

## Reformulation of Patent Law in Indonesia Regarding Patent Waiver of Vaccines in Certain Circumstances

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**Abstract.** *This research aims to reformulate patent law in Indonesia based on the 12<sup>th</sup> WTO MC Decision on the TRIPs Agreement related to patent waivers for vaccines in certain circumstances, such as pandemics. Patenting vaccines during a pandemic can hamper efforts to handle the pandemic quickly and effectively and make access to vaccines limited, especially for lower-middle-income countries (LMICs). This can be seen in the implementation of Covid-19 vaccination where there is a gap in vaccination rates and vaccine prices between developed countries and LMICs countries. For example, vaccine supplies in Indonesia as one of the LMICs countries could only meet 24% of the coverage target of 181 million people at the beginning of the Covid-19 pandemic. The patent law in Indonesia has provided flexibility regarding the implementation of patents for vaccines in certain circumstances through the implementation of patents by the government, but in fact it still cannot overcome the scarcity of vaccines in an emergency in Indonesia. This study uses normative (doctrinal) research types with statue, conceptual, and analytical. Based on the results of the research, in order to minimize existing problems so that they do not occur in the future, Indonesia can reformulate the formulation of patent laws in Indonesia based on the TRIPs Agreement, namely first, the regulation that the implementation of patent waivers for vaccines in certain circumstances does not require permission from the patent holder; second, the regulation on determining the amount of remuneration for inventors; and third, regulation on the prohibition of re-export of vaccines whose patents are ignored.*

**Keywords:** *Abandonment; Patents; Reformulation; Vaccines.*

### 1. Introduction

Corona Virus Disease 2019 (Covid-19) is an infectious disease that has been designated by the WHO as a global pandemic due to its very rapid spread and resulting in millions of deaths in various countries, including Indonesia (Amrita et al., 2021). In order to control the spread of Covid-19 and form herd immunity in the community, vaccination efforts are needed that must be given to all individuals without exception. Vaccination itself is a form of innovation in the health sector that aims to overcome diseases that threaten the safety of human lives (Larasati, 2021). Therefore, vaccines are categorized as objects protected by patent rights as stipulated in Article 27 paragraph (1) of the TRIPs Agreement and Article 3 paragraph (1) of Law No. 65 of 2024 concerning the Third Amendment to Law No. 13 of 2016 concerning Patents (Patent Law). In addition,

based on Article 6 paragraph (1) of the Patent Law, vaccines are not included in the category of inventions that are exempt from patent protection.

During the Covid-19 pandemic, quick and effective measures are needed to overcome the spread of the virus, including through the development of health technologies such as vaccines. However, patent protection for vaccines poses barriers to accessibility for some countries, especially low and middle income countries (LMICs). This inequality causes disparities in vaccination rates as well as vaccine price differences between developed countries and LMICs countries. For example, the vaccination rate in Africa has only reached 2 out of every 100 inhabitants, while in North America it has reached 62 out of every 100 inhabitants (Sari, 2021). The difference in vaccine prices is also seen, for example, the AstraZeneca vaccine per dose in South Africa costs USD 5.25, while in the European Union it is only USD 3.50 (Kohler et al., 2022).

In response to these problems, in 2020, India and South Africa, representing LMICs, submitted a proposal to the WTO to implement a policy of waiving patent rights for Covid-19 vaccines. The purpose of this policy is to enable wider access to vaccines, especially for LMICs countries, as a form of moral obligation to ensure justice and equality in accessing health services (Zhu, 2021). After going through various discussions and debates, on June 17, 2022, WTO member countries adopted a declaration known as the TRIPs Agreement. This decision provides restrictions on patent exclusive rights as stipulated in Article 28.1 of the TRIPs Agreement, by allowing eligible WTO member countries (especially LMICs countries) to use raw materials from a patented product to produce a Covid-19 vaccine without requiring prior approval from the patent holder (Crhaspati, 2023). This policy is in accordance with the provisions of Article IX paragraphs (3) and (4) of the TRIPs Agreement, which authorizes the WTO Ministerial Conference to waive certain obligations in exceptional circumstances (Fatizah, 2022). As part of the LMICs group of countries, Indonesia also supports the waiver of patent rights for Covid-19 vaccines to increase global production capacity. This step is also a response to the limited supply of vaccines in Indonesia. As of June 2021, the supply of vaccines in Indonesia was only able to meet 24% of the vaccination coverage target for 181 million people, while the number of confirmed positive cases of Covid-19 reached 2,156,465 with a case fatality rate of 2.7% or as many as 58,024 people (Health, 2021).

