

## APPLICATION OF PARALLEL IMPORTATION AND VOLUNTARY LICENSE IN THE COVID-19 VACCINES PATENT AS A STRATEGY FOR HANDLING THE HEALTH EMERGENCY SITUATIONS IN INDONESIA

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### Abstract

This article examines how the application of Parallel Importation and Voluntary License in the Application of the Covid-19 Vaccine Patent as a Strategy for Handling Health Emergency Situations in Indonesia. The problem of the Covid-19 vaccine happens in many countries around the world, including Indonesia who's trying to find a vaccine that can neutralize the Covid-19 Virus. As a consequence of the tremendous demand for vaccines, the world pharmaceutical industry is encouraged to provide Covid-19 vaccines for the needs of 7.8 billion. This article uses normative legal research with a statute, conceptual, and comparative law approach. The results showed that mechanisms such as parallel importation and voluntary licenses could be reached to procure the Covid-19 vaccine. If parallel importation and voluntary licenses are not successful, then the Government shall take a win-lose approach, such as Compulsory Licensing and Use of Patents by the Government, or initiate an anti-monopoly lawsuit.

### Keywords

Covid-19 Vaccine, patent, parallel importation

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## Introduction

Since the announcement of a positive case of Covid-19 confirmed in Indonesia on March 2, 2020, various anticipatory steps have been taken to minimize the spread of Covid-19, including calls for social distancing, enforcing work from home, closing shopping centres and tourist attractions, reducing the density of workers in the office installation, until the creation of the Covid-19 vaccine. The problem of the Covid-19 vaccine happens in many countries around the world, including Indonesia, who's also trying to find a vaccine that can neutralize the Covid-19 Virus. As a consequence of the great demand for vaccines, the world pharmaceutical industry is encouraged to provide Covid-19 vaccines for the needs of 7.8 billion people on earth at the same time. In fact, due to the assumption that it takes two vaccinations to reach herd immunity of one person, it means that the real need is greater than the total world population.

This condition illustrates the demand for the Covid-19 vaccine on a global scale. If all stages run smoothly, the vaccine will only be produced and available in 2021, with a production volume of around three billion doses. A number of countries that produce vaccines are indeed committed to meeting the demands of all countries. However, there is still scepticism about the equitable distribution and concerns that developed and rich countries will buy up and control the supply of vaccines, as happened in the swine flu pandemic in 2009. It was reported that the United States, Britain, the European Union and Japan have bought up 1.3 billion doses of the vaccine candidate. The United States has allocated a budget of 2.1 billion US dollars for spending on Covid-19 vaccines produced by Sanofi and GSK (Agus Rizal Ardy Hariandy Hamid, 2020).

From the data collected by the World Health Organization, it is stated that there have been 200 Covid-19 vaccine findings that have been attempted by scientists in a number of countries. Of that number, many vaccines have reached the clinical trial stage. This vaccine is the hope for 18.5 million worldwide patients who are infected with Covid-19, including more than 200,000 patients in Indonesia. The number of deaths as of September 8 2020, due to Covid-19 was recorded at 700,489, patients recovered nearly 10.9 million. The latest calculations say there is one death every 15 seconds due to Covid-19. From this data, it can be concluded that:

First, many Covid-19 patients recovered, but not a few died. Several weeks in a number of countries ended the lockdown, and a new normal era emerged. In fact, a dynamic youth community has become a new cluster. And in some countries, new cases are more likely to emerge from young people.

Second, the limited global production volume at an early stage in 2021 causes the Covid-19 vaccine to become a product that is contested by all countries. The initial production volume is estimated at three billion doses. In contrast, the world demand at the same time is estimated to be three to four times as much.

