



# Settlement of the COVID-19 vaccine patent waiver issue by the World Trade Organization

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## ABSTRACT

**Background:** This research focuses on the role of the World Trade Organization (WTO) in addressing the issue of vaccine patent waivers during the 2019 coronavirus disease (COVID-19) pandemic. The study examines the waiver applications submitted between the end of 2020 and 2022, highlighting the need to review the legal basis and enforcement mechanisms related to patents. The research aims to analyze the WTO's involvement in resolving patent disputes, particularly in the context of ensuring access to vaccines for developing and less developed countries. **Methods:** This is a normative legal research using a descriptive method. The study aims to describe and analyze the patent waiver applications within the context of existing regulations. The research adopts a descriptive-analytical approach, focusing on international legal instruments and their implementation, particularly those related to vaccine patent waivers. **Findings:** The study found that the WTO has fulfilled its roles and functions in accordance with applicable international legal instruments during the COVID-19 pandemic. However, there is a critical need to emphasize the WTO's principles of fairness and equity, especially the Special and Differential Treatment (SDT) provided to developing and less developed countries. The research highlights the ongoing challenges these countries face in accessing vaccines, despite the formal mechanisms in place. **Conclusion:** While the WTO has adhered to its mandates in managing vaccine patent waiver issues, further emphasis is needed on ensuring justice for developing nations through the proper application of SDT principles. Greater attention to these principles is necessary to balance the interests of intellectual property rights holders and the public health needs of developing countries. **Novelty/Originality of This Study:** This research offers a unique perspective by combining legal analysis with the principles of Special and Differential Treatment (SDT) under the WTO framework. It provides new insights into the application of international legal instruments related to patent waivers, emphasizing the need for equity in global health crises, particularly for developing and less developed countries.

**KEYWORDS:** world trade organization; coronavirus disease 2019; patent release.

## 1. Introduction

In early 2020, there was a spread of a new disease in various countries, which attacked the respiratory system. This disease was spread by a virus, which was later referred to as Coronavirus Diseases 2019 (COVID-19). The virus spread widely in a very short time and was declared a pandemic on March 11, 2020 (Kriz et al., 2020). The characteristics of this virus are that it is highly contagious only through droplets and air and this transmission takes place in just two weeks (Kriz et al., 2020). This problem is not only a health issue, but also a multidimensional crisis that affects the order of life and harms all communities in various parts of the world.

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By addressing the existing conditions, the hope of returning to the usual situation or the pre-pandemic norm is highly anticipated by all communities. One way to realize this hope is to build and achieve mass immunity (herd immunity) so as to get out of the crisis situation. According to Mckinsey, a research institute, in relation to when the COVID-19 pandemic crisis will end, it is related to the vaccination rate which plays an important role in shaping and determining the level of mass immunity. This emphasizes how important vaccination is for a country, even the entire world community, to be free from a pandemic.

Based on the above situation, many countries are working to access vaccines. This is aimed at achieving global health and reducing, or even breaking the chain of death caused by the pandemic. In turn, this is also done so that economic improvements can be made immediately. This situation then led to contestation between countries for vaccines. This has been a phenomenon that has accompanied the pandemic since the beginning. Dworkin (in Euronews, 2021) argues that with the emergence of contestation between countries to obtain vaccines, it is possible that vaccines will become an important element of geopolitics (Dworkin, 2021). This contestation will clearly have implications for the emergence of inequality.

Disparities exacerbate the pandemic and make the crisis situation unending. This is due to the uneven distribution of vaccines, but simultaneously, the virus is spreading and new variants are emerging and more deadly (Villines, 2021). However, many things stand in the way of noble efforts to get out of the crisis. This is due to the fact that vaccine quotas are generally monopolized and controlled by rich countries, which involves intellectual property.

The vaccine market is a major issue, mainly related to research procurement schemes and vaccine resources. Due to the success in addressing these schemes and resource issues, developed and wealthy countries that can afford to do so enter into bilateral agreements with vaccine manufacturers. The implication of this is that the vaccine stock is controlled by these countries. They receive more slots, even more than necessary (Vox, 2021). In addition, this also has negative implications for developing countries as the list of vaccine recipients is based solely on bilateral agreements. This limitation experienced by developing countries was further responded to by India and South Africa, who raised the issue of patent waivers, so that at least permission to produce vaccines can be obtained outside companies that own intellectual property rights.

South Africa and India first applied for a patent waiver on October 2, 2020, seven months after the COVID-19 virus was declared a global pandemic by WHO and two months before the vaccine was distributed to the public through clinical trials. The conversation about vaccines is also related to patents. This refers to an exclusive right, which allows the holder to patent three things: the product, the process, and the transfer, transfer and closing of the license (Purba, 2011). However, the patented item can be used and produced by third parties with the permission of the government, without the permission of the patent owner, through compulsory licensing (WHO and WTO, 2002).

