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Invoking Compulsory Licensing Amidst the COVID-19 Pandemic

Increasing Accessibility of Vaccines in Indonesia

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ABSTRACT
A patent gives inventors exclusive rights to profit from their products as well as preventing other parties from claiming it as theirs, which is regulated by both international law and Indonesia's national law. Patenting pharmaceutical products is controversial as companies can profit from the complex development of medicine, while at the same time, they are pressured to develop better and newer products. Furthermore, the world is facing the COVID-19 pandemic, which has caused the deaths of almost 3 million people worldwide and almost 40 thousand deaths in Indonesia alone. A working vaccine can stop this number from climbing as it can give enough immunity to the population. However, if pharmaceutical companies developing the vaccine amidst the COVID-19 pandemic want to gain profit from their development, they might be hindered by Article 31 of the TRIPS Agreement and Article 109 *juncto* 111 of the Indonesian Patent Law. In dire circumstances such as extreme urgency, national emergencies, and/or in the event of a widely-spread disease, the government can force compulsory licensing, which will allow for increased accessibility of the medicine but disabling companies from profiting off the medicine. COVID-19 fulfills the circumstances laid by both regulations. Pursuing compulsory licensing may provide better access to vaccines as part of their right to health. This study will discuss humans' right to life and health, as defined in several international human rights instruments and the Indonesian Human Rights Law. Conclusively, the matter of patenting the COVID-19 vaccine needs to consider several factors, such as financial, regulatory, and human rights.

Keywords: *COVID-19 pandemic, compulsory licensing, TRIPS Agreement, Indonesian Patent Law, COVID-19 vaccine, pharmaceutical patent.*

1. INTRODUCTION

A person or entity who has dedicated their time to develop something has an inclusive right to be recognized as the owner of their invention. This inclusive right is known as intellectual property rights ("**IPR**"). IPR has several types, one of which is patent [1]. The patent is an exclusive right with an invention value within the products or its process, and it is made in the first place to protect the owner's works and prevent people from selling or anything that makes it profitable [2]. In protecting patents, there is a specialized body, namely the World Intellectual Property Organization ("**WIPO**") [3]. WIPO has been acknowledged by the United Nations; hence WIPO is internationally recognizable [4]. WIPO's objectives are to help countries grant patents efficiently and balance the interests between innovators and the public [5]. This is because patents can be an agitator for economic advancement and human welfare. In regard to patents, WIPO has several international treaties that almost all countries have ratified, and the two most used are the Trade-Related Aspects of Intellectual Property ("**TRIPS**") Agreement and the Patent Cooperation Treaty ("**PCT**"). In Indonesia, patent rights are given by the Directorate-General of Intellectual Property following the procedure under Law of the Republic of Indonesia No. 13 of 2016 on patent ("**Indonesia patent law**"). Although it is named exclusive rights, there are limitations for the owner to exercise it. Generally, it is limited to a maximum of 20 years, as stated in Section 5, Article 33 of the TRIPS Agreement, and also under Article 22 (1) of Indonesia patent law.

Many things can be patented. However, patenting pharmaceutical products is controversial because several

difficulties transpire during the development. Firstly, the expensive costs of research and development to discover, develop, and market new drugs in which manufacturers experience severe financial pressure. Notwithstanding the health benefits and abundant economic correlation to innovation in pharmaceuticals, even prosperous nations struggle with high prices for patent medicines [6]. Secondly, there is insufficient collaboration amongst the government, corporations, and scientists. They are usually operating competitively on the same molecular targets rather than working together. It is because of their objective that they want to obtain profit solely. Lastly, the bureaucracy of granting a patent is complicated. The patent is restricted only in the country where the patent rights have been recognized [7]. Hence, there are urgencies to protect their invention due to a large amount of money they have invested in the research and development and strengthen the public-private partnerships to be more effective.

