



The legal basis for the application of patent waiver settlements in the covid 19 pandemic

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ABSTRACT

Background: The research on the role of the World Trade Organization in solving the vaccine patent waiver problem related to the 2019 coronavirus disease pandemic will address each issue one by one. Seeing the waiver applications that were made from the end of 2020 to 2022, it is necessary to further study the legal basis and enforcement of patents. Coupled with its relation to public health and equality for the global world to achieve. This study aims to provide an understanding of the role of the WTO in the patent waiver application process and the continuity of current and future patent law enforcement. **Methods:** This research is a normative research with a descriptive method that will explain with the aim of obtaining a description of the events of the patent waiver application. The data that has been obtained will be analysed qualitatively. Conclusions will be obtained from various descriptive data collected from primary and secondary sources that have been analysed. In this regard, this research will be descriptive-analytical in nature which will reveal existing regulations and their implementation. **Findings:** The results of this study are that the WTO has carried out its roles and functions in accordance with applicable international legal instruments. However, this research emphasises further on the principles of the WTO itself which emphasises justice for developing and less developed countries on the other words called Special and Differential Treatment of Developing Countries (SDT). Coupled with the existence of the Doha Declaration which should emphasise that public health should take precedence over intellectual property rights, including patents. **Conclusion:** Regarding the WTO's role in resolving vaccine patent issues during the COVID-19 pandemic, it can be concluded that the actions taken by the WTO, including its internal bodies and councils, adhere to applicable legal principles and the TRIPs Agreement. However, the decisions must fully align with the WTO's principles, particularly the Special and Differential Treatment of Developing Countries (SDT). **Novelty/Originality of this study:** This study analyzes the role of the WTO in resolving vaccine patent issues during the COVID-19 pandemic, focusing on the SDT principles and the Doha Declaration. It reveals the gap between international law and global health needs, offering a framework for balancing intellectual property rights with public health needs.

KEYWORDS: COVID-19; patent waiver; world trade organization.

1. Introduction

In early 2020, a new disease that attacks the respiratory organs began to spread in several countries. The disease that was eventually called and named Coronavirus Diseases 2019 (COVID-19) was declared a Pandemic on 11 March 2020 (Kriz et al., 2020). The virus quickly spread around the world and caused massive changes. The whole world seems to have to get used to new circumstances quickly and with an online way of life, not to mention the economic losses. Given also that the virus is highly contagious because it can be spread through droplets and air plus the virus can remain contagious in one person for up to two

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weeks (Kriz et al., 2020). In short, it can be said that the presence of this pandemic affects and harms all levels of society in various countries. Of course, for the various interests in many layers of society, a return to the state as before the pandemic is highly coveted. Not only public health and survival for groups vulnerable to COVID-19, but also the recession that has continued to hit various countries since the pandemic began has certainly made many countries fearful. The coveted way out is to immediately achieve mass immunity (herd immunity) and be free from pandemic status.

A team from the McKinsey research institute published a research article on when the COVID-19 pandemic will end, outlining the level of mass immunity seen through vaccination rates and COVID-19 survivors. Although, some recent studies have found that survivors will be more immune to the virus, since the emergence of the Omicron variation it can be seen that vaccination status is quite important to protect people from COVID-19. This is evident through the recent fact that those who have received the third injection tend not to need hospitalisation if they are infected (Charumilind et al., 2022). This certainly adds a new argument regarding how important vaccination is to the release of a country from COVID-19 pandemic status.

The first problem comes from the vaccine market itself, more precisely the COVID-19 vaccine research and resource procurement scheme. The stages of a vaccine reaching the public start from development, manufacture, and distribution. The development and manufacturing stages are usually held by developers and suppliers. At these two stages, many rich countries make bilateral agreements with developers and suppliers, the more the amount of investment given, the country will be at the top of the list as a vaccine recipient (Vox, 2022). According to the source (Vox, 2022) due to the uncertainty of success at both stages, countries that can afford it will make bilateral agreements with many developers or suppliers, so that the successful vaccine slots held by these countries become more or even more than necessary.

