

Drug Patent Monopoly During Covid-19 Outbreaks: How the Government Regulates this?

Devica Rully Masrur

Faculty of Law, Esa Unggul University, Jakarta, Indonesia
devica@esaunggul.ac.id

Ogah Chinyere Constance 

Faculty of Law, Ebonyi State University, Ebonyi, Nigeria
ogah.chinyere@ebsu.ed.ng

Abstract

Health is an inherent human right constitutionally guaranteed, and during the Global Covid-19 Pandemic, the Indonesian government faced a delicate balance between safeguarding public health and complying with its obligations as a member of the WTO under the TRIPS Agreement, which mandates patent protection for medicines, medical devices, and vaccines, crucially needed during the pandemic. International and national laws have addressed these challenges through the TRIPs Protector Article, providing options for member states to take specific measures, such as Parallel Imports, Bolar Provisions, Compulsory Licenses, and Government Use of Patents. These solutions demonstrate that even in emergency situations, the rights of inventors can still be upheld while ensuring access to essential medicines for the public. In the case of Indonesia, the government employed the Government Use of Patents policy through Presidential Regulations Number 77 of 2020, Number 100 of 2021, and Number 101 of 2021, pertaining to Remdesivir and Favipiravir medicines, respectively. This approach, though involving compulsory acquisition, is time-limited, non-



exclusive, and provides fair compensation to patent holders, reflecting a balanced and just approach to addressing the critical public health needs during the pandemic.

KEYWORDS

Patents, Drug, Covid-19, Patent Monopoly, Government Regulation

Introduction

The right to health is a fundamental constitutional right, enshrined in Article 28H paragraph (1) of the 1945 Constitution, which places the responsibility on the government to ensure its realization. This duty is further reinforced by Article 28I paragraph (4) of the Constitution, emphasizing the state's role in protecting and fulfilling human rights, including the right to health. Internationally, this obligation finds support in Article 2 paragraph (1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR). Moreover, domestic legislation such as Law no. 39 of 1999 on Human Rights and Law Number 36 of 2009 concerning Health further underscores the government's commitment to upholding the right to health for all citizens. Consequently, the government is mandated to provide accessible and affordable health services that promote equity and wellbeing within the community, encompassing preventive and curative measures, as well as ensuring the availability of essential medicines to safeguard public health.¹

In the ongoing battle against the Covid-19 pandemic, it is the government's paramount responsibility to ensure that the community's

¹ Hernadi Affandi, "Implementasi Hak atas Kesehatan Menurut Undang-Undang Dasar 1945: antara Pengaturan dan Realisasi Tanggung Jawab Negara." *Jurnal Hukum Positum* 4, No. 1 (2019): 36-56; Rico Mardiansyah, "Dinamika Politik Hukum Dalam Pemenuhan Hak Atas Kesehatan Di Indonesia." *Veritas et Justitia* 4, No. 1 (2018): 227-251.

right to health is protected and upheld. This entails ensuring the availability, fairness, and affordability of essential medicines and medical devices required to combat the virus effectively. However, a significant challenge arises when some medicines and medical devices, particularly patented drugs, become unaffordable for the general public due to their high prices. These patented drugs are still protected by patents according to the Patent Law, which is an integral part of intellectual property rights. The Patent Law is closely connected to our country's adherence to the TRIPs Agreement, which stands for The Agreement on Trade-Related Aspects of Intellectual Property Rights. Therefore, in this context, the government must strike a balance between honoring patent rights and addressing the urgent public health needs of its citizens during the pandemic.²

Drugs are granted patent protection when they meet the criteria specified in Article 27(1) of the TRIPs Agreement, which includes novelty, industrial applicability, and inventive step. This protection is necessary as drug discovery involves significant time, effort, and expenses, and granting exclusive rights allows inventors to monopolize the drug, preventing unauthorized production or development by others. However, this drug patent monopoly leads to expensive drug prices, as the right holder has the freedom to set prices due to their exclusive control.³

² Raden Bagoes Prasetyo Raharjo, and Kholis Roisah. "Hak Akses Kesehatan Masyarakat Terhadap Hak Paten Produk Farmasi." *Jurnal USM Law Review* 4, No. 2 (2021): 604-614; 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.

³ Imam Wicaksono, "Politik Hukum Pelindungan Hak Kekayaan Intelektual Di Indonesia Pasca Di Ratifikasinya Trips Agreement." *Pena Justisia: Media Komunikasi Dan Kajian Hukum* 18, No. 1 (2020). See also Murtala Ismail Adakawa, and N. S. Harinarayana. "Insight Into Intellectual Property in Patent Medicine: An Indian Perspective." *Unnes Law Journal* 8, No. 2 (2022); Dewi Sulistianingsih, and Raden Muhammad Arvy Ilyasa. "The Impact of Trips Agreement on the Development of Intellectual Property Laws in Indonesia." *Indonesia Private Law Review* 3, No. 2 (2022): 85-98. It is further explained that Article 27(1) of the TRIPs Agreement, which stands for the Agreement on Trade-Related Aspects of Intellectual Property Rights, sets out the criteria for granting patent protection to inventions, including drugs. To be eligible for patent protection, an invention must meet three main requirements: *First*, Novelty: The invention must be new and not part of the existing knowledge or public domain. In other words, it should be a new and original creation that has not been previously disclosed or used. *Second*, Industrial Applicability: The invention must be

During the Covid-19 pandemic, various efforts to find various drugs and vaccines to cure Covid-19 have been carried out, both by the private sector and the government, both domestically and abroad. The process of discovering drugs and vaccines for Covid-19 has certainly cost a lot of money, time, effort and thought and for reasons of a global pandemic it is impossible to immediately prohibit inventors from registering their research results for patents. However, the condition of the virus outbreak that has attacked all countries, including Indonesia, is important if it is linked to the concept of saving the public interest, especially saving citizens. If medicines related to the Covid-19 virus are granted patents exclusively, this will be in conflict with the public interest, namely the interest for public health in the face of a pandemic, because everyone is limited in buying patent medicines which are not cheap. Even so, there are several inventors of drugs related to Covid-19 and Covid-19 vaccines that are willing to relinquish patents in the public interest.⁴

The criteria for public interest in patent protection can basically be abstracted from the provisions of the Paris Convention, the TRIPS Agreement and National Law, namely the Patent Law. There is an exception article in TRIPS which allows Members to exclude inventions that can be patented to protect public order or morality including to protect human,

capable of being used or applied in some form of industry or business activity. It should have practical utility and not be a purely theoretical or abstract concept. *Third, Inventive Step:* The invention must involve a non-obvious and inventive step, meaning that it should not be an obvious improvement or combination of existing technologies. It should represent a significant advancement or innovation in its field. Furthermore, when a drug invention meets these criteria, it becomes eligible for patent protection. This protection grants the inventor exclusive rights to the drug for a specific period, usually 20 years from the date of filing the patent application. During this period, the patent holder has the authority to prevent others from making, using, selling, or importing the patented drug without their permission, providing them with a monopoly over the drug. This exclusivity is intended to incentivize innovation and investment in research and development, as it allows inventors to recoup their investments and benefit from their discoveries. However, the monopoly position can also lead to high drug prices, as the patent holder can set the price at their discretion, which may have implications for access to essential medications, particularly in cases of life-threatening diseases.

⁴ Setia Untung Arimuladi, "Perlindungan Negara, Paten Vaksin Covid-19, dan Potensi Monopoli." *Jurnal Hukum Progresif* 9, No. 1 (2021): 50-63.

plant and animal life or health or to avoid major damage to the environment (Article 27 paragraph 2).⁵ Those exclusions are often referred to as the protective clauses of the TRIPS Agreement.