In spite of the complexities within pharmaceutical development, it is necessary to frequently develop new medicines to protect humans from viruses or bacteria. Notably, our world is currently encountering a global health emergency where a highly contagious virus named COVID-19 is spreading around. A specialized health agency of the United Nations, the World Health Organization ("WHO"), has declared it a pandemic [8]. While the number of infections and mortality of the COVID-19 increases daily, pharmaceutical companies, universities, and Government-funded research worldwide is racing to produce vaccines that will tackle the COVID-19 pandemic [9]. Therefore, some obstacles have emerged amidst the COVID-19 pandemic to balance patent rights and public needs.

2. RESEARCH METHOD

This research uses juridical-normative methods. The juridical normative examines regulations, books, legal theories, court decisions, and doctrines. It is also known as a method that uses secondary data to be interpreted for the sources [10]. The secondary data used for this research including but not limited to the TRIPS Agreement, Law No. 3 of 2016 on Patent, the Doha Declaration on TRIPS Agreement and Public Health, Law No. 39 of 1999 on Human Rights in Indonesia, Universal Declaration on Human Rights ("UDHR"), the journal of Indiana International & Comparative Law "Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", Journal by American University International Law Review "The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health," and Journal by International Business Policy "Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence". Through this research method, the authors seek to analyze the compulsory licensing provision, both under international and national law, that perhaps can be invoked amidst a global health emergency, the COVID-19 pandemic.

3. FINDINGS AND DISCUSSION

3.1. Current Condition

In late December 2019, an outbreak of mysterious pneumonia characterized by fever, dry cough, and fatigue, and occasional gastrointestinal symptoms happened in a seafood wholesale wet market, the Huanan Seafood Wholesale Market, in Wuhan, Hubei, People's Republic of China [11]. This pneumonia spread rapidly around the world and is now known as the COVID-19 pandemic. It has so far become the biggest health catastrophe in the 21st century.

COVID-19 is a ribonucleic acid or RNA virus with a typical crown-like appearance under an electron microscope due to the presence of glycoprotein spikes on its envelope [12]. In March 2020, the WHO announced that there are about 87,317 cases of COVID- 19 globally as well as confirmed cases of deaths of 2,977 [13]. Currently, the death case has increased rapidly and hit more than 3 million worldwide cases and 49,205 death cases in Indonesia itself [14].

Every nation is now on the same boat in fighting against the COVID-19 pandemic. Many strategies in eliminating the virus have been executed. One of the strategies in order to overcome the pandemic is through the development of efficient and safe vaccines. Vaccines train our immune system to create antibodies and become defense mechanisms for our bodies. Vaccines contain only killed or weakened forms of germs like viruses or bacteria; they do not cause the disease or put you at risk of its complications. Most vaccines are given by injection, but some are given by mouth or sprayed into the nose [15].

When people get vaccinated, they don't just protect themselves yet those around them. When a person gets vaccinated, their risk of infection is decreased and they're less likely to transmit the virus to other people. The more people in a community get vaccinated, the fewer people are prone to the disease, and it leads to herd immunity.

"Herd immunity" or "Herd protection" can be understood as "when most of the population is immune to an infectious disease, this provides indirect protection to the rest who are not immune to the disease" [16]. It becomes the indirect protection from an infectious disease that happens when immunity develops through vaccination. Herd immunity refers to the indirect protection from infection provided to individuals who are vulnerable when large enough individuals in a

population. For example, if 80% of the people in a certain country get immune to a specific virus, four out of every five people who come in contact with the disease will not be affected or spread it further, and eventually, the virus transmission would stop in the population [16]. The proportion of the population needed to get herd immunity depends on how contagious the infection is. Generally, in order to achieve herd immunity, 70% to 90% of individuals need to be immune [16]. This concept of herd immunity shows that when a certain percentage of the population is vaccinated or immunized leads to preventing the outbreak from both unvaccinated and vaccinated individuals. Based on the concept explained previously, the more people the virus infects, the more substantial possibility for the virus to mutate, increasing the transmission risk and making the pandemic harder to control in the long run. Hence, vaccines play a major part in this pandemic to increase herd immunity and lower hospitalization numbers.