If rich countries have bought up nearly 50 per cent of the initial production volume, handling the Covid-19 pandemic in many countries will find it challenging to record progress. Especially in countries with a high number of new cases, especially in South America and Indonesia, which have now become the epicentre of Covid-19. In the interests of Indonesia's 270 million population, the presence and involvement of the government in this challenging endeavour is very relevant and urgent. Director-General; The World Health Organization, Tedros Adhanom Ghebreyesus, stated that a monopoly or vaccine nationalism would not help to recover from the global damage caused by the Covid-19 pandemic, because the pandemic is experienced in almost all countries and has a dependence on one another. A number of rich countries such as the US, UK, and Japan have invested heavily in vaccine development (Shreshth Tuli and Shikhar Tuli, 2020). The US has even ordered generous doses for its citizens. In contrast to China, which carries out soft diplomacy by planning to provide vaccines to the global public. It will strengthen their position internationally by helping emerging countries. The official report from the Chinese authorities states that China is positioning itself as a global leader in fighting Covid-19 and is ready to provide loans and priority access for the Covid-19 vaccine.

Throughout this time, the implementation of provisions for the protection of Intellectual Property Rights, both related to patents and the issue of know-how on drugs, vaccines, and health innovations in various provisions including WTO, WIPO, WHO, and so on, has made health as a business commodity, and ultimately eliminating public access to cheap, quality and just health. Vaccine from Covid-19, including independently producing test kits for virus identification, have been carried out, both at the national and global levels. There has been a lot of pressure from civil society groups in the world to immediately stop handling this pandemic in business as the usual way, including making public goods which can then be distributed and can be accessed relatively.

Countries pledging to pay up capital such as the European Commission pledged 1.4 billion euros. In comparison, other leading contributors included France (510 million euros), Germany (525 million), Japan (762 million), Spain (125 million), Canada (551 million), Norway (188 million), United Kingdom (441 million) and Italy (71.5 million). However, on the other hand, developing and underdeveloped countries question the existence of assurance of equitable access, both in terms of finance and distribution of the production of vaccines and medical equipment needed. Based on the background that has been elaborated, this article will discuss further in regards to the issue of knowledge monopoly and access to health innovations as well as equitable shared use in responding to Covid-19.

### Research Methods

This research is a normative juridical descriptive-analytical research. The data was collected through library research and field research, and the library research stage was carried out to find secondary data using primary, secondary and tertiary legal

materials. In this stage, a literature review is also carried out on several laws and regulations in several countries that are relevant to the problems studied.

## Discussion

### 1. Inequality in Drug Access and Overlapping of Domestic Regulations

Handling the COVID-19 pandemic cannot be separated from the need for medical equipment such as Personal Protective Equipment (PPE), test kits, ventilators, medicines, vaccines, and others. As a result, various kinds of medical equipment have become a struggle for many countries, causing their prices to be high. Especially when there are several countries that able to pay higher prices so that goods that have been scheduled for export can be cancelled in order to be sold to other countries.

This also applies to medicines. Although the WHO states that no medicines have been proven effective, medicines such as remdisivir and lopinavir are also contested. During this condition, several pharmaceutical companies such as Gilead, which produces remdisivir and Sanofi, which also research about Covid19 vaccines, have stated that they will prioritize large markets such as the United States. Another global initiative is the launch of the Access to Covid19 Tools (ACT) organized by several countries such as the European Union, Canada, France, Germany, Italy, Japan, Saudi Arabia, Norway, Spain, and the United Kingdom. The ACT program is an effort to accelerate the development of diagnostics, vaccines and treatments that the world needs to end the global COVID-19 pandemic (Mahoney, R. T., Pablos-Mendez, A., & Ramachandran, S, 2004). It is a collaborative work between WHO, States and the business sector. The response to this global initiative has resulted in countries pledging to pool resources in order to start development activities, which as of May 2020 had reached 7.4 billion euros. Countries pledging to pay up capital such as the European Commission pledged 1.4 billion euros. In comparison, other leading contributors included France (510 million euros), Germany (525 million), Japan (762 million), Spain (125 million), Canada ( 551 million), Norway (188 million), United Kingdom (441 million) and Italy (71.5 million) (Agung Prakoso and Rachmi Hertanti, 2020).