This basis for exclusion should be used as a basis for finding a solution to the monopoly on drug patents in order to overcome the high cost of medicines and medical devices amid the Covid-19 pandemic. There are several ways according to TRIPS and WTO provisions, which are referred to as the protective articles of the TRIPS agreement, namely Parallel Imports, Bolar Provisions, Compulsory Licenses and Patent Execution by the Government. The provisions for patents in Indonesia are regulated in Law Number 13 of 2016 concerning Patents, which regulates Compulsory Licenses in Articles 81 to 108 and regulates the use of patents by the government in Articles 109 to 120, but does not specifically regulate details on parallel import and bolar provision.⁶

⁵ Article 27(2) TRIPS: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law." However, Article 27(2) also contains certain exceptions and flexibilities that member countries can implement to balance the protection of patents with public health and other policy objectives. One of the critical flexibilities mentioned in the Doha Declaration on the TRIPS Agreement and Public Health is the ability of member countries to issue compulsory licenses, which allow them to grant third parties the right to produce and sell patented medicines without the consent of the patent holder, under certain circumstances. This provision is crucial in the context of public health emergencies like the Covid-19 pandemic, as it allows countries to take measures to ensure access to affordable medicines and medical devices for their populations, even if they are subject to patent protection. By employing these flexibilities, countries can address public health crises effectively while still respecting international intellectual property rights obligations under the TRIPS Agreement. *See also* L. Deshko, et al. "Patenting of Medicines in Ukraine Through the Prism of the Association Agreement with the EU and the TRIPS Agreement: Improvement in Medical and Administrative Regulations." *Georgian Medical News* 288 (2019): 154-158; Hembadoon Iyortyer Oguanobi, "Broadening the conversation on the TRIPS agreement: access to medicines includes addressing access to medical devices." *The Journal of World Intellectual Property* 21, No. 1-2 (2018): 70-87; Hans Morten Haugen, "Does TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) prevent COVID-19 vaccines as a global public good?." *The Journal of World Intellectual Property* 24, No. 3-4 (2021): 195-220.

⁶ Joseph M. Gabriel, *Medical Monopoly: Intellectual Property Rights and the Origins of the Modern Pharmaceutical Industry*. (Chicago: University of Chicago Press, 2019). *See also* Thamidela Mythri Devi, and Bhupathiraju Harika. "Analysis On Generic Medicine v. Patented Medicine." *Journal of Positive School Psychology* 6, No. 3 (2022): 826-834.

According to Dede Mia Yusanti, the Director of Patents, Integrated Circuit Layout Design (DTLST), and Trade Secrets of Republic of Indonesia, patents for Corona drugs can be registered and granted intellectual property protection without compromising the public interest. In the global patent system, there are no specific provisions restricting the registration and granting of patents, even during emergency situations like the ongoing Covid-19 pandemic faced by many countries worldwide. As long as a drug, vaccine, or medical device meets the criteria for patentability, such as being new, involving inventive steps, and having industrial applicability, it can be eligible for patent protection, even if it is in high demand by the global community to combat the pandemic.⁷

In light of the two conflicting conditions, the protection of drug and medical device inventors' exclusive rights is important, yet the government's constitutional obligation to safeguard its citizens during a pandemic is equally crucial. This study proposes an examination *Public Health Protection of Drug Patent Monopolies Relating to Handling the Covid-19 Pandemic*. The main issues to be addressed in this study are: *first*, how does public health protection intersect with drug patent monopolies in the context of handling the Covid-19 pandemic, considering both national and international law, and *second*, what are the Indonesian Government's efforts in addressing the Covid-19 pandemic while taking into account patent protection for drug inventions related to the Covid-19 pandemic.

⁷ Muh Ali Masnun, and Dilla Nurfiiana Astanti. "Urgensi Pembatasan Hak Eksklusif Paten COVID-19 Melalui Penerapan Lisensi Wajib di Indonesia." *Jurnal Komunikasi Hukum (JKH)* 6, No. 2 (2020): 456-464; Adzhani Tharifah, and Agus Sardjono. "Eksistensi Perlindungan Paten atas Vaksin Covid-19." *Jurnal Hukum & Pembangunan* 51, No. 4 (2022): 1074-1099; Nynda Fatmawati Octarina, Evi Kongres, and Mardika Mardika. "Urgensi Penemuan Vaksin Covid-19 sebagai Hak Milik Publik." *Pandecta Research Law Journal* 16, No. 1 (2021): 106-119; Gabriela Madeline Hutauruk, Ahmad M. Ramli, and Tasya Safiranita Ramli. "Pelaksanaan Paten oleh Pemerintah Vaksin dan Obat Covid-19 di Masa Pandemi Berdasarkan Hukum Indonesia dan TRIPS-WTO." *Jurnal Sains Sosio Humaniora* 6, No. 1 (2022): 538-550; Miriam Marcowitz-Bitton, and Yotam Kaplan. "Recalibrating Patent Protection for COVID-19 Vaccines: A Path to Affordable Access and Equitable Distribution." *UC Irvine Law Review* 12, No. 2 (2022): 423; Aisling McMahon, "Global Equitable Access to Vaccines, Medicines and Diagnostics for COVID-19: The Role of Patents as Private Governance." *Journal of Medical Ethics* 47, No. 3 (2021): 142-148.

Method

This research employs a juridical-normative approach, which involves using a theoretical and analytical method within the dogmatic legal discipline. It relies solely on secondary data sources, such as laws, regulations, court decisions, legal theories, and scholarly opinions. Being a qualitative analysis, it deals with qualitative data. The study will adopt both a statute approach and a conceptual approach. The statute approach entails examining all laws and regulations pertinent to the research topic, ensuring their coherence and conformity from higher to lower levels of legal regulations. Meanwhile, the conceptual approach involves utilizing legal expert opinions and doctrines.⁸ The research will comprehensively analyze drug patent-related laws and regulations, alongside people's rights to health, incorporating national and international legal instruments, and consulting experts in patents, intellectual property rights, and public health rights.

Result and Discussions

Drug Patent During the Covid-19 Outbreaks: Between Monopoly and Public Interest

Drug discovery refers to the process of inventing new pharmaceutical substances, which are classified as inventions under the patent category according to Article 3, paragraph (1) of Law No. 13 of 2016 concerning Patents. For an invention to be eligible for a patent, it must meet specific criteria, including being novel, containing inventive steps, and having industrial applicability. Drugs fall into the category of patents because they are the result of extensive research and development that requires

⁸ Soerjono Soekanto and Sri Mamudji, *Penelitian Hukum Normatif Suatu Tinjauan Singkat* (Jakarta: PT Raja Grafindo Persada, 2010), p. 24.

significant time and resources. Consequently, drugs can be further divided into patented drugs and non-patented drugs, as specified by Article 1 of the 2011 Regulation of the Head of the Food and Drug Supervisory Agency (BPOM) concerning Criteria for Drug Registration Procedures.⁹

Patented drugs are newly discovered medications resulting from rigorous research and development processes. These drugs are manufactured, marketed under specific trade names, and protected by patents for a duration of 20 years. During this 20-year period, the patent owner, typically the pharmaceutical industry, has the exclusive right to produce and distribute the patented drug or license this right to other parties.

This protection for inventors within the realm of patents serves as a form of acknowledgment for the extensive efforts, resources, and costs invested in research and development. While the primary goal of granting patents is to reward inventors for their innovative contributions, it's crucial to consider the potential negative effects that drug patents can have on public access to essential medicines. The exclusivity granted by patents can lead to drug monopolies, limiting the availability of certain medications and driving up their prices to unaffordable levels for many people.