Furthermore, compulsory licensing may accelerate the distribution of vaccines to hard-to-reach communities and thus achieve herd immunity by providing a way for governments to access vaccine production despite disregarding companies' right to patent their inventions. Compulsory licensing is a tool to ensure people's right to health as stated in Article 25 of the UDHR, which provides that, "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care…". Furthermore, pursuing compulsory licensing also ensures the people's right to life as stated in Article 3 UDHR, which stipulates that, "Everyone has the right to life, liberty, and security of person." By invoking compulsory licensing, we may protect and uphold the right to health and life amidst the pandemic.

3.2. International Law

Pharmaceutical inventions, including vaccines, are protected by IPR. Regarding laws on intellectual property rights, the owners of the patent have the right to invoke exclusive rights to prevent others from using their invention or selling pharmaceutical products that contain the invention. The owners of patented inventions can sell pharmaceutical products manufactured from a patent-protected method to fund next research and development and also to gain profit [17].

The Paris Convention for the Protection of Intellectual Property ("**Paris Convention**"), as the first treaty on industrial property rights protection, stipulates that contracting member states have an obligation to protect inventions in all fields of technology [17]. However, in some circumstances, there is an exception to protecting inventions, such as in public health emergencies that urgently need collaboration in inventing medicines to tackle it. The Paris Convention birthed the idea for this exception on Article 5, known as compulsory licensing [18]. Compulsory licensing aims to prevent patent abuse. The idea of compulsory licensing was born from the desire of developing countries to get access to medicines at a low and affordable price with the aim to improve public health [19].

Amendments to the Paris Convention led to the creation of WIPO in 1967 [20]. As IPR issues become more prevalent in trade, the WTO drafted the TRIPS Agreement, including provisions on patent and compulsory licensing [21]. The term "compulsory licensing" does not appear in the TRIPS Agreement; however, its Article 31 is titled "other use without authorization of the right holder" [22]. Article 31 (b) of the TRIPS Agreement states the preconditions related to the issuance of a compulsory license. Under normal conditions, the licensee, whether a member or third-party entity, must engage the patent holder in negotiations before gaining a compulsory license. Nevertheless, requirements may be waived in the event of a national emergency or another extremely urgent situation. TRIPS fails to define the term "national emergency" and brings such ambiguity in interpretations of the specific exceptions [23].

One purpose of the fourth WTO Ministerial Conference held in Doha, Qatar, in November 2001 ("**Doha Declaration**") was to reduce any ambiguities relating to compulsory licensing [24]. It was adopted in 2001 to protect public health and, in particular, to promote access to medicines for all. Paragraph 5 of the Doha Declaration reaffirmed that "each WTO member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted" [25]. The Doha Declaration also clarified that in the situations of "national emergencies" and "other circumstances of extreme urgency," governments can issue compulsory licenses without normal requirements, such as negotiating with the patent holder [25]. Paragraph 5(c) further clarified that "public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics" can constitute "a national emergency or other circumstances of extreme urgency" [25]. We can infer that the COVID-19 pandemic is a public health crisis within the meaning of clause 5(c) and justifies the use of compulsory licenses.

On the other hand, compulsory licensing remains debatable regarding its substantive grounds, legal and political economy conditions. The gap between expected remuneration and the actual payment may in itself become a trade issue, in part because it is an area of comparative uncertainty [26]. In the year 2001, the Pharmaceutical Manufacturers Association of South Africa and 39 pharmaceutical companies sued the government of South Africa over their compulsory licensing application for HIV/AIDS medicine [27]. The South African government aims to import patented AIDS medicine at a lower price from other countries without

license of the manufacturer and then to manufacture such medicine locally (compulsory licensing), but the government's attempt to legalize the importation is being sued in a class-action lawsuit filed by 39 pharmaceutical companies and stated that the attempts to increase the availability of affordable medicines violated both the South African constitution and the TRIPS Agreement which turned the legal action into a disaster for the drug companies [27]. In practice, compulsory licensing is often depicted as a threat for companies to provide better accessibility to their products. The urge to gain from monopoly profits and corporate goals of research includes as one of the considerations that induce the patent holder to refrain from reaching an agreement on authorizing licenses voluntarily.