However, on the other hand, developing and underdeveloped countries question the existence of equitable access assurance, both in terms of finance and distribution of the production of vaccines and medical equipment needed. To address the imbalance in access to drugs and medical devices, eventually the WHO, through the 73rd The World Health Assembly (WHA) meeting, adopted a resolution related to Covid-19 which calls for fair access and distribution of all essential health technologies and products to fight the virus. This resolution also reaffirms the commitment of all countries on the importance of meeting the needs of low and middle-income countries to fill the gap to overcome the pandemic. Including recognizing the role of widespread immunization against COVID-19 as a global public good for health in preventing, holding and

stopping transmission to end the pandemic, a safe, quality, a potent, practical, accessible and affordable vaccine is available. (Lutfiyah Hanim, 2020).

The importance of ensuring medicines, treatment and health products as global public goods in dealing with the Covid pandemic<sup>19</sup> is due to the reluctance of some rich countries to open access to these things which have been protected by regimes protecting intellectual property rights. Innovation during a pandemic is still used as a business commodity that benefits a small number of groups. This is shown by the reluctance of countries such as the US and Europe which still apply double standards by reluctantly giving explicit confirmation to refer to the flexible application of TRIPS for public health related to medicines access and other health product innovations.

The United States, although not rejecting the resolution produced in the 73rd WHA, become a powerful country to refuse to be bound by specific paragraphs in the resolution instead. As paragraphs 4, 8.2 and 9.8 operatives which refer to the TRIPS Agreement and the 2001 Doha Declaration on the flexibility of TRIPS and Public Health, in implementing policies related to COVID-19 (Santos Rutschman, A. (2020), The government needs various legal instruments. This regulation will serve as a basis for government. However, in practice, it is often less than optimal. For example, the government is often fickle in issuing legal instruments to control society. As cases increase, the government has relaxed regulations instead. Overlapping regulations have hampered efforts to research and deal with the pandemic.

The government issued four policies. First, forming covid research and innovation consortium. Second, membership of covid research and innovation<sup>19</sup>. Third, carry out a research consortium program. Fourth, a collaboration between the consortium and State Non-Ministry Agencies. However, these policies still overlap. In the search for vaccines, for example, no term refers to the formation of a unique team to seek vaccine discovery or supply (<https://twm.my/title2/health.info/2020/hi200506.htm> accessed on September 8 2020).

The government must quickly resolve these overlapping regulations because in handling a pandemic, vital legal instruments are needed for the public interest. Overlapping regulations will hamper several other regulations, such as those regarding compulsory licenses which are already accommodated by the Patent Law, but still require more specific legal instruments regarding public emergencies. Moreover, the broad definition of a public emergency in Article 109 of the Patent Law is in line with Article 31 of the TRIPS.

The government in making budget-related policies that focuses on three priorities, namely: First, the health sector of IDR 75 trillion, a social safety net of IDR 110 trillion, and business support (DTP Taxation (DTP Tax and DTP Import Duty) IDR 70.1 trillion. (Andrej Zwitter and Oskar J. Gstrein, 2020).

The budget for handling COVID-19 does not only involve the Central Government but also involves the Regional Government. The government issued Permendagri Number

20 of 2020 which regulates the acceleration of the handling of COVID-19 within the Regional Government. Some regions procure their own medical devices outside of those provided by the Central Government. In this case, the government is also encouraging the production of medical devices such as PPE and medicinal raw materials in the country (Hannah Van Kolfshooten, 2020: 18). The government, through Ministries and Agencies led by Bappenas, has also prepared a road map for health insurance and reform of the National Health System.