The existence of a list of vaccine recipients based on bilateral agreements also makes it difficult for many developing countries to get vaccines. For this problem, there is already a problem-solving scheme, namely the presence of the COVAX Facility Cooperation initiated by WHO, GAVI, and CEPI with the aim of tackling COVID-19 globally and evenly. Ideally, this scheme is run with each participating country will help provide investment funds to accelerate vaccine research and production. Later, vaccine distribution will be carried out evenly in each participating country through facilities created by COVAX. However, this collaboration is also difficult to get ideal investment because many countries have entered into bilateral agreements before this collaboration was formed, so they do not provide much money channel to COVAX (Vox, 2022). Seeing some of these facts, of course there are still many developing countries that really need the COVID-19 vaccine but have difficulty getting it. Due to the limited availability of vaccines, the term patent waiver was first launched by India and South Africa, to at least obtain permission to produce vaccines outside companies that own intellectual property rights. The effort made is not to abolish international legal norms regarding intellectual property, but rather a temporary waiver of several regulations in the TRIPs Agreement for a certain period of time. Of course, this is related to global health that must be achieved by all levels of society (Zaman, 2022).

This waiver proposal was first submitted by India and South Africa on 2 October 2020. In the proposal, point 12 explained that the two initiating countries requested that the TRIPs Council immediately provide recommendations to the General Council regarding the waiver of the implementation, application, and implementation of Part II Section 1, 4, 5, and 7 of the TRIPs Agreement (WTO, 2020) Sequentially the four Sections discuss Copyright and Related Rights, Industrial Designs, Patents, and Protection of Undisclosed Information. Article 31 is also included as a basis for this waiver request to be submitted in point 10. (WTO, 2020) Keep in mind that this request was submitted 7 months after WHO declared COVID-19 a global pandemic, and about two months before the vaccine was finally held clinical trials and given to the wider community.

At the time of this research, the latest news from the negotiations and discussions on Patent Waiver is the approval by members of the World Trade Organization (WTO) at the

12th Ministerial Conference (MC12) in June 2022. This annual conference discusses various multilateral negotiations that are part of the Geneva Package, one of the topics discussed is the WTO's response to the pandemic by granting waivers to several provisions in the TRIPS Agreement, especially regarding licences for the manufacture of COVID-19 vaccines (WTO 2022). Ngozi Okonjo as Director General of the WTO at the 12th Ministerial Conference press conference said that this waiver will be valid for 5 years and its duration can be changed or reviewed by the General Council.

2. Methods

The type of research used in this writing is normative research, which is a legal research that examines the law as norms or rules in society (Muhaimin, 2020). This normative legal research is internal research in the discipline of law which usually uses more document studies such as sources of legal material from laws and regulations to legal theories (Muhaimin, 2020). Normative juridical research will focus on discussing principles in legal science and research will work inductively analytically (Zainuddin, 2013). Data collection was conducted through literature study and interviews. The literature study involved reviewing legal information relevant to the research, sourced from various materials and publications such as legislation, jurisprudence, legal textbooks, law journals, and print media. Interviews were conducted with representatives from the Ministry of Foreign Affairs of the Republic of Indonesia and the Ministry of Trade of the Republic of Indonesia.

In this study, the collected data will be analyzed qualitatively. A qualitative approach is a research method that does not require a population or sample (Zainuddin, 2013). Conclusions will be drawn from various descriptive data gathered from primary and secondary sources that have been analyzed. Furthermore, this research is descriptive-analytical, aiming to reveal existing regulations and their implementation in society as the research object. It is descriptive because it provides a clear explanation of the legal issues at hand and analytical because the obtained data will be thoroughly examined (Zainuddin, 2013).