It is the duty of a state to make available the lifesaving pharmaceutical invention such as a vaccine to all, yet the state should also ensure that fair remuneration is given to the inventor for the subsequent inventions. Each country has different approaches to setting remuneration based upon administrative capabilities, such as the Japanese Patent Office ("**JPO**") Guidelines 1998 that stipulates guidelines for royalties for the non-voluntary licensing system for government-owned patents (compulsory licenses). It allows normal royalty of 2% to 4% of the price of the generic product. This can be altered by 2%, i.e., increased or decreased by as much as 2%, giving an absolute range of 0% to 6% [28]. Then, Canadian Export Guidelines 2005 established a compensation system and guidelines [28]. These guidelines are a sliding scale of 0.02 to 4% of the price of the generic product, based upon the country rank in the UNDP Human Development Index ("**UN HDI**") [28]. For most developing countries, the rates are less than 3%, and for most countries in Africa, the rate is less than 1% [28]. From 1969 to 1992, Canada issued more than 600 compulsory licenses on medicines. In nearly every case, the compensation to the patent owner was a standard 4 percent royalty applied to the generic competitor's sale price [29]. Indonesia itself issued a decree by the President authorizing compulsory licensing of patents nevirapine and lamivudine, both drugs to treat AIDS. According to the decree, The Government shall give a 0.5 percent compensation fee of the net selling value of Antiretroviral Drugs to the Patent Holder [30]. The Indonesia rate was considerably lower than previous royalties.

3.3. Indonesian law

Compulsory licensing is explicitly stated in **Indonesia patent law**, particularly on Articles 109 and 111. Article 109 declares the government's right to invoke a patent on its own accord "*in events relating to national defense and security or very urgent need for the benefit of society.*" In the latter incident, Article 111 defines further as to include pharmaceutical products that are necessary to treat the disease of "worldwide public health emergency." Pursuant to Article 109(3) of Indonesia patent law, this gives the government a broad definition of their ability to invoke their own patent, of which the procedure "shall be defined further through President Regulation."

The aforementioned President Regulation was ratified in 2020 ("**PR 77/2020**") [31]. Implementation for patents relating to the very urgent need for the benefit of society is further fleshed out in its Third Division, Articles 13 to 21. The implementation of the patent itself does not need to come from the government. The government may appoint a third party to implement the patent as long as the third party fulfills the requirements: proper facilities, no diverting implementation of the patent to other parties, and have a "good production method, circulation, and supervision in accordance with provisions of laws and regulations" (Article 14 of [31]). The patent holder is required to pay an annual fee for patents implemented by the government; however, they do not lose their exclusive rights (Article 15 of [31]).

The application process for patent implementation by the government is fleshed out in PR 77/2020. Firstly, the application for the patent should be submitted to the related ministry, including a proposal of which the patent shall be pursued, the essence of the pursuance, and the reason for the implementation (Article 16 of [31]). Secondly, the application shall undergo administration and legal examinations (Article 17 of [31]). If the application passes its administration examination, the related Minister shall notify the patent holder within five business days (Article 18 of [31]). Thirdly, a team will be assembled by the related Minister to provide consideration and determine the royalty amount within 90 business days (Article 19 of [31]). Should the Minister approve of the implementation, the result will be stipulated in a President Regulation within fifteen business days (Article 20 of [31]). Lastly, the implementation should be announced by the related Minister through the media (Article 21 of [31]).

The royalty or remuneration mentioned within Article 19 is further defined in Chapter III: Royalty. Article 31(2) finds that "*the provision of Royalty is a compensation for the implementation of a patent by the government*." If the patent is conducted by a third party, then the third party shall be the one conducting the royalty (Article 31(3) of [31]). However, the amount of royalty depends on the case and will be decided further on the President Regulation overseeing the implementation (Article 32 of [31]).