Handling COVID-19 requires comprehensive handling from the Government. The government must be able to be strongly committed to utilizing existing data sources such as maximizing the use of the flexibility of TRIPS in order to encourage access to medicines and promote health as a public good, not as a commodity (Padmanabhan, S., Amin, T., Sampat, B., Cook-Deegan, R., & Chandrasekharan, S. (2010: 671-678). On the other hand, the government must also anticipate encouragement from foreign countries who continue to want a more comprehensive regulation of TRIPS, known as TRIPS Plus in various FTAs.

## **2. Patents between Monopoly and Rights**

Until now, the public is still questioning the patent rights for the Covid-19 medicines or vaccine. For pharmaceutical products, especially medicines and vaccines during a pandemic, the government can enforce patents, which Indonesia has the right to do. Indonesia has the right to exercise patents for vaccines and medicines. The government, in Article 109 of Law Number 13 of 2016 concerning new patents, can apply its patents based on considerations related to state security or a very urgent need for the benefit of society and the implementation of patents by the government, is carried out on a limited basis and may not be sold at a price that is expensive and not for export. Indonesia can use a mechanism, such as WTO TRIPS for the use of foreign patents, in order to question the provisions of international law (Kremer, M. (2000: 35-37).

Patents are fundamental rights granted by the state to inventions in the field of technology, which must meet novelty requirements, have inventive steps, and can be applied in industry, even though they are still in the form of ideas or concept so that a patent can protect the invention before the invention becomes a product. Particularly in the pharmaceutical sector, countries that are familiar with the patent system, generally they will apply for patents as early as possible before they are produced, even promoting so many compounds (Fedson, D. S, 2005: 29). And then from so many of these compounds, if the best compound is found, it will be re-registered, because in patent registration we recognize the name selection invention. They still propose the best that has ever been filed, and the point is that a patent is not just a product, but includes a process. The medical indications that are commonly used are based on the clinical condition of the patient without regard to social factors (Elfan Winoto, 2020).

Meanwhile, from another party, Director of Operations for Bio Farma, M. Rahman Roestan said that patents are one of the barriers to entries in the pharmaceutical



industry. By having a patent, a company can limit the space for other companies to innovate, because they have to wait for the medicines become off-patent, which take a long time. Therefore, the national pharmaceutical industry needs to innovate by prioritizing the discovery of new medicinal products at affordable prices (Tejomurti, K, 2017: 42-52). Uniqueness in the pharmaceutical industry lies in discovering more new ones at the production process stage of a product. With this invention, pharmaceutical manufacturers can become patent owners. Plus innovation and protection of Intellectual Property, sustainability will be created, which in turn will create a competitive advantage for the company and the organizations involved in it. (Tejomurti, K., & Widyantari, P, 2018: 116).

Achmad Zein Umar Purba stated that a patent right which is an exclusive right for a brand or product holder could not be equated with a monopoly. During the validity period of a patent, can the actions of entrepreneurs permitted by the Patent Law be declared to have violated Law Number 5 the Year 1999? In fact, the Law clearly states that this is exempted. Two pharmaceutical companies, namely Pfizer and Dexa, were declared to have practised cartel by the Komisi Pengawas Persaingan Usaha (KPPU). The two companies were proven to have violated Article 5, Article 11, Article 16, and Article 25 paragraph (1) letter an of Law Number 5 the Year 1999. Based on this decision, all Pfizer companies were sentenced to pay a fine of IDR 25 billion. Article 16, paragraph 1 of the Patent Law states that patent holders can make, use, sell, import, rent, deliver, or make available to sell or rent or deliver the patented product. Due to the nature of a patent as an exclusive right, during the period of protection, it is essentially a monopolistic right. Therefore, the enforcement of legal ties relating to this right in Law Number 5 the Year 1999 must be excluded.

National law regulates compulsory licensing and patent enforcement. Compulsory licenses are regulated in Articles 82 to 106 of the Patent Law. The use of patents by the government is regulated in another separate section, namely Articles 109 up to 120 Patent Law. The rules for implementing the Compulsory License are further elaborated in Permenkumham No. 30 of 2019. Currently, there are no derivative regulations regarding the Use of Patents according to the Patent Law. In the absence of these derivative regulations, we view that based on Article 170 of the Patent Law, Government Regulation No. 27 of 2004 can still be applied on a limited basis for conducting Patents by the Government on pharmaceutical products.