It is necessary to strike a balance between rewarding inventors for their contributions and ensuring that the public's health needs are adequately addressed. Policymakers and regulatory bodies must work together to design systems that incentivize innovation while also promoting competition and affordability in the pharmaceutical industry. This way, the benefits of drug discoveries can be maximized, and access to life-saving medications can be expanded to those who need them the most.¹⁰

⁹ Abdul Kadir Jaelani, Alexander A. Kurniawan, and Lusiana Indrastuti. "Pelaksanaan Standarisasi Pemberian Paten dalam Inovasi Bidang Obat-Obatan di Indonesia." *Legality: Jurnal Ilmiah Hukum* 27, No. 2 (2019): 259-274; Samariadi Samariadi. "Pelaksanaan Compulsory Licensing Paten Obat-obatan Bidang Farmasi di Indonesia Dikaitkan dengan Doha Declaration on the TRIPS Agreement and Public Health." *DE LEGA LATA: Jurnal Ilmu Hukum* 1, No. 2 (2016): 448-465.

¹⁰ Winner Sitorus, "Kepentingan umum dalam perlindungan paten." *Yuridika* 29, No. 1 (2014): 39-60; Putu Ayu Sriasih Wesna, "Doha Declaration sebagai Perlindungan

Provisions regarding patents in Indonesia are regulated by Law no. 13 of 2016 concerning Patents as amended by Law Number 6 of 2023 concerning the Stipulation of Government Regulations in Lieu of Law Number 2 of 2022 concerning Job Creation to Become Laws hereinafter referred to as the Patent Law, our national laws are of course refers to an international agreement, namely the TRIPs Agreement. However, the main issue that made the TRIPS agreement so controversial that it forced the WTO delegation to enter into additional negotiations was the impact of TRIPS on access to medicines, especially in poor countries and especially for epidemic diseases such as AIDS, tuberculosis, avian flu and malaria¹¹. The TRIPs provisions contain patent flexibility which provides several privileges for poor countries in implementing the TRIPs standards, including patents related to access to public health. The existence of protective articles in the TRIPS agreement referred to as the TRIPS Safeguard gives hope to developing and underdeveloped countries to have access to cheap and affordable drugs.

The TRIPs agreement contains 12 articles governing drug patent protection, and 3 articles regarding policies to address the impact of drug patents which are often referred to as the TRIPs Safeguards. The TRIPs Safeguards that can be used as a strategy to overcome patent threats to public health access include Bolar Provision, Parallel Import, Compulsory License, and Government Use¹². Another provision governing the flexibility of TRIPs is the Doha Declaration. The IV Ministerial Conference was held on 9-14 November 2001 which was attended by 142 countries, WTO member countries produced a declaration known as the Doha Declaration

Masyarakat atas Akses Obat Esensial di Negara Berkembang Pasca Trips Agreement." *Kertha Wicaksana* 14, No. 1 (2020): 56-62; Suparno Suparno, and Faisal Santiago. "Perubahan Paradigma Politik Hukum Hak Kekayaan Intelektual (HKI) untuk Mewujudkan Daya Saing Nasional: Studi Perlindungan Rahasia Dagang Bidang Obat-Obatan Tradisional." *Lex Publica* 5, No. 1 (2018): 8-15.

¹¹ Lidya Shery Muis, "Hak Atas Aksesibilitas Obat Paten Bagi Masyarakat." *Widya Pranata Hukum: Jurnal Kajian dan Penelitian Hukum* 1, No. 1 (2019): 36-64.

¹² Dwiatin Lindati, Rohaini Rohaini, and Eka Rusmawati Dianne. "Kepentingan Umum dalam Pemberian Paten Obat di Indonesia: Menyoal Pemberian Paten Vaksin dan atau Obat Covid-19." *Research Report* (Lampung: Universitas Lampung, 2021).

on the TRIPs and Public Health. This conference discussed dealing with developing countries' concerns about patent regulations that limit access to medicines that are affordable for the community, in an effort to control diseases that affect public health, such as HIV/AIDS and so on¹³.

The Doha Declaration on the TRIPs and Public Health provides a solution to the problem of public health protection, namely the existence of compulsory licensing . Paragraph 4 of the Doha Declaration on the TRIPs and Public Health states, " TRIPs Agreement does not and should not prevent members from taking measures to protect public health ", According to WHO, in the WHO Action Program on Essential Drugs document it says: *"every country needs to limit the implementation exclusive rights in its patent law, especially by applying mandatory licenses and parallel imports"*.

With various international provisions that are mutually sustainable, they provide a way out for countries that want to protect the health of their people by temporarily setting aside the obligation to provide patent protection for drugs and medical devices in their countries. This becomes relevant and a solution when developing countries like Indonesia are faced with the Covid-19 Pandemic situation. As stated in Article 27 paragraph (2) of the TRIPs Agreement " Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law ." On the basis of this article, in the case of protecting public order or morality, including protecting life or health of humans, animals or plants, Indonesia may refuse patent applications or exclude inventions that can be patented, or make other efforts which constitute the protective articles of TRIPs. In line with

¹³ Samariadi. "Pelaksanaan Compulsory Licensing Paten Obat-obatan Bidang Farmasi di Indonesia Dikaitkan dengan Doha Declaration on the Trips Agreement and Public Health".

this, the World Health Organization WHO said that “ The World Health Organization (WHO) on March 11, 2020, has declared the novel coronavirus (COVID-19) outbreak a global pandemic ”¹⁴.

Handling the Covid-19 Pandemic is inseparable from the need for medicines, medical equipment such as personal protective equipment (PPE), ventilators, vaccines, vitamins, masks, rapid test kits and swab tests, and other medical devices. The need for these medical devices is very high because many countries need them and from a business perspective this will cause the prices of medical devices and medicines to become more expensive. In addition to the urgent condition of medical devices and medicines which causes prices to be expensive, the public is also faced with high prices due to patent protection for the inventors.

In the handling of Covid-19, almost everything is related to the issue of protecting intellectual property rights (IPR). That almost all health products in handling Covid-19 such as test kits, diagnostics, masks, medicines, vaccines and ventilators are protected by patents, trade secrets and industrial designs. This is what ultimately opens up opportunities for the pharmaceutical industry to take advantage of the pandemic situation to get as much profit as possible from the abuse of IPR protection and encourage monopoly practices in knowledge, production, price and distribution (supply). Pharmaceutical corporations are still using a business scheme approach in responding to the needs of handling pandemics in the world¹⁵.

¹⁴ WHO, “WHO Director-General’s opening remarks at the media briefing on COVID19 - 11 March 2020”, available online at <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>

¹⁵ Rachmi Hertanti and Agung Prakoso, “Hentikan Monopoli HAKI Terhadap Covid19, Laksanakan TRIPs Waiver”, *Briefing Paper Indonesia for Global Justice*, February (2021): 1-17. Online at <https://igj.or.id/wp-content/uploads/2021/02/BP-FEB-2021-2.pdf>

Table 1. IPR protection related to handling Covid-19¹⁶

Health Products	IPR
Test kits, diagnostics	Patents, Trade Secrets
Masks (especially N95 respirators)	Patents, Industrial Designs
Drugs	Patens
Vaccine	Patents, Trade Secrets
Ventilator, ventilator valves, programs, machines, software, etc.	Patents, Trade Secrets, Industrial Designs, Copyrights and more

To overcome inequality in access to medicines and medical devices, in the end, WHO through the 73rd meeting of The World Health Assembly (WHA) adopted a resolution related to Covid-19 which called for access and fair distribution of all important health technologies and products to fight the virus. For these reasons, countries are given the right to take steps, which are then embodied in a country's regulations.

Article 7 TRIPS states: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." Article 7 implies a public interest through emphasizing that the protection and enforcement of IPR must contribute to the transfer of technology and the dissemination of technology by taking into account the balanced interests of producers of technological knowledge and users of technology, and in a way that supports social and economic welfare and balances rights and obligations.¹⁷ If you look at the provisions in the TRIPS, Indonesia should have taken fair steps for drug patent inventors during the Covid-19 pandemic and also for the public interest, in this case the people's right to health.