The applications submitted by South Africa and India were rejected by the General Council as well as many countries, such as the United Kingdom and Germany, due to intellectual property protection (Hassan, 2021). These two countries then continued to submit a revised waiver application with support from various countries on May 25, 2021. Furthermore, at the 12th Ministerial Conference (MC12) in June 2022, it was approved by members of the World Trade Organization (WTO). During the conference, one of the things discussed was the WTO's response to the pandemic through granting waivers in accordance with the provisions of the TRIPS Agreement, mainly related to licenses for vaccine production (WTO, 2022).

However, efforts to obtain a patent waiver are not easy and take place over a relatively long period of time, namely two years. The length of this process is due to the consideration of intellectual property rights issues and the position of a number of WTO member countries that have the resources to invest in vaccine manufacturers. In the midst of these difficulties, we must also keep in mind something far more important, namely the existence

of all humanity and the state of the earth which is increasingly being destroyed, allowing the creation and spread of new viruses that can trigger pandemics in the future.

In the above conditions and problems, this research seeks to further explore the role played by the WTO as a world trade organization in dealing with the issue of patent waivers on vaccines during the COVID-19 pandemic. Research on more or less similar issues has been carried out by a number of people. First, Syahroni conducted a study entitled "Application of the TRIPs Agreement flexibility clause in article 20 of law number 13 of 2016 concerning patents to the importation of the covid-19 vaccine". The research differs from this research in terms of its formal object because Syahroni's research highlights the flexibility of the TRIPs Agreement and vaccine imports.

Second, a study entitled "Review of parallel importation of patents for pharmaceutical products based on Law No. 13 of 2016" by Ahmad. This research focuses on the provisions of pharmaceutical patents in Indonesia by using the Indonesian Patent Law as the basis for taking a broad public health perspective. This is different from this study, which uses the basis of international law as an instrument in taking a viewpoint that concerns global public health. In other words, this study focuses more on the provisions of pharmaceutical patents globally through the WTO, not the national provisions in Indonesia.

## 2. Methods

This research methodologically operates normative research, which is research in the field of law that examines law as a rule or norm in society (Muhaimin, 2020). This research uses legal data, both primary and secondary. Secondary data is obtained from previous sources, both legal and non-legal opinions, taken from books, journal articles, online articles or news, minutes, and interviews with representatives of the Ministry of Foreign Affairs of the Republic of Indonesia and the Ministry of Trade of the Republic of Indonesia. The data collected is then analyzed qualitatively, which is a research method that does not require populations and samples (Zainuddin, 2013).

## 3. Results and Discussion

### 3.1 World Trade Organization as a world trade organization

In the WTO, there are principles that become the basis for running the organization, namely the principle of reciprocity, the principle of non-discrimination, and the principle of equality before international treat law. The Patent Waiver application basically violates the principle of reciprocity which requires reciprocity between WTO members, but it is allowed considering the presence of the Special and Differential Treatment of Developing Countries (SDT) principle which can be used as the core in this research. The SDT principle was first established during the Tokyo Round of the GATT, and it became an important norm in trade and the various rounds of the GATT as it reinforced the issue of different trade rules for developing countries (Hawthorne, 2013). In relation to the continuity of the WTO, the GATT has been included as part of the legal basis for the running of the organization, of course the principle is also taken as a WTO principle.

In the case of the Patent Waiver, all requests would have to go to the General Council first since the Ministerial Conference is held every two years. In the case of the patent waiver, in addition to the request addressed to the General Council on several occasions during the two-year period, India also met with the General Council to further emphasize the importance of their waiver request being granted (Knowledge & News Network, 2022). Underlying these two bodies, there are further supporting bodies that report to the General Council, commonly referred to as councils. These councils are subdivided into three sections namely the Council for Trade in Goods; Council for Trade in Services; and Council for TRIPs

which can set procedures to rules respectively (Knowledge & News Network, 2022). Specifically, the council that will be discussed in this research is the Council for TRIPs, considering that this council also follows up on the 12th Ministerial Conference decision which finally granted the waiver in mid-2022 (WTO, 2022).

In relation to research that talks about the COVID-19 Patent Waiver, basically the WTO itself has principles that support this. There are two principles that researchers consider to be reference stones, namely the principles of Non-Discrimination and Special and Differential Treatment of Developing Countries (SDT). In short, the principle of non-discrimination is the same treatment among all WTO members in this case including quotas, entry tariffs, and tariff convenience (Jhamtani, 2005). On the other hand, SDT itself comes from the awareness of many developing countries that see inequality in international trade, especially in making various agreements, especially when determining the rights and obligations of each party (Michalopoulos, 2022). With this, the presence of SDT introduces two categories in every WTO agreement, namely: (a) positive action from developed country members and international institutions in relation to developing countries; and (b) some exemptions for developing countries and on occasion additional exemptions for Least Developed countries (Michalopoulos, 2022).