The provisions of the Patent Law are the implementation of Article 31 of the Intellectual Property Agreement, known as the WTO Trade and Related Issues of Intellectual Property Rights (TRIPS) Agreement. Article 31 is entitled: "Other Use Without Authorization of the Right Holder". In connection with this problem, agreement on medical or health indications is actually unclear in the medical community itself (Elfan Winoto, 2020). This norm was later clarified in the Doha Declaration on the TRIPS Agreement and Public Health in 2001 (Nicol, D., & Nielsen, J, 2020).

The aspects that need to be considered in conducting compulsory licensing and implementing patents in Indonesia:

a) Only applies to medicines which the patent is registered

The text of the Patent Law stipulates that compulsory licensing and use of patents can only be applied to registered patents. This is regulated in Article 93 of the Patent Law which reads: "*The Minister can grant a compulsory license to produce pharmaceutical products that are patented in Indonesia for the treatment of diseases in humans*". As for Article 112 paragraph (2) stipulates: "*In the case that the implementation of a Patent by the Government for urgent needs for the benefit of the community ... does not reduce the rights of the Patent Holder ...*" Who is the Patent Holder? Article 1 paragraph (6) of the Patent Law confirms that the Patent Holder is the owner. Patents that have been registered in Indonesia. If the patent is not registered in Indonesia, there is no need for compulsory licensing and the use of patents by the government.

b) The effect on the investment climate

Although the Patent Law allows compulsory licensing and use of patents by the government, it is necessary to consider the impact on the investment climate in Indonesia. According to Rahmi Jened, investors often feel uncomfortable with compulsory licenses because they are often seen as an act of expropriation. According to Dede Mia Yusanti, the issue of the compulsory license is quite a pending issue for bilateral negotiations. The Government's Patent Application for HIV / AIDS and Hepatitis drugs in 2012, for example, received very sharp criticism, especially from pharmaceutical investors and international pharmaceutical associations.

c) Complications of Article 20 of the Patent Law

Many investors object to the provisions of the Patent Law which allow compulsory licensing and use of patents by the government if the investor holding a patent in Indonesia does not build a factory or produce its products in Indonesia. The obligation of Article 20 of the Patent Law is known as a local working patent requirement. The issue of Article 20 of the Patent Law then became a national debate. Some have proposed to abolish Article 20, but some have suggested that they keep this provision. Various legal experts, for example, have criticized the plan to abolish Article 20 of the Patent Law in the Omnibus Law on Job Creation (Eric Mangajaya, 2020).

Based on the research of Paul Champ and Amir Attaran in the Yale Journal of International Law in 2002, it can be seen that until now the clarity of the legality local working patent requirements is still the status quo. This happens due to there is no jurisprudence of the WTO Dispute Settlement decision that can be used as a reference. The US versus Brazil case or the Measures Affecting Patent Protection case (DS-199) was not resolved because, in 2001, the disputing parties agreed to withdraw the case.



As a result, every country has its arguments according to its national interests. Until now, various countries still have local working patent requirements in their patent laws (Munoz Tellez, V, 2020).

Apart from compulsory licensing and the use of patents by the government, intellectual property law provides several other tools, including (i) The use of unjust enrichment doctrines to challenge medicines monopolies; (ii) parallel importation (parallel import); and (iii) voluntary license.