Both according to national law and international law, it is regulated regarding 4 (four) things as a way out for WTO member countries to protect

¹⁶ Hertanti and Prakoso

¹⁷ Lindati, et.al., "Kepentingan Umum dalam Pemberian Paten Obatdi Indonesia: Menyoal Pemberian Paten Vaksin dan atau Obat Covid-19."

public health which at the same time must face the monopoly on drug patents as a result of the TRIPS agreement. In general, there are 4 (four) types of options provided in the protective articles in the TRIPS agreement, including Parallel Imports, Bolar Provisions, Compulsory licensing, Government Use of Patents).

Provisions regarding Parallel Import and Provision of Bolar are regulated in Article 167 of Law no. 13 of 2016 concerning Patents, it is stated that exempted from criminal provisions and civil lawsuits for: the import of a pharmaceutical product protected by a patent in Indonesia and the said pharmaceutical product has been legally marketed in a country provided that the pharmaceutical product is imported in accordance with the provisions of laws and regulations; and production of patent-protected pharmaceutical products in Indonesia within a period of 5 (five) years prior to the expiration of patent protection with the aim of the licensing process and then marketing after said patent protection ends.

According to the elucidation of Article 167, the exclusion of the import of pharmaceutical products is intended to guarantee a fair price and fulfill a sense of justice for pharmaceutical products which are urgently needed for human health. This provision can be used if the price of a product in Indonesia is very expensive compared to the price that has been circulating legally in the international market. The exception as referred to in the bolar provision is to guarantee the availability of pharmaceutical products by other parties after the expiration of the patent protection period. Thus, a reasonable price for pharmaceutical products can be sought. What is meant by the licensing process in this letter is the process for issuing a distribution permit and production permit for a pharmaceutical product at the relevant agency.

However, in various studies regarding solutions to protect the public from the Covid-19 outbreak which are associated with the patent protection system, each WTO participating country has a policy of adopting protective articles from TRIPs, including 2 models of systems used by most countries.

countries in the world, namely compulsory licensing and the implementation of patents by the government (government use).¹⁸

Presidential Decree Number 11 of 2020 concerning the Establishment of a Public Health Emergency for Corona Virus Disease 2019 has declared the Covid-19 outbreak as a disease that causes a Public Health Emergency and based on the Decree of the Public Health Emergency for Covid-19 in Indonesia, it is mandatory to carry out prevention efforts in accordance with statutory regulations. . There are two choices of steps that the Indonesian government can take in terms of tackling the Covid-19 pandemic, namely mandatory licensing and the implementation of patents by the government.¹⁹

Furthermore, it is emphasized that it is possible for Corona drug patents to be registered and receive intellectual property protection without compromising the public interest. In the global patent system, including drug and medical device patents, there are typically no restrictions on obtaining patent protection, even during emergency situations like the Covid-19 pandemic that affects almost all countries worldwide.

In this context, if a drug, vaccine, or medical device meets the standard patentability criteria, which includes being novel, involving inventive steps, and having industrial applicability, it can be eligible for patent protection. This applies irrespective of the fact that the drug is in high demand by the global community for dealing with the ongoing pandemic. It is important to

¹⁸ It is also explained that several legal and ethical issues may arise regarding the registration of patents for the COVID-19 vaccine, especially with regard to intellectual property, intellectual property rights, and fair public health access rights. In addition, some countries may be concerned about how strict patent protection might affect universal access to COVID-19 vaccines. High prices or exclusive use of patents can make it difficult for countries with low-income levels to access the necessary vaccines. *See also* Ahmed S. Alshrari, et al. "Innovations and development of COVID-19 vaccines: A patent review." *Journal of infection and public health* 15, No. 1 (2022): 123-131; Matteo Nioi, and Pietro Emanuele Napoli. "The waiver of patent protections for COVID-19 vaccines during the ongoing pandemic and the conspiracy theories: lights and shadows of an issue on the ground." *Frontiers in Medicine* 8 (2021): 756623.

¹⁹ Anang Sugeng Cahyono, "Implementasi Model Collaborative Governance dalam Penyelesaian Pandemi Covid-19." *Publiciana* 13, No. 1 (2020): 83-88; Dalinama Telaumbanua, "Tinjauan Yuridis Penetapan Kedaruratan Kesehatan Masyarakat Akibat COVID-19." *Jurnal Education and Development* 8, No. 2 (2020): 30-30.

note that the decision to grant a patent for a particular drug or medical device is based on its adherence to the established patentability criteria. The patent system's primary purpose is to reward and incentivize innovation by providing inventors with exclusive rights to their inventions for a limited period. This exclusivity enables inventors or companies to recoup their investment in research and development and fosters continued innovation in the pharmaceutical and medical industries.

However, the issue of patents, particularly during times of public health emergencies, has been a subject of debate. Critics argue that granting exclusive patent rights during such crises may hinder timely access to life-saving medications and essential medical devices, especially when they are needed on a global scale. The high demand and limited supply could lead to monopolistic pricing and limited accessibility for vulnerable populations. In response to these concerns, there have been calls for more flexibility in patent enforcement during emergencies like pandemics. Some countries and international organizations have explored options like compulsory licensing, which allows governments to license patented products to third parties or produce them themselves for public health reasons. This approach aims to strike a balance between encouraging innovation and ensuring equitable access to critical medical interventions.

Article 31 of the TRIPs Agreement recognizes the possibility for a country to seek a mandatory license or government use of a patent, particularly in emergency situations related to health. In such cases, a country can utilize a patent without seeking permission from the patent owner. Although TRIPs does not explicitly mention government use or compulsory licensing, Article 31 (b) of the TRIPs Agreement addresses other situations where certain uses are allowed without the authorization of the patent holder. This provision is crucial for enabling the mass availability of drugs during emergency situations, such as the Covid-19 pandemic.²⁰

²⁰ Janet Sultana, et al. "Challenges for drug repurposing in the COVID-19 pandemic era." *Frontiers in pharmacology* 11 (2020): 588654; Wachiraporn Pongjinda, Shubham Pathak, and Ivan Bimbilovski. "Legal Protection against Patent and

In times of public health emergencies like the Covid-19 pandemic, it becomes essential for drugs needed for treatment to be widely accessible. The available recourse within the patent system, in such circumstances, is through a compulsory licensing mechanism and government use of patents. These mechanisms allow governments to take action to ensure that necessary medications are made available to their populations promptly.

The Covid-19 pandemic meets the conditions that warrant the use of the Government Use mechanism as a way to provide essential drugs for treatment. The government can step in to use patents without the permission of the patent owner to address urgent health needs and protect public health during this crisis. Choosing the Government Use mechanism becomes a practical option to rapidly scale up production and distribution of vital drugs without being hindered by potential patent barriers. By exercising Government Use rights, the government can take swift and effective measures to make sure that the required drugs reach those who need them most during the pandemic.

Protection of Drug Patent from Monopoly During Covid-19 Outbreaks: How Indonesian Government Regulates this?

In line with the TRIPs Agreement, Law No. 13 of 2016 concerning Patents regulates compulsory licenses and government use of patents. Compulsory license is defined as a government action that allows other people to produce products or processes that have been patented without prior approval from the patent owner. The Compulsory License itself is a form of patent protection flexibility as stipulated in the WTO-TRIPs (Compulsory license is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It

Intellectual Property Rights Violations Amidst COVID-19." *Emerging Science Journal* 7 (2023): 225-237.

is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property-the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement).²¹

The Doha Declaration states that for the implementation of a compulsory license each member country must pay attention to the following conditions:²²

- 1) There are epidemic public health problems such as HIV/AIDS, malaria, tuberculosis or other epidemics, requiring medicines that are expensive because they are protected by patents;
- 2) There is a national emergency and the need is urgent. In this regard, each country is given the freedom to determine the meaning of "national emergency" or "very urgent need" according to the national needs of each country;
- 3) There are problems regarding the inability and lack of capacity of member countries to produce pharmaceutical patents.