3. Results and Discussion

Before discussing further about the TRIPs Agreement, researchers -see the need to straighten out the understanding of intellectual property rights first. Purba (2011) in his book "Intellectual Property Rights Post TRIPs" explains that there are at least five basic principles contained in intellectual property rights, namely:

A patent is a right that can be used for a certain period to independently implement an invention or grant permission to others to do so, and it is an exclusive right granted by the state (Sudarmanto, 2012). Rights Authority: Intellectual property rights are not like human rights that have existed since humans were not even born. There needs to be a prior application given to a public authority that has been mandated by the state (Purba, 2011). International law itself has placed the state as the highest authority that can grant such ownership rights to intellectual property applicants, with three main elements, namely the existence of exclusive rights, the existence of state intervention in granting rights, and a given period of time (Purba, 2011). Private Rights and Article: Intellectual property rights, although private, should still provide benefits to the market mechanism and even be a driver of economic growth (Purba, 2011). Principle of Sustainability: Again, although intellectual property rights are private, the balance must be considered with the public interest.⁷⁸ This principle is even confirmed in the principles and objectives of the TRIPs Agreement which reads:

"The protection and enforcement of intellectual property rights should contribute to, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." 79 "Members may,, adopt measures necessary to protect public health

and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development,....."

One Unit: Intellectual property rights is a system consisting of various fields that are interrelated and cannot stand alone. For example, in Indonesia itself, the application for intellectual property rights is carried out at the Ministry of Law and Human Rights, but in its management it coordinates with various related parties. TRIPs Binding: The TRIPs Agreement itself is one of the annexes of the Marrakesh Agreement or commonly referred to as the WTO Agreement, and with the principle of *pacta sunt servanda*, at least seventy-six countries that have ratified it already have an obligation to implement it (Purba, 2011). This is important considering that there is legal understanding in trade throughout the world, especially regarding intellectual property rights.

Looking at the five principles, the existence of an international instrument that unites the legal provisions regarding intellectual property rights is certainly very necessary. Before the presence of the TRIPs Agreement, there were certainly several other provisions that were international in nature and regulated intellectual property rights. However, the presence of the TRIPs Agreement not only unifies but also confirms it because it directly applies to members. Its presence will be closely related to the birth of the WTO considering that the TRIPs Agreement itself is part of the WTO Agreement.

3.1 Analysis of the Settlement of the 2019 Corona Virus Disease Vaccine Patent Waiver Issue by the World Trade Organization

3.1.1 The role of the world trade organization

Prior to the WTO, in 1946 right after the end of the Third World War, the International Trade Organisation (ITO) was set up under the UN Economic and Social Council as a multilateral trade negotiating body (Jhamtani, 2005). However, ITO failed to be formed because the Havana Charter was not ratified by many countries, so of course the goal of becoming a trade body that oversees all countries cannot be implemented. Finally, at the end of 1947, the General Agreement on Tariffs and Trade (GATT) was formed as one of the main and final tasks of the ITO. Initially, GATT was created only as a multilateral agreement containing general principles on trade, however, ITO failed to be adopted as the third pillar of the economy as intended by the Bretton Woods Convention. Initially, the GATT only acted as a vacuum filler, gradually turning into an international body centred in Geneva.

As the Havana Charter was not adopted by the majority of the countries participating in the 1947 Havana Convention, the 1948 GATT became an *ad interim* international agreement. However, subsequently GATT was considered to have many of its own defects. Until finally on 15 April 1994, the Marrakesh Agreement (part of the Uruguay Round) gave birth to the WTO and was automatically binding on all members as a law (Matsushita et al., 2015). Basically, the Marrakesh Agreement or commonly called the WTO agreement is an amalgamation of various agreements on world trade in which there are four annexes or commonly referred to as Annex.32 The first annex is further divided into three parts, with Annex 1A containing the GATT 1994 consisting of the Marrakesh Protocol, GATT 1947, and 12 other agreements on goods. Annex 1B contains the General Agreement on Trade in Service (GATS), and Annex 1C contains the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement). Followed by the second Annex 2, the Annex Understanding on Rules and Procedures Governing the Settlement of Dispute, which regulates the procedures for resolving trade disputes that occur among WTO members. Annex 3 contains the Trade Review Policy Mechanism which regulates the periodic review of each WTO member that is adjusted in the WTO, there are principles that become the basis for running the organisation, namely the principle of reciprocity, the principle of non-discrimination, and the principle of equality before international treat law (Purwaningsih, 2015).