The Indonesian Patent Law has actually provided flexibility in the implementation of vaccine patents through a patent implementation scheme by the government as stipulated in Article 109 paragraph (1) of the Patent Law. However, this provision has not been fully effective in overcoming vaccine limitations during emergencies. Referring to the long process of ratification of the TRIPs Agreement and Indonesia's experience in dealing with the pandemic, it is necessary to reformulate the existing mechanism in the Patent Law to accommodate the provisions in the TRIPs Agreement related to patent waivers for vaccines under certain conditions.

To maintain the originality of the research and distinguish it from previous research, the author conducted a review of several previous studies to find elements of novelty. The first research by Nabila Putri Lintania and Zain Maulana entitled Trade Related Aspects of TRIPs Waiver Proposal for Global Health Equity in Pandemic: They discusses the possibility of successful submission of TRIPs Waiver proposals in ensuring access to health services based on pros and cons analysis. The second research by Ilham Kurniawan Abdullah and Happy Yulia Anggraeni entitled Dilematization of Intellectual Property Law in Pharmaceutical and Vaccine Patents During the Covid-19 Pandemic

examines the aspects of patent protection exemptions in health emergencies. The third research by I Made Bayu Brhaspati entitled TRIPs Waiver: Lessons from the Covid-19 Pandemic focuses on analyzing whether the TRIPs Waiver policy can be a solution to limited access to vaccines and medicines.

Different from the previous study, this study aims to reformulate the provisions in the Indonesian Patent Law based on the TRIPs Agreement in order to create a patent waiver mechanism for vaccines under certain conditions. The main objective of this study is to ensure more equitable access to vaccines for all Indonesian people and improve the mechanism for patent enforcement by the government to be more responsive to future health emergencies.

## **2. Research Methods**

This research approach uses a type of normative (doctrinal) research with the method of statute, conceptual, and analytical. The legal materials will be analyzed by authors using grammatical interpretation and systematic (logical) interpretation. The scope of this study is only limited to reformulating the provisions in the Indonesian Patent Law based on the TRIPs Agreement to create a mechanism for waiving patents for vaccines under certain conditions.

## **3. Results and Discussion**

### **3.1. Patent Waiver Mechanism for Vaccines in Certain Circumstances in the 12th WTO MC Decision on the TRIPs Agreement**

The TRIPs Agreement sets out the main policy related to vaccine patent waivers to facilitate global access to Covid-19 vaccines, which at that time were urgently needed. WTO member countries agreed to temporarily waive some provisions of the TRIPs Agreement, especially related to vaccine patents, so that vaccine production and distribution can be carried out more widely and equitably, so that access to vaccines becomes more inclusive for all countries without exception. The main goal of this policy is to increase vaccination coverage globally to accelerate the achievement of herd immunity as an effort to overcome the Covid-19 pandemic. In principle, the waiver of patents on vaccines as stipulated in the TRIPs Agreement is carried out by providing a temporary dispensation to several provisions in the TRIPs Agreement. This is as stipulated in Paragraph 1 of the decision, eligible member states refer to Low and Middle Income Countries (LMICs) that are bound by a commitment not to use this policy for personal commercial gain. The commitment is stated in the form of a declaration to the WTO General Council and is recorded and published publicly on the official WTO website. With this provision, eligible member states have the right to use patented vaccines without the consent of the patent holder, as long as it is necessary to overcome the Covid-19 pandemic.

This patent waiver mechanism can be applied through legal instruments applicable in each country. Based on these provisions (Paragraph 2 of the decision), Indonesia can adopt the TRIPs Agreement in the Law on Patents through reformulation and adjustment of regulations related to the mechanism for implementing patents by the government. This reformulation aims to clarify and reaffirm the mechanism for waiving patents for vaccines in emergencies in order to increase the country's responsiveness in dealing with future health emergencies and contribute to vaccine production for other LMICs countries.

Based on Paragraph 3 letter (a) of the Agreement, it is affirmed that:

"Eligible member states are not required to require patent users to seek permission from the rights holder as provided for in Article 31(b) of the TRIPs Agreement."