### *3.2 Settlement of the 2019 coronavirus disease vaccine patent waiver issue by the world trade organization*

Dispute settlement within the WTO has a hierarchy and bodies that have been arranged in such a way with the WTO Agreement as the main legal source. Set forth in the WTO Agreement Article IV regarding the structure of the WTO which regulates the Ministerial Conference, General Council, Trade Policy Review Body, Council for Trade in Goods, Council for Trade in Service, and Council for Trade-Related Aspects of Intellectual Property Rights (WTO Agreement, Art. IV). Related to the waiver application is regulated in the WTO Agreement Article IX on decision-making, namely through the relevant council (in this case the TRIPs Council) and then submitted to the Ministerial Conference or if it occurs in the interval period submitted to the General Conference (WTO Agreement, Art. IX). In the case of a waiver, the request is addressed to the TRIPs Council and forwarded to the General Council and then a decision is made at the 12th Ministerial Conference.

As of 2018, out of 250 (two hundred and fifty) waiver requests approved by the WTO, only 3 (three) of them were related to the TRIPs Agreement (Taubman et al., 2020). The first waiver is regarding exclusive marketing rights in Article 70 (9), the second is related to Article 70 (8), and when it comes to patents, namely the amendment of TRIPs in order to establish a special compulsory license for standard pharmaceutical product patents (Taubman et al., 2020). In the latter case, a waiver was made of several conditions in Article 31 of the TRIPs Agreement specifically on medical compulsory licenses (Taubman et al., 2020). Legally, the basis for the formation of the TRIPs Council, apart from being regulated in the WTO Agreement, is also regulated in the TRIPs Agreement Article 68 which contains:

"Dewan TRIPs akan memantau pelaksanaan Perjanjian ini dan, khususnya, kepatuhan Anggota terhadap kewajiban mereka di bawah Perjanjian ini, dan akan memberikan kesempatan kepada para Anggota untuk berkonsultasi mengenai hal-hal yang berkaitan dengan aspek-aspek yang berkaitan dengan perdagangan hak kekayaan intelektual. Dewan akan melaksanakan tanggung jawab lain yang ditugaskan kepadanya oleh para Anggota, dan secara khusus akan memberikan bantuan yang diminta oleh para Anggota dalam konteks prosedur penyelesaian sengketa. Dalam menjalankan fungsinya, Dewan TRIPs dapat berkonsultasi dengan dan mencari informasi dari sumber manapun yang dianggap tepat. Dengan berkonsultasi dengan WIPO, Dewan akan berusaha untuk menetapkan, dalam waktu satu tahun sejak pertemuan pertamanya, pengaturan yang tepat untuk kerjasama dengan badan-badan Organisasi tersebut. (Perjanjian TRIPs, Pasal 68).

Regarding the role of the TRIPs Council in resolving cases of COVID-19 vaccine waiver applications, it is carried out in accordance with the legal basis that regulates it, namely the WTO Agreement and the TRIPs Agreement. In accordance with the provisions in the TRIPs

Agreement regarding "It shall carry out such other responsibilities as assigned to it by the Members.....", namely when the TRIPs Council is given the responsibility to follow up on waiver requests. It also continues that its role is in accordance with the arrangements in the WTO Agreement both Article IV and IX, namely following up with the Ministerial Council and held in accordance with a period of less than 90 days.

Although the role in the form of procedures and actions is in accordance with applicable law, especially regarding the submission of applications and the duties of the board, however, there are other matters that need attention. In the WTO, there is a principle that can be used as the core in this research, namely the principle of Special and Differential Treatment of Developing Countries (SDT). This principle is presented in awareness of the differences and injustices encountered by developing and least developed countries in global trade (TRIPs Agreement, Art. 68). The COVID-19 vaccine waiver request that was first submitted by India and South Africa at the Ministerial Conference was granted with conditions, namely only waiving Article 28 (1) of the TRIPs Agreement and still having to make payments to patent holders. Of course, this will be burdensome for the Least Developed Country (LDC).

The Least Developed Country (LDC) in the WTO was adjusted by the United Nations so that it currently consists of 46 countries, 35 of which are already WTO members (WTO, 20220). On the LDC list are countries that not only have low gross national income, but are also caught up in conflicts such as Pakistan and Bangladesh. Of course, a waiver that still requires WTO members to make payments to patent holders will be very burdensome. In addition, the waiver was only granted for the production of vaccines, not the entire prevention and treatment of COVID-19 as requested.

Seeing all these analyses and facts, of course, it is doubtful to use the word "granted" in the patent waiver application. The reason is that the acceptance is not only conditional but also almost does not grant all requests from sponsors. In the WTO statement as well as various mass media written that the Patent Waiver application was granted with conditions, it can be seen further about the bridge that exists between the reality on the ground and the news.

#### **4. Conclusions**

In relation to the role played by the WTO to address the issue of vaccine patents during the COVID-19 pandemic, it can be concluded that the WTO's actions, including its internal bodies and councils, basically do not deviate from the applicable legal rules. The considerations made in decision-making during the 12th Ministerial Conference are also in line with the rule of law, namely the TRIPs Agreement itself. However, it is not in line with the principles held by the WTO, especially the principle of Special and Differential Treatment of Developing Countries (SDT).

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Not applicable.

### Conflicts of Interest

The authors declare no conflict of interest.

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