a) Anti-monopoly lawsuit

In a Scientific Workshop on Intellectual Property for the Development of the Pharmaceutical and Agricultural Industry in Surabaya in 2018, Professor Dr. Rahmi Jened from Airlangga University stated that in fact, we could sue companies that hold patents suspected of having monopolized medicines using the unjust enrichment doctrine (Tejomurti, K., Gumbira, S. W., Husna, N. F., & Jaelani, A. K, 2020: 4). This proposal is exciting and actually possible because it is in line with the TRIPS regulations. However, the lawsuit and evidence process are likely to take some time while we currently need access to drug/medicines patents as soon as possible (an emergency). Furthermore, from the national law point of view, it still needs to be reviewed regarding its operationalization according to Law no. 5 of 1999 concerning the Prohibition of Monopolistic Practices.

b) Voluntary License

The Patent Law allows a pharmaceutical company that owns a foreign patent to voluntarily grant a patent license to another party and manufacture the COVID-19 drug in Indonesia. Regarding royalties, technology transfer, trade secrets and others can be arranged in the contract. This is actually a matter of negotiation. Voluntary licensing has many advantages. First, good relations with investors will be maintained because it is not a coercive mechanism. Second, the brand image and reputation of the investor's companies will also be built. Third, pharmaceutical companies feel appreciated for incurring high cost and time-consuming research to produce a drug. Fourth, we can work together to develop the national pharmaceutical industry in the future.

The author's view is based on the research results of K.D. Raju in 2017 which said that investors would be more willing to undertake voluntary licensing than being threatened with compulsory licensing or the use of patents by the government. According to him: "*Compulsory License encourages parties for entering into voluntary licensing, and it is economical and an alternative option (not exclusive) for developing countries in providing essential medicines to poor people*".

However, the authors see the need for efforts to prevent voluntary license contracts from turning into a market monopoly. Please take into account, in a pandemic situation like today, the pharmaceutical company that owns the

patent holds a higher bargaining position, so it is necessary to prevent monopolies.

The author proposes that consideration should be given to implementing *Permenkumham* No. 8 of 2016. Based on this regulation, every license contract must be recorded and announced at the Ministry of Law and Human Rights. This is in the interest of third parties, ensures transparency and prevents market monopolies.

#### c) Parallel Importation

Indonesia can conduct voluntary imports under Article 167 of the Patent Law. Through parallel imports, Indonesia can import drugs from third countries. We can import drug X from Country A, where the drug patent is registered and manufactured. The original patent owner is from Country B.

In accordance with the Elucidation of Article 167 of the Patent Law, imports of COVID-19 drugs can be carried out to ensure a fair price and fulfil a sense of justice from pharmaceutical products that are urgently needed for human health. Imports can also be carried out if the price of a product in Indonesia is costly compared to prices that have been legally circulating on the international market (Tejomurti, K, 2017: 42). However, unfortunately, there is no specific derivative regulation regarding parallel importation according to the Patent Law.

The use of all intellectual property legal tools to gain access to the above COVID-19 drugs needs to be done using a measured strategy. Considering the various weaknesses and strengths of each of the above intellectual property instruments, the authors suggest that mechanisms such as parallel importation and voluntary licensing should be first taken. We can import drugs from third countries, or invite these pharmaceutical companies to volunteer license and produce their drugs in Indonesia. If parallel importation and voluntary licenses are not successful, then the Government can take a win-lose approach such as Compulsory Licensing and Use of Patents by the Government, or initiate anti-monopoly suit. The use of all alternatives outside the compulsory license mechanism does not violate international law. This is confirmed in Paragraph 6 of the Doha Declaration which reads: *"We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement ..."*.

#### Conclusion

Apart from Mandatory Licenses and Patent Application by the Government, there are still several alternative intellectual property legal instruments that can be used to gain access to COVID-19 drugs, such as parallel importation, voluntary licenses and anti-monopoly lawsuits. Given the intense competition, from a strategic point of view, we can take steps such as parallel importation and voluntary licensing. If that does not work, we can use firmer approaches such as Mandatory Licensing and the Use of

Patents by the Government, or sue patent owners on anti-monopoly grounds. The suggestion that can be pursued is that we need to identify the patent registration status of several potential COVID-19 drugs in Indonesia to assist in choosing which intellectual property legal instrument to use.

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