According to Article 82 of the Patent Law and Article 8 of Permenkumham No. 14 of 2021 concerning Amendments to Regulation of the Minister of Law and Human Rights Number 30 of 2019 Concerning Procedures for Granting Compulsory-Patent Licenses, states that "The Minister may grant a Compulsory License on the basis of an application with the following reasons:

- 1) The Patent Holder does not carry out the obligations referred to in Article 107 point 2 of Law Number 11 of 2020 concerning Job Creation within 36 months after being granted the Patent;
- 2) The patent has been implemented by the patent holder or licensee in a form and manner that is detrimental to the public interest; or

²¹ World Trade Organization, "Compulsory licence of pharmaceuticals and TRIPS," World Trade Organization, 2020.

²² Mayas Mutias Sari, Tatty Aryani Ramli "Pelaksanaan Paten oleh Pemerintah Terhadap Obat Antiviral dan Antiretroviral Ditinjau dari UU No. 14 Tahun 2001 Tentang Paten dan Deklarasi Doha." *Prosiding Ilmu Hukum Seminar Penelitian Sivitas Akademika Unisba* 1, No. 1 (2015): 9-19.

- 3) A patent resulting from the development of a previously granted patent cannot be implemented without using another party's patent which is still under protection.

On this basis, the implementation of mandatory licenses becomes less flexible for drugs needed during the Covid-19 pandemic, as well as for drugs that have just been discovered to treat Covid-19 because mandatory licenses are only aimed at finding drugs that have been registered for a certain time.

Thus, the government has not decided to use a Compulsory Licensing policy in terms of drug patents to tackle the Covid-19 Pandemic, because if you look at the more relevant legal basis, it is the policy to take Patent Execution by the Government or what is known as Government Use.

Article 31 (b) TRIPS Agreement provides limited exceptions to the exclusive rights granted by patents, this article allows WTO members to use patents without permission from the patent holder based on certain conditions, such as the emergency situation of the Covid-19 pandemic, and this can be taken with the Government Use policy. TRIPS also requires that the form of application for government use must be in the form of a non-exclusive license, there is appropriate compensation (royalty) to the patent holder and there is an agency or authority that reviews the implementation through an independent legal mechanism.

Government use is different from a mandatory license because government use does not require an initial effort to apply for the implementation of someone's patent as is required for a mandatory license. These conditions are not included in government use by the TRIPS agreement because government use is only related to emergencies and urgent situations. Even so, the government needs to notify the patent holder of the plan to carry out²³ government use.

²³ Tomi Suryo Utomo, "Deklarasi Doha dalam Perspektif Akses Obat Murah dan Terjangkau: Sebuah Pelengkap Perjanjian TRIPS." *Unisia* 30, No. 64 (2007): 122-132; Tomi Suryo Utomo, "Implikasi Pasal-Pasal Pelindung (The Trips Safeguards) dalam UU Paten Indonesia: Kritik, Evaluasi dan Saran Dari Perspektif Akses Terhadap Obat yang Murah dan Terjangkau." *Jurnal Hukum IUS QUIA IUSTUM* 14, No. 2 (2007): 271-294.

Article 109-120 of Law no. 13 of 2016 concerning Patents provides a comprehensive regulation for Government Use, also known as the Implementation of Patents by the Government, which fully complies with the requirements stipulated by the TRIPS agreement. In Indonesia, Article 109, paragraph (1), letter b, explicitly grants the Government the authority to execute patents based on the consideration of very urgent needs in the public interest. This provision aligns with Article 31 of the TRIPS Agreement, which allows countries to issue compulsory licenses in situations of national emergencies or other circumstances of extreme urgency.

Furthermore, Article 115 of the Patent Law maintains consistency with Article 31 of TRIPS by ensuring that the Patent Holder receives reasonable compensation for the use of their patent by the Government. If the Patent Holder disagrees with the compensation amount offered, they have the right to file a lawsuit against the Commercial Court to resolve the dispute. This mechanism safeguards the interests of patent holders while allowing the Government to address pressing public health needs. Moreover, Article 114 of the Patent Law outlines the Government's obligation to provide written notification to the Patent Holder regarding the implementation of the patent. This notification requirement is in line with the TRIPS Agreement, which emphasizes the importance of transparency and communication in matters related to the use of patents by the Government.

By enacting these provisions, the Indonesian Patent Law strikes a balance between encouraging innovation through patent protection and promoting the public interest by facilitating access to essential technologies during critical situations. The regulations surrounding Government Use in Indonesia align with the principles of the TRIPS Agreement, ensuring that both patent holders and the broader society are considered in the process of implementing patents for public welfare.

With the provisions in Article 31 (b) TRIPS and the Patent Law, it is possible for the government to overcome patent barriers for the supply of

Covid-19 drugs and or vaccines by using the government use mechanism (Patent implementation by the Government). In addition to being regulated in Article 109 to Article 120 of Law Number 13 of 2016 concerning Patents, the use of patents is further regulated by Presidential Regulation Number 77 of 2020 concerning Procedures for the Use of Patents by the Government.

In dealing with the Covid-19 Pandemic situation, one of the steps taken by the Indonesian government is the policy of implementing patents by the government through by issuing Presidential Regulation Number 77 of 2020 concerning Procedures for Implementing Patents by the Government. The 2 (two) drugs mentioned in the presidential regulation regarding the implementation of patents are Remdesivir Drug and Favipiravir Drug which are regulated in Presidential Decree Number 100 of 2021 concerning the Implementation of Patents by the Government for Remdesivir Drug and Presidential Regulation Number 101 of 2021 concerning the Implementation of Patents by the Government for Favipiravir Drug.

Government use is a crucial aspect of intellectual property, enabling its application without the need for prior permission from the rights holder. The purpose of this Presidential Decree is to grant the government the flexibility to seek patents for pressing public interests, particularly in critical areas like pharmaceuticals and biotechnology. By invoking this provision, the government can address urgent needs, such as the availability of essential pharmaceutical products during crises like the Covid-19 pandemic, including vaccines and drugs.

The Government of Indonesia follows a Government Use system, outlined in Article 109 of the Patent Law, which grants the government the authority to independently implement patents within the country. This implementation is justified by considerations related to national defence, security, or other urgent needs for the public interest. This system empowers the state to secure sufficient pharmaceutical products required

to combat the Covid-19 pandemic and fulfil the public's health requirements effectively.

The application of Government Use Patents in Indonesia is particularly relevant and crucial during the pandemic, as it addresses urgent needs for the benefit of society. This system enables the government to implement patents in two key fields: defence and security, as well as pharmaceuticals and/or biotechnology.²⁴

According to Article 111 letter a of the Patent Law and Article 13 of Presidential Decree 77 of 2020, patents related to very urgent needs for the public interest can be utilized for pharmaceutical and/or biotechnology products that are either expensive or essential in treating diseases that can lead to a high number of sudden deaths, significant disability, and constitute a global public health emergency (*Kedaruratan Kesehatan Masyarakat yang Meresahkan Dunia* hereinafter as KMMMD). For instance, this allows government use to be applied to treatments for HIV/AIDS, which necessitate antiretroviral drugs (ARVs). However, these patented drug versions are often expensive in the market, and the high demand for ARV drugs arises from the fact that they are required for life by people living with HIV/AIDS.

The situation with COVID-19 mirrors that of a global health emergency, causing a large number of deaths and leading to expensive drug prices due to high demand. The World Health Organization (WHO) officially declared COVID-19 as a Public Health Emergency of International Concern in early 2020. In light of these circumstances, the utilization of Government Use Patents becomes a vital tool for the Indonesian government to ensure the availability of essential pharmaceutical and/or biotechnology products required to combat the COVID-19 pandemic effectively, benefiting society at large.