The researcher sees the need to look at the General Agreement on Tariffs and Trade (GATT) since the WTO Agreement is its successor. During the period of 1947 to 1994, there were various changes and negotiations until finally the WTO Agreement came into force in 1995, including various changes in the field of intellectual property rights. The General Agreement on Tariffs and Trade 1947 has several provisions regarding intellectual property, which broadly speaking allows each party to have its own arrangements regarding intellectual property rights as long as they are still based on the principle of non-discrimination and obstruction of trade. Since the entry into force of the TRIPs Agreement in 1995, changes have been felt in various intellectual property protections in the international world (Busche & Stoll, 2009). However, it should be emphasised that the existence of the TRIPs Agreement does not replace existing intellectual property protection systems such as the WIPO Convention and the Paris Convention, but adds to existing agreements and systems (Busche & Stoll, 2009). This can be seen from Article 2 which further emphasises the involvement of previous conventions by writing: In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967). Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits."

The presence of the TRIPs Agreement is the cornerstone of many changes regarding the protection of intellectual property, which in WIPO basically covers the area of industrial property and copyright. The agreement, which is also included in the WTO Agreement annex 1C, is of course also an instrument of international law if based on the Statute of the International Court of Justice which mentions treaties as one of the main sources of international law. However, before the presence of TRIPs, there were many that regulated intellectual property and became the basis for the formation of TRIPs, such as the Paris Convention which mostly regulates patents, the Berne Convention, and the Madrid Agreement. There are four parts of the regulation in TRIPs, which include: (1) the link between intellectual property and international trade; (2) the obligation for each member to comply with the Paris Convention and the Berne Convention, both of which regulate Patents and Copyrights respectively; (3) the establishment of separate provisions and arrangements; (4) some arrangements regarding general provisions including law enforcement in each member in the form of legislation.

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 itself was first established during the Tokyo Round of GATT, and it became an important norm in trade and various rounds of 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 is already included as part of the legal basis for the running of the organisation, of course the principle is also taken into the WTO principles. Regarding duties and functions, in general, the presence of the WTO is to facilitate the implementation, administration, and operation of the WTO agreement. While its specific duties are: (1) to provide a forum for members to negotiate on current issues and agreements; (2) to manage the DSU system; (3) to manage the Trade Policy Review Mechanism; and (4) to co-operate, if necessary, with the IMF and the World Bank.

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 source of law. Set out in the WTO Agreement Article IV on 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 waiver requests are 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 during the interval

submitted to the General Conference (WTO Agreement, Art IX) (Van den Bossche & Zdouc, 2010). 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 taken at the 12th Ministerial Conference.

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). The principle was presented on the awareness of the differences and injustices encountered by developing and least developed countries in global trade.¹⁴⁹ 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 is adjusted to the United Nations so that it currently consists of 46 (forty-six) countries of which 35 (thirty-five) are already members of the WTO.¹⁵⁰ On the LDC list there are countries that not only have low gross national income, but are also trapped in conflicts such as Pakistan and Bangladesh. Surely a waiver that still requires WTO members to make payments to patent holders would 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, it is certainly a doubt 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's 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.

3.1.2 Legal basis for problem solving and future effects

Regarding the legal basis for problem solving, as explained above, in the procedure to the role of each WTO institution and council, it is in accordance with the WTO Agreement and the TRIPs Agreement as a binding regulation. However, in the decision taken, there is an irregularity when related to public health itself, the TRIPs Agreement (as a regulation that is the main character in the waiver application) has passed the amendment and the Doha Declaration. Both of these are motivated by the same large and deadly disease, namely the HIV/AIDS epidemic.

Finally, on 14 November 2001, the Doha Declaration on TRIPs Agreement and Public Health was ratified at the fourth Ministerial Conference. There are 3 (three) main things that are the concern of the Doha Declaration, namely: the granting of compulsory licences is the right of every WTO member in terms of public health protection, the determination of the grounds for compulsory licences is at the discretion of each WTO member, and epidemics fall within the scope of "national emergencies" and "extremely urgent circumstances" listed in Article 31(b) of the TRIPs Agreement.

These facts certainly raise questions related to the decisions taken at the 12th Ministerial Conference. A little illustration, the amendment to the TRIPs Agreement is quite useful in the HIV/AIDS epidemic because it allows many developing and less developed countries to make generic drugs (Noerhadi, 2020). As has been explained, many developed countries reject patent waivers on the grounds that there is already a COVAX facility to cope with the global spread of vaccines. The sponsor members' answer regarding COVAX's inability to accommodate all members was proven when more than half of the countries did not get enough raw materials to produce vaccines (Reuters, 2021).