This provision confirms that patent waivers can only be made in national emergencies or extraordinary situations of an urgent nature. The Covid-19 pandemic, which was declared a global pandemic by the WHO on March 11, 2020 and designated as a public health emergency through Presidential Decree Number 11 of 2020 and Presidential Decree Number 12 of 2020, meets the criteria as a national emergency, so that the implementation of vaccine patent waivers in accordance with the TRIPs Agreement can be applied.

Regarding the export and import mechanism, Paragraph 3 letter (b) of this decree states that:

"Eligible member states may waive the provisions of Article 31(f) which require the use permitted under Article 31 for most domestic market supplies, and may allow some or all of the products produced under this authorization to be exported to other eligible member states, including through international or regional initiatives aimed at ensuring equitable access to Covid-19 vaccines."

This provision provides an exception to Article 31(f) of the TRIPs Agreement which in principle limits the use of patents without the permission of the rights holder to domestic purposes only. Thus, eligible WTO member countries are allowed to export vaccines produced in their territories to other countries that are also eligible in order to ensure equitable access to vaccines globally.

The agreement also confirms the prohibition for member states to re-export vaccines obtained under this patent waiver. As stipulated in Paragraph 3 letter (c). The re-export ban aims to prevent market distortions that can hinder the distribution of vaccines to countries that need them most, as well as avoid speculative practices that can lead to unreasonable spikes in vaccine prices.

In addition to paying attention to member countries' access to vaccines during the pandemic, this decision also considers the rights of vaccine inventors affected by patent waivers while still regulating the remuneration mechanism. As stipulated in Paragraph 3 letter (d). This provision recognizes the importance of balancing the interests of patent holders with the needs of the global community. Therefore, even though the exclusive rights of inventors are restricted, the principle of remuneration is still applied by considering the factors of fairness, urgency, and social impact.

This agreement also emphasizes the importance of transparency in its implementation.

With a transparent recording mechanism, it is hoped that this policy can be implemented in an accountable manner and not abused by member countries.

This Agreement has a period of application for five years from the date of its agreement, so that Indonesia can adopt the TRIPs Agreement into the Patent Law to ensure legal certainty over the patent waiver mechanism in certain circumstances. This reformulation is to clarify rules related to mandatory licensing and patent enforcement by the government to be more responsive in dealing with future health emergencies and ensure a more equitable distribution of vaccines for the community.

### **3.2. Reformulation of Patent Law in Indonesia Based on the 12th WTO MC Decision on the TRIPs Agreement Regarding Patent Waiver of Vaccines in Certain Circumstances**

The ratification of the TRIPs Agreement has caused various responses, both pro and con, among developed countries and low-middle-income countries (LMICs). One of the views that rejected the decision stated that the flexibility that has been provided in the TRIPs Agreement through the mechanism of compulsory licensing and patent enforcement by the government is sufficient to overcome the problem of access to pharmaceutical patents. Provisions regarding mandatory licensing and the implementation of patents by the government in Indonesia have been accommodated in Law No. 13 of 2016 concerning Patents.

However, the mandatory licensing mechanism and patent enforcement by the government still face various obstacles. One of the main problems is the negative reaction of pharmaceutical industry patent holders, who generally come from developed countries, to the implementation of mandatory licensing of drug patents in LMICs countries, including Indonesia. In addition, this mechanism still requires permission from the patent holder, which can lead to delays in the approval process, especially in emergency situations that require a quick response (Ichsan, 2014). Complicated administrative procedures that require various documents and in-depth verification are also obstacles in the implementation of mandatory licenses and patent enforcement by the government in Indonesia. As a result, in emergency conditions such as pandemics, this mechanism cannot always be used effectively to overcome vaccine supply limitations (Hakim, 2023).

In addition, the implementation of patents by the government also has several weaknesses compared to the patent waiver mechanism for vaccines regulated in the TRIPs Agreement. One of the main obstacles is administrative procedures that are still convoluted in the submission, implementation, and verification stages (Demmassabu, 2017). In a series of discussions on the patent waiver proposal, South Africa argued that the implementation of patents by the government is less transparent, has geographical restrictions that hinder exports to other developing countries, and does not significantly increase the supply of vaccines in the global market (Council, 2021). Meanwhile, India highlighted potential delays in the Article 31 and Article 31bis TRIPs Agreement proceedings due to ownership disputes among Covid-19 vaccine patent holders, which could extend the required notification and approval process.