²⁴ Rustam Agus, "Government Use dan Akses Terhadap Obat Covid-19", *Bisnis Indonesia*, September 1, 2021. Available online at <https://bisnisindonesia.id/article/government-use-dan-akses-terhadap-obat-covid19>

In the event that the Government cannot implement a Patent on its own, the Government may appoint a third party to implement the Patent, by first submitting a written application to the Minister of Law and Human Rights, this is stated in Article 116 of the Patent Law. In terms of the patent enforcement process by the government, the Indonesian government should apply the principles of fairness and balance between the interests of society in dealing with the Covid-19 pandemic and also comply with inventor rights proportionally, patent enforcement by the government still respects the exclusive rights of inventors. Inventors still get economic rights through the provision of reasonable compensation as a form of compensation to patent holders.

In the further context, the concept of justice for inventors includes that the patent implementation mechanism by the government is carried out in a limited manner, namely limited only based on the purpose of implementation, namely to meet the very urgent need for the health rights of the Indonesian people, to meet domestic needs, and is non-commercial in nature. , this is in accordance with Article 109 paragraph (2) of the Patent Law. A patent by the Government can be exercised as long as it is not used for commercial purposes. The patent implementation by the government for the COVID-19 vaccine is also not intended for commercial purposes, including export activities, and is carried out only to fulfil the health rights of the Indonesian people.

In addition, the implementation of patents by the government uses a casuistic approach in a short time (case per case approach), in which the government must independently determine the details of what products are to be patented, along with the implementation period. This is quite a challenge in a pandemic situation, because the state is obliged to take care of various administrative needs.²⁵

²⁵ Hutaeruk, et.al., "Pelaksanaan Paten oleh Pemerintah Vaksin dan Obat Covid-19 di Masa Pandemi Berdasarkan Hukum Indonesia dan TRIPs-WTO."

Regarding the implementation of patents by the government, patent holders still receive legal protection, including being able to fully exercise their exclusive rights to their patents as under normal conditions, so that patent holders do not lose the economic benefits of their pharmaceutical product patents. In the implementation of pharmaceutical product patents by the government, whether carried out by the Ministry of Health or third parties appointed by the government, pharmaceutical product patent holders are entitled to receive reasonable compensation. However, the implementation of patents by the government still creates obligations for patent holders, including pharmaceutical product patent holders still have the obligation to pay an annual fee even though the patent implementation is carried out by the government as a form of reciprocity for exclusive rights which can still be exercised by pharmaceutical product patent holders themselves. When the pharmaceutical product patent holder does not pay the annual fee until the specified time, the patent is declared null and void even though the patent is being implemented by the government. In addition, holders of pharmaceutical product patents must comply with government decisions regarding the implementation of pharmaceutical product patents by the government along with all of its legal provisions. The government's decision cannot be taken by civil, criminal, state administration or other legal remedies and applies to the parties involved.

In line with the use of patents by the government as stipulated in Presidential Regulation Number 77 of 2020 concerning Procedures for the use of patents by the government, during the Covid-19 pandemic the government issued 2 regulations governing the implementation of drugs related to Covid-19, namely presidential regulations regarding patent implementation: Remdesivir and Favipiravir drugs are regulated in Presidential Decree Number 100 of 2021 concerning Government Patents for Remdesivir Drugs and Presidential Decree Number 101 of 2021 concerning Government Patent Applications for Favipiravir Drugs. Remdesivir and Favipiravir are drugs needed during the Covid-19

pandemic, which according to Presidential Decree Number 100 of 2021 Remdesivir is owned by a patent holder under the name Gilead Sciences, Inc and according to Presidential Decree Presidential Decree No. 101 of 2021 Favipiravir is owned by a patent holder named Fujifilm Toyama Chemical Co., Ltd. The two regulations contain provisions which stipulate that the Government's patent implementation of Remdesivir and Favipiravir drugs is intended to meet the availability and very urgent need for the treatment of Covid-19. Government patents for Remdesivir and Favipiravir are implemented for a period of 3 years after the Presidential Regulation comes into force. If after the 3 years period has not expired, the patent implementation by the Government is extended until the Covid-19 pandemic is declared to have ended by the Government.

Pursuant to Article 115 of the Patent Law, the Government provides reasonable compensation to the Patent Holder as compensation for the use of the Patent by the Government. In this pandemic situation, reasonable compensation is measured by taking into account the economic benefits that can potentially be obtained by the Covid-19 vaccine patent holder with the state's capacity to pay, so that through the patent mechanism by the government, the economic rights of vaccine inventors can be accommodated.²⁶ According to the Presidential Regulation on Patent Implementation by the Government for Remdesivir and Favipiravir Drugs, the Minister who administers government affairs in the health sector appoints the pharmaceutical industry as the executor of the patent and the appointed pharmaceutical industry pays compensation to the patent holder in the amount of 1% (one percent) of the net sales value. the drug Favipiravir and the reward is carried out every year.

The government, in this case the Ministry of Health of the Republic of Indonesia, appointed PT Kimia Farma as the executor of the patent by the Government to produce and distribute remdesivir and favipiravir drugs. Patents for Remdesivir and Favipiravir drugs through Decree of the

²⁶ Hutaauruk, et.al.

Minister of Health of the Republic of Indonesia Number HK.01.07/MENKES/256/2022. On that basis, the government appointed PT Kimia Farma as the executor of the patent for and on behalf of the Government for Remdesivir and Favipiravir drugs, on a limited basis to meet domestic demand and are non-commercial in nature. In carrying out the appointment, PT Kimia Farma is required to use active raw materials for drugs that have been produced domestically and PT Kimia Farma provides compensation to the Patent Holder in the amount of 1% (one percent) of the net selling value of Remdesivir and Favipiravir drugs whose implementation is in accordance with the provisions of the legislation.

Seeing the provisions regarding the implementation of drug patents by the government during the Covid-19 pandemic had several impacts related to the two drugs referred to above, namely Remdesivir and Favipiravir drugs, one of which was that these two drugs could be produced by PT Kimia Farma using active drug raw materials. which have been produced domestically. According to the Main Director of PT Kimia Farma who gave a statement that PT Kimia Farma was producing and distributing three variants of therapeutic drugs for the recovery of the health of Covid-19 patients of the Azithromycin, Favipiravir and Remdesivir types. PT Kimia Farma is also producing Favipiravir which is targeted to roll out until July 23 2021 in a total of seven million tablets and Fulfilment of injectable Remdesivir products for domestic needs which are expected to be launched in September 2021. Then in July 2021 the Government through Regulation of the Minister of Health of the Republic of Indonesia Number HK 1.7 /Menkes/4826/2021 stipulates 11 highest retail prices for drugs during a pandemic,²⁷ two of which are Favipiravir 200 mg tablets costing IDR 22,500 per tablet and Remdesivir 100 mg injection costing IDR 510,000 per vial. This has shown that there is a significant effect on the decision to intervene

²⁷ Andi Firdaus, "Kimia Farma produksi tiga varian obat terapi COVID-19 jenis Azithromycin, Favipiravir dan Remdesivir", *ANTARA News*, July 7, 2021. Retrieved from <https://sumbar.antaranews.com/berita/443414/kimia-farma-produksi-tiga-varian-obat-terapi-covid-19-jenis-azithromycin-favipiravir-dan-remdesivir>

in the patents of the two drugs through government use where the government can control the price of drugs which were originally very expensive to become affordable for the public and these drugs are no longer monopolized by patent holders who take advantage of the Covid-19 pandemic situation. to sell the price of Covid-19 therapy drugs at very high prices.

However, even though there is a Highest Retail Price provision, the Business Competition Supervisory Commission found that a number of Covid-19 therapeutic drugs had soared above the Highest Retail Priciset (HET) by the government. A shop was found selling Favipiravir produced by pharmaceutical chemicals and the brands Avigan and Avicov being sold above the HET in the range of Rp. 35,000 - Rp. 85,000 per tablet. Meanwhile, the 200 mg Favipiravir HET is IDR 22,000 per tablet. Then, Remdesivir 100 mg under the brands Remdac, Remcor and Covicor are sold in the range of Rp. 1,480,000-Rp. 2,320,000 per vial. ²⁸ This condition shows that even though there has been government intervention related to the production of the two Covid-19 therapeutic drugs, prices on the market can be manipulated by irresponsible elements to get big profits from the Covid-19 pandemic situation.