The principle in dealing with a global pandemic is "no one is safe before everyone is safe", so the granting of patent waivers should also be a favourable thing for developed countries. Based on the results of interviews conducted with Umar Badarsyah as staff in the Directorate of Economic Treaty Law of the Ministry of Foreign Affairs of the Republic of

Indonesia, it was found that developed countries have an interest in maintaining the status quo in the stance around intellectual property rights and encourage the use of voluntary licences. For the sponsors themselves, waiving patents in the context of a pandemic will help prevent and cure pandemics in each country.

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. Regulated in the WTO Agreement Article IV on 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. 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 during the interval submitted to the General Conference. In the case of a waiver, the application is addressed to the TRIPs Council and forwarded to the General Council and then a decision is made at the 12th Ministerial Conference. Until 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 was regarding the exclusive marketing rights in Article 70 (9), the second was related to Article 70 (8), and the third was regarding patents, namely the amendment of TRIPs in order to establish a special compulsory license for standard pharmaceutical product patents. In the last case, the waiver was made against several conditions in Article 31 of the TRIPs Agreement specifically on compulsory medical licenses. Legally, the basis for the establishment of the TRIPs Council in addition to being regulated in the WTO Agreement is also regulated in the TRIPs Agreement Article 68 which contains:

“The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights. It shall carry out such other responsibilities as assigned to it by the Members, and it shall, in particular, provide any assistance requested by them in the context of dispute settlement procedures. In carrying out its functions, the Council for TRIPS may consult with and seek information from any source it deems appropriate. In consultation with WIPO, the Council shall seek to establish, within one year of its first meeting, appropriate arrangements for cooperation with bodies of that Organization.”

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. Furthermore, 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 council, 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). The principle was presented on the awareness of the differences and injustices encountered by developing and least developed countries in global trade.¹⁴⁹ 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).

3.1.3 Waiver Application

The waiver application can be made in accordance with the arrangements in Article IX 3 and 4 of the Marrakesh Agreement, which confirms that in exceptional circumstances the waiver of some matters in various WTO agreements such as TRIPs, can be decided at the WTO Ministerial Conference. The same article also explains the time period for the process of submitting requests to the relevant council (in this case the TRIPs Council) is < 90 days, then the results will be submitted to the Ministerial Conference. Given that the Ministerial Conference is held every two years, it will be submitted to the General Council in between. Regarding whether or not the waiver application is accepted, the conclusion will be made when all WTO members have given consensus or the agreement is taken through voting. Basically, the waiver application does not only focus on one process or intellectual property product, but on various matters related to COVID-19. This means that the waiver request is not only for vaccines, but also for COVID-19 treatment and technology including ventilators and masks. Following up on the request, an informal TRIPs Council meeting was held on 20 November 2020 to discuss the waiver requests by India and South Africa (Singh & Dhir, 2022).

At the meeting, statements from India, South Africa, Kenya, and Eswatini were presented along with a collection of examples where intellectual property rights were a barrier to access to vaccines and medicines by South Africa. Briefly in the collection of examples, it was explained that the time-consuming patent publication process is one of the barriers to the global treatment process. On 27 November 2020 Australia, Canada, Chile, and Mexico provided several formal statements related to intellectual property rights being a barrier for some members in fighting the COVID-19 pandemic. The eight questions focused on the experiences, needs, and efforts of the applicant members regarding intellectual property and manufacturing for COVID-19 purposes. On 3 December 2020, another informal meeting of the TRIPs Council was held which included interventions by India, South Africa, Pakistan, and Mozambique. The meeting was more of a discussion with some members asking questions related to the relationship between intellectual property waivers and the resolution of the COVID-19 pandemic and the sponsoring countries answering them.