The Ministry of Foreign Affairs of Indonesia has expressed its support for the COVID-19 vaccine waiver in the hopes "for an increase in global vaccine production" [32]. This was further reiterated after the United States' push for the patent waiver [33]. Previously, Indonesia had invoked their right of compulsory licensing for HIV/AIDS medicine in 2004,

particularly on Lamivudine, Nevirapine, and Zidovudine [34] under older patent law. This pursuance for waiving patent right in the COVID-19 pandemic is also seen in Canada [35], which allows the "state to produce, sell, and use a patented invention" [34] and in France [36] which the Article L.3131-15 allows the Prime Minister to practice "*price control and launch generics to address the health crisis before the expiry of the patent*" [34].

Conclusively, Indonesia has set out the regulation to pursue and invoke compulsory licensing for pharmaceutical products in the event of a worldwide public health emergency. The country has also invoked compulsory licensing for HIV/AIDS medicine in the early 2000s, showing that there is a possibility of such enactment should the government see fit. However, we have yet to hear an opinion from the Ministry of Health, the ministry related to pharmaceutical products, on the interest for compulsory licensing for the COVID-19 vaccine.

3.4. Human Rights Perspective

3.4.1. Right to life

Article 3 of the UDHR stipulates, "*Everyone has the right to life, liberty, and security of person*." Furthermore, Article 9 of Law No. 39 of 1999 on Human Rights in Indonesia ("**Indonesian human rights law**") follows this stipulation and defines the rights into: "*defend life and improve their standard of living*," "*live in peace, security, happiness, physical, and spiritual prosperity*," and "*good and healthy environment.*" Focusing on the second stipulation, it is clear that the Indonesian human rights law finds that **physical prosperity** is included in the people's right to life. This shall include good physical condition. The government may be expected to take appropriate measures to protect life, even taking direct steps if our lives are at risk [37]. With the current condition of nearly 3,5 million deaths worldwide and 50 thousand deaths in Indonesia, the pandemic has become an emergency against our right to life. It is within reason to expect the government to step in and try to protect our lives from the pandemic, including the pursuance of compulsory licensing for COVID-19 vaccines to give better accessibility to the medicine.

3.4.2. Right to health

Article 25(1) of the UDHR stipulates that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control." This right to health is further protected by the WHO Constitution; for instance, Article 1 states that the organization's objective is the "attainment by all peoples of the highest possible level of health." WHO Constitution also defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."

Protection of the right to health is further strengthened by the International Covenant on Economic, Social, and Cultural Rights ("**ICESCR**"). Firstly, Article 12.1 states that States Parties shall "recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." Secondly, Article 12.2 (c) adds that the State Parties shall include "the prevention, treatment, and control of epidemic, endemic, occupational, and other diseases."

Thirdly, General Comment No. 14 (2000) of the ICESCR ("**General Comment**") expands what the Covenant means as "right to health." Paragraph 8 explains that the "right to health" is not limited to the right to be healthy; it also contains both the freedom to control one's health and body and entitlement to a system of health protection for people to enjoy the highest attainable level of health. Paragraph 9 admits that the right takes into account not only the person's biological and socio-economic condition but also the state's available resources. States cannot provide protection against every possible cause of human ill health, although the right includes the enjoyment of facilities, goods, services, and conditions necessary for the highest attainable standard of health. Furthermore, paragraph 11 explains that the right to health is an inclusive right, including appropriate health care and also underlying determinants of health, such as proper resources. The precise application of the right to health, according to Paragraph 12, depends on the availability, accessibility, acceptability, and quality of health care conditions in each State Party. Health care facilities should be functioning and available for the people, given without discrimination, respectful of the surrounding culture, and shall be scientifically and medically appropriate. Paragraph 16 delves deeper into Article 12.2 (c), where the prevention requires education programs for behavior-related health concerns (e.g., HIV/AIDS), treatment includes a system of good urgent medical care, and control of diseases referring to the state's effort to make available relevant technologies, using, and improving epidemiological data, implementation of immunization programs, and other strategies of infectious disease control.