The Indonesian government's decision to implement patents for therapeutic drugs for Covid-19 is one of the right steps to provide a balance between granting patent holders rights for their inventions and the public's right to health. Even though the implementation of drug patents has been taken by force by the government, this is not a very detrimental thing for patent holders because patent holders can still use their exclusive rights and also get compensation from drugs whose patents are implemented by the government.

²⁸ Arief Rahman Hakim, "KPPU Temukan Harga Obat Terapi Covid-19 Melambung, Ini Daftarnya" *Liputan6 Online*, July 30, 2021. Retrieved from <https://www.liputan6.com/bisnis/read/4619836/kppu-temukan-harga-obat-terapi-covid-19-melambung-ini-daftarnya>

Implementation of government patents for Covid-19 therapeutic drugs that appoint third parties is not exclusive, not arbitrary and for a limited period of time, limited to the purpose of using the patent, namely only in the context of tackling the Covid-19 pandemic. In the event of an objection to the compensation determined by the government for a drug whose patent is implemented by the government, the patent holder can file a lawsuit with the Commercial Court, however the Patent Law does not regulate cassation as in other IPR cases. Although there is a written notification to the drug patent holder and compensation for the patent holder, there are no more detailed provisions regarding the technical implementation of the relationship between the patent holder and a third party appointed by the Government to implement the patent. In the case of drugs whose patents are implemented by the government that are already circulating in the community, there is no clear mechanism for the patent holders to monitor in order to find out the amount of compensation that should be received. Even though the government has made efforts to implement patents for Covid-19 therapeutic drugs for the community, drug prices on the market are not immediately under control because of the condition of the public where panic buying is used by unscrupulous individuals to stockpile drugs and sell them at unreasonable prices, because Therefore, in order to achieve the goal of controlling the Covid-19 pandemic, the intervention of various stakeholders to keep an eye on the distribution of drug prices is necessary.

Conclusion

This study concluded that international law governing Intellectual Property Rights, particularly patents, offers an opportunity for its members to respond to emergency situations like the Covid-19 Pandemic by employing measures outlined in TRIPS and the WTO. These measures include Parallel Imports, Bolar Provisions, Compulsory Licenses, and Execution of Patents by the Government. In line with this, national law,

specifically Law no. 13 of 2016 concerning Patents, has addressed these four aspects, although it lacks detailed regulations regarding parallel imports and Bolar provisions. This demonstrates that there are solutions available to tackle the issue of patent drug monopolies, which have posed challenges to people's rights to health, especially during health emergencies. Furthermore, these measures strike a balance between safeguarding the inventors' rights to patent protection and ensuring the public's access to essential medicines. This approach can be seen as a proportionate and justice-oriented regulation.

The study also highlighted that the government has effectively addressed the challenges posed by the Covid-19 Pandemic through the implementation of patents by the government (government use) for drugs used in Covid-19 therapy. This policy is governed by Presidential Regulation Number 77 of 2020, which outlines the procedures for implementing patents by the government. Specifically, two drugs, Remdesivir and Favipiravir, have been subject to the implementation of patents, as stipulated in Presidential Decree Number 100 of 2021 for Remdesivir and Presidential Regulation Number 101 of 2021 for Favipiravir. Despite the compulsory nature of implementing these drug patents by the government, the process is not arbitrary. It adheres to certain limitations, including a defined period of use, non-exclusivity, and the provision of compensation to the patent holder for the drugs whose patents are implemented by the government. This ensures that patent holders can still exercise their exclusive rights and receive fair compensation while enabling broader access to crucial medications during the pandemic.

References

- Adakawa, Murtala Ismail, and N. S. Harinarayana. "Insight Into Intellectual Property in Patent Medicine: An Indian Perspective." *Unnes Law Journal* 8, No. 2 (2022): 377-391. <https://doi.org/10.15294/ulj.v8i2.60716>

- Affandi, Hernadi. "Implementasi Hak atas Kesehatan Menurut Undang-Undang Dasar 1945: antara Pengaturan dan Realisasi Tanggung Jawab Negara." *Jurnal Hukum Positum* 4, No. 1 (2019): 36-56. <https://doi.org/10.35706/positum.v4i1.3006>
- Agus, Rustam. "Government Use dan Akses Terhadap Obat Covid-19", *Bisnis Indonesia*, September 1, 2021. Available online at <https://bisnisindonesia.id/article/government-use-dan-akses-terhadap-obat-covid19>
- Alshrari, Ahmed S. et al. "Innovations and development of COVID-19 vaccines: A patent review." *Journal of Infection and Public Health* 15, No. 1 (2022): 123-131. <https://doi.org/10.1016/j.jiph.2021.10.021>
- Arimuladi, Setia Untung. "Perlindungan Negara, Paten Vaksin Covid-19, dan Potensi Monopoli." *Jurnal Hukum Progresif* 9, No. 1 (2021): 50-63. <https://doi.org/10.14710/jhp.9.1.50-63>
- Atmaja, Yustisiana Susila, 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>
- Cahyono, Anang Sugeng. "Implementasi Model Collaborative Governance dalam Penyelesaian Pandemi Covid-19." *Publiciana* 13, No. 1 (2020): 83-88. <https://doi.org/10.36563/publiciana.v13i1.207>
- Deshko, L. et al. "Patenting of Medicines in Ukraine Through the Prism of the Association Agreement with the EU and the TRIPS Agreement: Improvement in Medical and Administrative Regulations." *Georgian Medical News* 288 (2019): 154-158.
- Devi, Thamidela Mythri, and Bhupathiraju Harika. "Analysis on Generic Medicine v. Patented Medicine." *Journal of Positive School Psychology* 6, No. 3 (2022): 826-834.
- Firdaus, Andi. "Kimia Farma produksi tiga varian obat terapi COVID-19 jenis Azithromycin, Favipiravir dan Remdesivir", *ANTARA News*, July 7, 2021. Retrieved from <https://sumbar.antaraneews.com/berita/443414/kimia-farma-produksi-tiga-varian-obat-terapi-covid-19-jenis-azithromycin-favipiravir-dan-remdesivir>
- Gabriel, Joseph M. *Medical Monopoly: Intellectual Property Rights and the Origins of the Modern Pharmaceutical Industry*. (Chicago: University of Chicago Press, 2019).
- Hakim, Arief Rahman. "KPPU Temukan Harga Obat Terapi Covid-19 Melambung, Ini Daftarnya" *Liputan6 Online*, July 30, 2021. Retrieved from <https://www.liputan6.com/bisnis/read/4619836/kppu-temukan-harga-obat-terapi-covid-19-melambung-ini-daftarnya>
- Haugen, Hans Morten. "Does TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) prevent COVID-19 vaccines as a global public good?." *The Journal of World Intellectual Property* 24, No. 3-4 (2021): 195-220. <https://doi.org/10.1111/jwip.12187>
- Hertanti, Rachmi, and Agung Prakoso, "Hentikan Monopoli HAKI Terhadap Covid19, Laksanakan TRIPS Waiver", *Briefing Paper*