In brief, sponsor countries are WTO members who are the main applicants for the patent waiver proposal, in this case, India and South Africa. Furthermore, on 10 December 2020 at the TRIPs Council meeting, WTO members agreed to continue the discussion, the status of which will then be addressed to the General Council meeting on 16-17 December 2020. At the General Council meeting, members discussed their views and clarified the information provided in the waiver application. The different views on the waiver were discussed at length as, for developed countries, especially for global pharmaceutical manufacturers, they have an interest in maintaining the status quo. It was also at this meeting that India gave its statement on the waiver proposal to the General Council. India emphasised that this proposal will not only be useful for India but also for the global community because dealing with a global-scale pandemic certainly requires a global solution. Other things that India emphasised were the COVAX and ACT-accelerator programmes which were considered not to meet the needs of 7.8 billion people around the world as well as mandatory licensing which is very complex because it has differences in each jurisdiction. On the other hand, the European Union made a statement which briefly emphasised that the production of vaccines and medicines is certainly greatly assisted by the presence of intellectual property rights and the equitable distribution of vaccines is considered to have been fulfilled by the COVAX programme.

In response to the questions raised at the 16 October, 20 November, 3 December and 10 December 2020 meetings, the sponsoring and co-sponsoring countries answered them in one official statement. One of the highlights was the response to the question at the 16 October meeting on compulsory licensing. Sponsoring and co-sponsoring members stressed that there were two delegations that rejected the waiver request but at the same time took action to prevent countries from using compulsory licences. Unlike sponsoring

members, co-sponsoring members could engage in negotiations on the proposal. The two delegations are the European Union and the United States, which in 2020 condemned and criticised countries (including developing countries) for their emphasis on compulsory licensing. Regarding the existence of the ACT-Accelerator and COVAX programmes, it was also answered that although the sponsoring and co-sponsoring countries are very supportive of the two programmes, it is inevitable that global needs will not be met by them.

At the formal meeting of the TRIPs Council on 10-11 March 2021, members still questioned the significant role of intellectual property waivers in providing access to vaccines and medicines. Following this, members agreed to request further evidence on instances where intellectual property rights are a barrier to access to vaccines and cannot be resolved by the arrangements in the TRIPs Agreement. At this time, India is entering the second wave of the pandemic from March to June 2021 which has claimed at least 9,441 lives. On 25 May 2021, a revised waiver application was submitted again (Rake, 2022). In the revised application, there are 5 points of change with the core being in the fourth point, namely regarding the main focus of the proposal is a waiver only for health products and technology as an effort to prevent and treat COVID-19. Furthermore, on 30 September 2021 the sponsor delegation again issued a conclusion statement regarding the requested waiver. This statement again emphasised the importance of the waiver for the production, supply and access to health products and technology for COVID-19.¹³² Of course, the waiver would not apply to Article 14 of the TRIPs Agreement regarding the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations. In the same statement document, the use of waivers for patents (section 5 of the TRIPs Agreement), protection of confidential information (section 7 of the TRIPs Agreement), copyright (section 1 of the TRIPs Agreement), and industrial designs (section 4 of the TRIPs Agreement) is also emphasised.

As a form of defence, patents explain that patents grant monopoly rights and prevent others from using the patented process or product. This raises two issues, namely: (1) regarding the uncertainty of the number of patent applications and grants due to differences in the laws of each jurisdiction and the length of time for publication. (2) regarding the difficulty of relying on and efficient application of the legal basis of Article 31 of the TRIPs Agreement. In this regard, an example is given of a vaccine company that has a product development patent but does not have underlying patents such as process and laboratory results. Another point that needs to be highlighted in the 30 September 2021 statement is the duration of the waiver. The applicant members have stated that regarding COVID-19 until the document is made it is not clear when it will end, of course, determining the duration will be difficult.¹³⁵ So looking at the 2003 waiver request for Article 31 (f) and (h) of the TRIPs Agreement, a flexible duration is needed to create sufficient conditions to improve supplier manufacturing.

4. Conclusions

Regarding the role of the WTO in resolving vaccine patent issues during the COVID-19 pandemic, it can be concluded that what is done by the WTO, including its an a internal bodies and councils, is in accordance with applicable legal principles. The considerations present in making decisions at the 12th Ministerial Conference are also in accordance with the rule of law, namely the TRIPs Agreement itself. However, the decision is not in accordance with the principles held by the WTO, especially regarding the principle of Special and Differential Treatment of Developing Countries (SDT).

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