthy price negotiations with the patent holder failed[27].

Section 84 of the Patent Law allows the government to use a patented invention even without the consent of the patent owner "where there is a national emergency or where the public interest, in particular, national security, nutrition, health, or development of other vital sectors of the national economy determined by the government, thus requiring." Patent owners must be informed of the government's decision to exercise their rights as soon as reasonably practicable and must be adequately compensated. Patent owners will have the right to be heard about remuneration, to request that the authorization be terminated or amended, as well as to appeal to the High Court against the government's decision.

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[27] Shearn Delamore & Co Mike Ho Mun Keat, "Government Rights Over Patented Inventions In Malaysia," *Conventuslaw.Com*, October 2018, https://conventuslaw.com/report/government-rights-over-patented-inventions-in/.

Section 84 of the Patent Law is very similar to Article 31 of the TRIPS Agreement on Other Uses Without the Permission of Rights Holders which also states that "authorization for such uses must be responsible, subject to adequate protection of the legitimate interests of those duly authorized, to terminate if and when the circumstances giving rise to them cease to exist and are unlikely to recur. The competent authority has the power to review, upon motivated request, the continued existence of these circumstances."

Paragraph 5(c) of the Doha Declaration further states that: "Each Member reserves the right to determine what constitutes a national emergency or other situation of extreme urgency, it is understood that a public health crisis, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics, may represent a national emergency or other circumstances of extreme urgency."

The Malaysian Patent Act also clearly distinguishes Compulsory Licenses from the Rights of Government (Patent Implementation by the Government). Mandatory license applied by third parties strictly for the specified reasons based on Article 5(A) of the Paris Convention and under Section X of the Patent Act, while ROG is implemented by the Government for system implementation, "The government or a third party authorized by the government" for two specific reasons. First, ROG is done in case of an "emergency national" or "public emergency", such as matters of "national security and health" (Article 31(b)). Second, granted when "the judicial or relevant authority has determined" that the patent owner has exploited his invention by "anti-competitive" means (Article 31(c)). Although Article 31 does not distinguish between a Compulsory License and a Government Patent, the Malaysian Patent Act has limited these rights to two categories of rights that

are exercised by different parties. This allows for a much simpler and clearer determination of rights to ensure the right balance of rights between patent owners and the public[28]. Issues involving patent misuse in the local area are arranged by MyIPO.

However, the drawbacks of this system can be seen from the results of the exercise of the Malaysian government's usage rights in relation to Sofosbuvir. Malaysia's international rating of its intellectual property system has undergone a significant downgrade in the latest Annual International IP Index released by the US Chamber of Commerce Global Innovation Policy Center (GIPC). Special Report 301 of 2018 stated that "USTR will conduct a Malaysia Beyond Cycle Review, which will consider the extent to which Malaysia provides adequate and effective protection and enforcement of intellectual property rights, including with respect to patents." It remains to be seen whether Malaysia's newly elected government will continue to enforce government use permits as a means of providing affordable medicines to Malaysians.

The mechanism for patent implementation by the government in Indonesia and Malaysia can be compared in the following table:

Table 1: The Comparison of the Use of Patents Between the Government of Indonesia and the Government of Malaysia

Comparative Aspect	**Indonesia**	**Malaysia**
Protection Instruments	Law No. 13 of 2016 concerning Patents	1983 Act
Patent definition	Patents are "exclusive rights	Patents are “Exclusive rights granted to

[28] Feroz Ali, “Nexavar: The First Market-Initiated Compulsory Licence,” *NUJS Law Review* Juli-Desem (2016): 229–57, https://doi.org/10.2139/ssrn.2729681.

	granted by the state to inventors for their inventions in the field of technology for a certain period of time to carry out the invention themselves or give approval to other parties to implement them."	inventions (products or processes) that allow in practice Solutions to Specific Problems in the Field of Technology"
Patent Protection Objects	Any new invention that does not include aesthetic creations, schemes, rules, and methods of activity (charity, games, business), rules and methods of computer programs, presentation of information and knowledge in new forms from familiar products and existing compounds that do not improve efficiency.	Every new and inventive discovery (not a scientific theory), mathematical method, business scheme, and medical treatment methods for humans and animals.
Protection Period	20 years	20 years