- Indonesia for Global Justice*, February (2021): 1-17. Online at <https://igj.or.id/wp-content/uploads/2021/02/BP-FEB-2021-2.pdf>
- Hutauruk, Gabriela Madeline, Ahmad M. Ramli, and Tasya Safiranita Ramli. "Pelaksanaan Paten oleh Pemerintah Vaksin dan Obat Covid-19 di Masa Pandemi Berdasarkan Hukum Indonesia dan TRIPS-WTO." *Jurnal Sains Sosio Humaniora* 6, No. 1 (2022): 538-550. <http://dx.doi.org/10.22437/jssh.v6i1.19723>
- Jaelani, Abdul Kadir, Alexander A. Kurniawan, and Lusya Indrastuti. "Pelaksanaan Standarisasi Pemberian Paten dalam Inovasi Bidang Obat-Obatan di Indonesia." *Legality: Jurnal Ilmiah Hukum* 27, No. 2 (2019): 259-274.
- Lindati, Dwiatin, Rohaini Rohaini, and Eka Rusmawati Dianne. "Kepentingan Umum dalam Pemberian Paten Obat di Indonesia: Menyoal Pemberian Paten Vaksin dan atau Obat Covid-19." *Research Report* (Lampung: Universitas Lampung, 2021).
- Marcowitz-Bitton, Miriam and Yotam Kaplan. "Recalibrating Patent Protection for COVID-19 Vaccines: A Path to Affordable Access and Equitable Distribution." *UC Irvine Law Review* 12, No. 2 (2022): 423-470.
- Mardiansyah, Rico. "Dinamika Politik Hukum Dalam Pemenuhan Hak Atas Kesehatan di Indonesia." *Veritas et Justitia* 4, No. 1 (2018): 227-251. <https://doi.org/10.25123/vej.v4i1.2918>
- Masnun, Muh Ali, and Dilla Nurfiiana Astanti. "Urgensi Pembatasan Hak Eksklusif Paten COVID-19 Melalui Penerapan Lisensi Wajib di Indonesia." *Jurnal Komunikasi Hukum (JKH)* 6, No. 2 (2020): 456-464. <https://doi.org/10.23887/jkh.v6i2.28096>
- McMahon, Aisling. "Global Equitable Access to Vaccines, Medicines and Diagnostics for COVID-19: The Role of Patents as Private Governance." *Journal of Medical Ethics* 47, No. 3 (2021): 142-148. <http://dx.doi.org/10.1136/medethics-2020-106795>
- Muis, Lidya Shery. "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>
- Nioi, Matteo, and Pietro Emanuele Napoli. "The waiver of patent protections for COVID-19 vaccines during the ongoing pandemic and the conspiracy theories: lights and shadows of an issue on the ground." *Frontiers in Medicine* 8 (2021): 756623. <https://doi.org/10.3389/fmed.2021.756623>
- Octarina, Nynda Fatmawati, Evi Kongres, and Mardika Mardika. "Urgensi Penemuan Vaksin Covid-19 sebagai Hak Milik Publik." *Pandecta Research Law Journal* 16, No. 1 (2021): 106-119. <https://doi.org/10.15294/pandecta.v16i1.28997>
- Oguanobi, Hembadoon Iyortyer. "Broadening the conversation on the TRIPS agreement: access to medicines includes addressing access to medical devices." *The Journal of World Intellectual Property* 21, No. 1-2 (2018): 70-87. <https://doi.org/10.1111/jwip.12091>

- Poungjinda, Wachiraporn, Shubham Pathak, and Ivan Bimbilovski. "Legal Protection against Patent and Intellectual Property Rights Violations Amidst COVID-19." *Emerging Science Journal* 7 (2023): 225-237. <https://doi.org/10.28991/ESJ-2023-SPER-016>
- Raharjo, Raden Bagoes Prasetyo, and Kholis Roisah. "Hak Akses Kesehatan Masyarakat Terhadap Hak Paten Produk Farmasi." *Jurnal USM Law Review* 4, No. 2 (2021): 604-614. <http://dx.doi.org/10.26623/julr.v4i2.3231>
- Samariadi, Samariadi. "Pelaksanaan Compulsory Licensing Paten Obat-obatan Bidang Farmasi di Indonesia Dikaitkan dengan Doha Declaration on the Trips Agreement and Public Health." *DE LEGA LATA: Jurnal Ilmu Hukum* 1, No. 2 (2016): 448-465. <https://doi.org/10.30596/dll.v1i2.804>
- Sari, Mayas Mutias, Tatty Aryani Ramli "Pelaksanaan Paten oleh Pemerintah Terhadap Obat Antiviral dan Antiretroviral Ditinjau dari UU No. 14 Tahun 2001 Tentang Paten dan Deklarasi Doha." *Prosiding Ilmu Hukum Seminar Penelitian Sivitas Akademika Unisba* 1, No. 1 (2015): 9-19. <http://dx.doi.org/10.29313/.voio.412>
- Sitorus, Winner. "Kepentingan Umum dalam Perlindungan Paten." *Yuridika* 29, No. 1 (2014): 39-60. <https://doi.org/10.20473/ydk.v29i1.357>
- Soekanto, Soerjono and Sri Mamudji, *Penelitian Hukum Normatif Suatu Tinjauan Singkat* (Jakarta: PT Raja Grafindo Persada, 2010).
- Sulistianingsih, Dewi, and Raden Muhammad Arvy Ilyasa. "The Impact of Trips Agreement on the Development of Intellectual Property Laws in Indonesia." *Indonesia Private Law Review* 3, No. 2 (2022): 85-98. <https://doi.org/10.25041/iplr.v3i2.2579>
- Sultana, Janet. et al. "Challenges for drug repurposing in the COVID-19 pandemic era." *Frontiers in Pharmacology* 11 (2020): 588654. <https://doi.org/10.3389/fphar.2020.588654>
- Suparno, Suparno, and Faisal Santiago. "Perubahan Paradigma Politik Hukum Hak Kekayaan Intelektual (HKI) untuk Mewujudkan Daya Saing Nasional: Studi Perlindungan Rahasia Dagang Bidang Obat-Obatan Tradisional." *Lex Publica* 5, No. 1 (2018): 8-15.
- Telaumbanua, Dalinama. "Tinjauan Yuridis Penetapan Kedaruratan Kesehatan Masyarakat Akibat COVID-19." *Jurnal Education and Development* 8, No. 2 (2020): 30-30. <https://doi.org/10.37081/ed.v8i2.1659>
- Tharifah, Adzhani, and Agus Sardjono. "Eksistensi Perlindungan Paten atas Vaksin Covid-19." *Jurnal Hukum & Pembangunan* 51, No. 4 (2022): 1074-1099. <https://doi.org/10.21143/jhp.vol51.no4.3302>
- Utomo, Tomi Suryo. "Deklarasi Doha dalam Perspektif Akses Obat Murah dan Terjangkau: Sebuah Pelengkap Perjanjian TRIPS." *Unisia* 30, No. 64 (2007): 122-132. <https://doi.org/10.20885/unisia.vol30.iss64.art2>
- Utomo, Tomi Suryo. "Implikasi Pasal-Pasal Pelindung (The Trips Safeguards) dalam UU Paten Indonesia: Kritik, Evaluasi dan Saran Dari Perspektif Akses Terhadap Obat yang Murah dan

- Terjangkau." *Jurnal Hukum IUS QUIA IUSTUM* 14, No. 2 (2007): 271-294.
- Wesna, Putu Ayu Sriasih. "Doha Declaration sebagai Perlindungan Masyarakat atas Akses Obat Esensial di Negara Berkembang Pasca Trips Agreement." *Kertha Wicaksana* 14, No. 1 (2020): 56-62. <https://doi.org/10.22225/kw.14.1.2020.56-62>
- WHO. "WHO Director-General's opening remarks at the media briefing on COVID19 -11 March 2020", available online at <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>
- Wicaksono, Imam. "Politik Hukum Pelindungan Hak Kekayaan Intelektual di Indonesia Pasca di Ratifikasinya TRIPs Agreement." *Pena Justisia: Media Komunikasi dan Kajian Hukum* 18, No. 1 (2020): 37-47. <http://dx.doi.org/10.31941/pj.v18i1.1088>

DECLARATION OF CONFLICTING INTERESTS

The authors state that there is no conflict of interest in the publication of this article.

FUNDING INFORMATION

None

ACKNOWLEDGMENT

None

HISTORY OF ARTICLE

Submitted : October 27, 2022
Revised : February 27, 2023; April 30, 2023
Accepted : May 17, 2023
Published : May 30, 2023