Lastly, Fact Sheet No. 31 on the Right of Health by WHO and Office of the United Nations High Commissioner for Human Rights ("**OHCHR**") expands even further the right of health already stipulated by the ICESCR and its General Comment. On Obligation on States and Responsibilities of Others Towards the Right

to Health, it finds the Committee on Economic, Social, and Cultural Rights has stressed the States Parties' core minimum obligation to ensure the satisfaction of minimum essential levels of all rights in the Covenant. Regarding the right to health, this includes the right of access to health facilities, goods, and services on a non-discriminatory basis, especially for the vulnerable or marginalized groups; access to the minimum essential food which is adequate and safe nutritionally; access to shelter, housing, and sanitation and an adequate supply of safe drinking water; the provision of essential drugs; and equitable distribution of all health facilities, goods, and services [38].

Through these instruments, we can infer that the right to health is a human right that is taken seriously, with multiple expansions into its limitation. Right to health is not only speaking of a healthy condition, but also our right to access proper health care facilities, and the fact that the government has a minimum obligation to provide their best to ensure the highest attainable standard of health possible. This includes access to proper medication and control of infectious diseases. While Paragraph 9 of the General Comment admits that the state cannot possibly protect its population against all diseases, it must be noted that the state is still responsible for making sure its population is as healthy as it can be. This standard is dependent on the state's available resources; the more resources, then the higher the health standard it must achieve.

Indonesia as a country has limitations to its health care facilities, as much as other countries. However, the country currently has access to COVID-19 vaccines [39] and is now distributing them gradually, starting from the elderly population [40]. It is safe to say that Indonesia has access to the vaccine and the ability to distribute it. However, until the 20th of May 2021, only 5% of the Indonesian population has ever been given at least one dose of vaccination [41]. Pursuance of compulsory licensing towards vaccine producers, or even patent waiver, may expedite this process for the rest of the population. Invoking compulsory licensing is not something new for Indonesia, as Indonesia has previously enacted compulsory licensing for HIV/AIDS medication, which shows that the country was not shy to pursue proper facilities for its population. As mentioned before in section III.A. on Current Condition, the more herd immunity we attain, the better our population will be at expelling COVID-19 from the community. Hence, protecting the right to health of the population, in actual physical health, and in the entitlement for proper health facilities. While we acknowledge the right of pharmaceutical companies to protect their inventions from their competitors to make a profit out of them by patenting their inventions, we must also acknowledge the fact that people's lives and health are at risk; no monetary gain is more important than saving lives.

4. CONCLUSION

4.1. Conclusion

Invoking compulsory licensing amidst the COVID-19 pandemic to increase the accessibility of vaccines in Indonesia is legally and ethically correct. This is because the COVID-19 pandemic fulfills the circumstances that allowed the government to overrule the pharmaceutical companies' right to intellectual property. These circumstances include international and national law on IPR as well as human rights. However, at the same time, we also need to reconsider an adequate remuneration for the pharmaceutical company that has developed the vaccine, as developing it requires expensive costs and in-depth research by the scientist. By considering the companies' right to receive financial compensation for their invention and the need for the COVID-19 vaccine for the people, Indonesia can handle the unprecedented situation justly and increase the access to the COVID-19 vaccine to be more widely available than it currently is.

4.2. Recommendations

Through this research, the authors urge the authorities to:

1. Ensure equal distribution of vaccines in both rural and urban areas to uphold the right to life and health of the people in times of emergency like the Covid-19 pandemic; and
2. Invoke the compulsory licensing provisions under the Indonesia patent law and its implementing regulations due to the current pandemic situation to ensure that all people have access to vaccines as it will be mass-produced locally, and no big pharmacies will gain profits in this unprecedented time.

AUTHORS' CONTRIBUTIONS

GR designed the ideas. All authors conducted research and analyzed the ideas. DAS presented the paper. All authors wrote and revised the paper. All authors finalized and approved the paper.

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