Consideration of Patents by the Government	Consideration: a) related to national defense and security; or b) an urgent need for the benefit of society.	Consideration: a) in the event of a national crisis or public interest, particularly national security, food, health, or the development of other important sectors of the national economy, determined by the government; b) when "the judicial or relevant authority has determined" that the patent owner has exploited his invention in an "anti-competitive" manner.
Patent notification by the government	a. In the event that the government intends to implement a patent that is important for national defense and security or for urgent needs, the government shall notify the patent holder in writing regarding the said	The patent holder must be notified of the Minister's decision as soon as possible.

	matter. b. A copy of the presidential regulation regarding the approval of patent implementation by the government is sent by the Minister to the Patent Holder	
Patent Compensation by the government	Reasonable fees to patent holders	Adequate compensation, taking into account the economic value of the Minister's authority as stipulated in the decision. It further stipulates that the patentee must be paid an "adequate remuneration", the amount of which must be decided after hearing representations by the patent holder and other interested parties (if they wish to be heard). Patents can

		also request that the compulsory license be changed or terminated, and the minister can change or terminate the license after listening to the relevant parties.
Third-party appointment	In the event that the Government is unable to implement the Patent itself, the Government may appoint a third party who meets the following requirements: a. has facilities and is able to apply for a patent; b. not transfer the patent implementation to another party; and c. have good production methods, distribution, and supervision in accordance with the	a. In the event that a third person has been appointed by the Minister, authorization can only be transferred in good faith; b. Appointment of third parties appointed by the Minister especially for the Department of market providers in Malaysia.

	provisions of laws and regulations.	
Further provisions	Regulated by presidential regulation.	Regulated by ministerial regulations.

VI. CONCLUSION

This study describes examples of patent implementation by the government for Remdesivir and Favipiravir drugs to meet the treatment needs of COVID-19 patients in Indonesia and compares them with regulations on patent implementation by governments in other countries, namely Malaysia. The Government Use refers to the government using or permitting other parties to use rights to product patents or process patents for the benefit of the government without the need to obtain permission from the patent holder. The provisions of Article 31 TRIPS Agreement open up the possibility of filing an application for patent use 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 circumstances of extreme urgency) or non-commercial use for the public interest (public non-commercial use). The mechanism for implementing Government Use for pharmaceutical products is one of the policies that can overcome the problem of access to drugs during the COVID-19 pandemic in Indonesia. This is in line with Article 109 paragraph (1) of Law No. 13 of 2016 concerning Patents, which states that the government can independently implement patents in Indonesia based on consideration of very urgent needs for the public interest. While the patent enforcement mechanism by

The government in Malaysia was granted when the country was faced with public health problems in 2004 and 2017, the provisions for patent enforcement by the government are in accordance with those set out in Section 84 of the Malaysian Patent Act. The implementation of patents by the government for the Covid-19 drugs remdesivir and favipiravir carried out by Indonesia has referred to the regulations regulated by TRIPS Agreement and the DOHA Declaration. The implementation of this policy was due to an urgent need in efforts to deal with the Covid-19 pandemic. In comparison with the Malaysian Patent Act, the provisions for implementing patents by the government in the two jurisdictions have similarities and differences. The similarity is that the two jurisdictions both differentiate between Compulsory Licenses and Patents by the government, the two jurisdictions limit these rights into two categories of rights that are used by different parties. Then the difference lies in procedural aspects such as in terms of payment of remuneration, in which the Malaysian Patent Act regulates the provision of "right to hear" the amount of which must be decided after hearing representations by patent holders and other interested parties, if they want to be heard. In order to facilitate public access to medicines needed for the treatment of dangerous pandemic diseases, it is recommended that developing country governments optimize the implementation of patents by the government. In the framework of the development of science, especially law, it is deemed necessary to carry out development research with a wider scope of problems regarding the implementation of mandatory licenses and the implementation of patents by the government.

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COMPETING INTEREST

The author(s) will be asked to sign this statement once the submission has been accepted.

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