Nationally, the regulations that apply in Indonesia, the provisions regarding the implementation of patents by the government have been regulated in Article 109 paragraph (1) letter b of the Patent Law, which gives the government the right to execute a patent if there is an urgent need for the benefit of the community. Article 111 letter a of the Patent Law stipulates that the implementation of patents can be applied to pharmaceutical products, medical devices, and/or biotechnology that have a high price or are necessary to treat diseases that may cause mass death, significant disability, or public health emergency. Thus, the Patent Law can be used as a legal basis to implement the TRIPs Agreement, as stipulated in Paragraph 2 of the Agreement.

In this regard, a reformulation of the Patent Law is needed so that the patent waiver mechanism for vaccines in certain circumstances can be accommodated more effectively. Some of the aspects that can be refined in this regulation include:

### 1. Affirmation that the implementation of patent waivers on vaccines in certain circumstances does not require permission from the patent holder

Currently, the Patent Law does not explicitly state whether approval from the patent holder is required in the implementation of the patent by the government. Therefore, it is necessary to reformulate this provision to comply with the Doha Declaration, which confirms that patents can be used without the consent of rights holders to ensure access to medicines and vaccines.

Paragraph 1 of the TRIPs Agreement explicitly states that during the Covid-19 pandemic, the use of patents can be carried out without the permission of the rights holder. In line with this principle, the Patent Law can be updated by adding a paragraph in Article 109 which states:

" The implementation of patents by the government is exempted as long as it is necessary to address urgent emergencies."

### 2. Determination of the amount of remuneration for patent holders

The amount of remuneration in the TRIPs Agreement is submitted to each country by taking into account global practices and the principle of fair use.

One method that can be applied in Indonesia is the 2005/Canadian Royalty Guidelines, which takes into account the HDI of the beneficiary countries. Based on calculations with this method, the ideal remuneration for Indonesia is around 1.5% of the price of generic products. Therefore, the government can reformulate Article 115 paragraph (2) of the Patent Law to:

"The government provides compensation or remuneration to the patent holder as compensation of 1.5% of the price of generic products."

### 3. Arrangements regarding re-export prohibition

The Patent Law only regulates provisions regarding the export-import of diversified products as stipulated in Article 111A paragraphs (1) and (2). This provision has not accommodated the re-export ban as stipulated in Paragraph 3 letter (c) of The TRIPs Agreement.

A re-export ban is necessary to prevent market distortions that can occur due to uncontrolled re-exports, especially if vaccine products are diverted to developed countries that can afford higher prices. It also aims to ensure that vaccines remain available to LMICs countries that need them more. Therefore, the Patent Law can be added with one paragraph in Article 111A which reads:

"Patents on all forms of vaccines that have been exported are prohibited from being resold in any country."

Through this reformulation, the Patent Law can be more aligned with the TRIPs Agreement, so that the patent waiver mechanism for vaccines in certain circumstances can be applied more effectively in Indonesia.

## 4. Conclusion

The reformulation of the provisions in the Patent Law in Indonesia to adjust to the TRIPs Agreement regarding patent waivers for vaccines in certain circumstances can be done by adopting several new provisions in Law No. 65 of 2024 concerning the Third Amendment to Law No. 13 of 2016 concerning Patents. The reformulation consists of (1) Article 109, which is adjusted to Paragraph 1 of the TRIPs Agreement, to affirm that the implementation of patent waivers on vaccines in certain circumstances can be carried out without requiring permission from the patent holder. (2) Article 115 paragraph (2), which refers to Paragraph 3 letter (d) of the TRIPs Agreement, relates to the determination of the amount of remuneration for patent holders of 1.5%, using the calculation method of 2005/Canadian royalty guidelines. (3) Article 111A, which refers to Paragraph 3 letter (c) of the TRIPs Agreement, which regulates the re-export prohibition of pharmaceutical products that have been imported to prevent market distortions. With this reformulation, the patent waiver mechanism for vaccines in certain circumstances can be implemented more effectively in accordance with Indonesia's national interests and international commitments in the TRIPs Agreement.

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