

Trade-Related Aspects of Intellectual Property Rights (TRIPS) Waiver Proposal for Global Health Equity in COVID-19 Pandemic: The Challenges and Dynamics

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ABSTRACT

The TRIPS waiver is a proposal by India with South Africa submitted to the WTO. The Proposal contains certain exceptions to the applicable TRIPS Agreement. This Waiver Proposal was submitted because of the inequity conditions between rich and poor countries accessing health products in eradicating the COVID-19 pandemic. This study aims to analyze the success of the TRIPS Waiver in fighting for equity distribution of global health facilities in the context of the COVID-19 pandemic from the start of the pandemic to the end of 2022 by examining the challenges and dynamics of the proposal submission process at the WTO. This study uses a qualitative descriptive method by reviewing literature or secondary data. In analyzing the challenges and dynamics of the TRIPS Waiver Proposal process at the WTO, the authors use the norm life cycle concept and find results that the internalization of norms has not been fully formed because the domination of big countries of WTO members have not agreed on all aspects of the TRIPS Waiver proposal, or it can be said that the TRIPS Waiver Proposal has not been fully agreed upon as a new norm in overcoming global health inequity. Even though the supporting tipping point has exceeded 1/3, full support is needed for the success of the TRIPS Waiver Proposal, as voting in the WTO is based on consensus. The novelty of this research is the use of the norm life cycle concept in the implementation process.

Keywords: TRIPS Waiver, WTO, Intellectual Property Rights, COVID-19, Global Health

INTRODUCTION

On January 30, 2020, the World Health Organization (WHO) declared that coronavirus disease (COVID-19) was a global emergency. It continued on March 11, 2020, the WHO upgraded the status to a pandemic. It was a sign that the COVID-19 virus had spread and attacked many people worldwide.

The health crisis due to the COVID-19 pandemic has increased the urgency in addressing urgent global health access challenges fairly. However, the condition created when the COVID-19 pandemic hit the world was scarcity and lack of access to medical products.

Since the beginning of the pandemic, many large countries have continued to restrict exports. For example, the US had given an export ban to 3M companies (Minnesota Mining and Manufacturing Company) because they had to meet US domestic needs. The US had also secured supplies of Remdesivir drugs, namely drugs considered effective in COVID-19 treatment for the country only (IGJ, 2021). Other big countries are trying to create a COVID-19 vaccine, including China, Russia, Australia, Britain, and Germany. These countries' discovery of vaccines and drugs can be a step in an

excellent superpower trade war because vaccines and other medicines related to COVID-19 have economic value and legal aspects that protect them due to human intellectual work (Fatizah, 2022). Given the existence of such protection, it is considered that intellectual property rights have become the main obstacle factor related to the affordability of access to vaccines, drugs, and technology, especially for developing countries.

Given the large number of victims and suffering in all countries in the world caused by COVID-19, India and South Africa, on October 2, 2020, submitted the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Waiver proposal to the WTO's TRIPS Council. Submission of this proposal is not only in the interest of India and South Africa but also for developing countries or other poor countries in achieving equitable access to vaccines and other medical products.

The progress is still plodding and debatable from the initial submission of the TRIPS Waiver proposal in 2020 to 2022. The finding of (Fatizah, 2022) found that there are two different interests between developed and developing countries: one wants to protect its investors,

and the other protects its people. Furthermore, the study (Sariola, 2021) explains that Intellectual Property Rights need to be subverted to ensure global vaccine access. Previous findings revealed that IPR in the Trips Waiver Proposal process at the WTO is still under-fought. Therefore, this research examines further the TRIPS Waiver Proposal process, which is seen as a new norm in the international community or WTO to fight for IPR in the context of global health equity, using the norm life cycle concept by Martha Finnemore and Kathryn Sikkink. There is no research that makes and examines the TRIPS Waiver Proposal as a new norm based on implementing the norm life cycle concept. This research aims to find out whether the submission process of the TRIPS Waiver Proposal proposed by India and South Africa can be a success in fighting for equitable distribution of health facilities in the context of the COVID-19 pandemic until the end of 2022.

THEORETICAL FRAMEWORK

Intellectual Property Rights (IPRs)

With the development of the times, trade in various commodities can occur at the global level, making the existence of intellectual property no exception to this. IPR is a legal protection regime for intellectual property in the form of inventions in technology, science, arts, and literature, a distinguishing mark of a product of goods and services (Ferianto, 2021). The rights people give to creative works of their minds are known as intellectual property rights.

Usually, Intellectual Property Rights (IPR) will give the creator the exclusive right to use a work for a certain period (WTO, 2022). Intellectual Property Rights were indeed born and developed in western countries because these countries are dominated by developed countries which usually act as producing countries and as owners of Intellectual Property Rights (Ferianto, 2021).

The Norm Life Cycle

Martha Finnemore and Kathryn Sikkink have created a norm concept called the norm life cycle. This concept explains that norms will bring a shift to a change in a system or an order. Like the spark of an idea that then turns into a norm and develops into something widely accepted through a process that passes through three cycles of levels.

The stages of the norm life cycle are the first, norm emergence; the second, norm cascade; and the third, norm internalization (Finnemore & Sikkink, 1998).

1) The first stage; norm emergence.

In this stage, there are two elements synergize with each, namely the norm entrepreneur and organizational platforms.

(1) Norm Entrepreneur

A Norm entrepreneur is an actor who has a strong idea in trying to create a new norm with consideration of the logical consequences because of the condition of the old norms that are currently developing. Usually, the norm entrepreneur will bring a follow-up framework and new norms as a counter form of the old norm and based on an interest that is brought in to be introduced to a system (Richter, 2017). Norm entrepreneurs have an important role in carrying out issue framing related to forming an issue.

Persuasively, the norm entrepreneur aims to convince the wider community to accept the norms being promoted. The position of the norm entrepreneur is very vital in the formation of norm internalization in a system because the norm entrepreneur is an actor who builds new ideas that will be made into a norm and implemented in a system to become a solution to global problems.

(2) Organizational Platforms

An organizational platform is a container norm entrepreneurs use as a promotional system. As mentioned by (Finnemore & Sikkink, 1998), the salient features of modern organizations and an important source of influence for an international organization are regarding the use of expertise and information in changing the behavior of other actors in the organization. This is related to professionalism regarding empirical studies that can help or even prevent the emergence of new norms in international organizations. In most cases in this process, emergency norms can move to the next stage if these norms are successfully institutionalized in a set of rules in international organizations.

Norm entrepreneurs usually need support from state actors in supporting the norms they carry, and to achieve the next level, they must reach a tipping point. Persuasion carried out by Norm Entrepreneurs is said to be successful if the critical mass can adopt the norm. The critical mass is the power of countries adopting these norms. According to the argument (Finnemore & Sikkink, 1998), critical mass can be achieved if at least approximately 1/3 of the countries in the system are willing to start adopting the norms they carry. This tipping point is the boundary for the norm emergence and norm cascade phases.

2) The second stage: norm cascade.

This stage is marked after the tipping point, and there is an increase in countries that accept the norm, creating new dynamics. As has been adopted by (Finnemore & Sikkink, 1998), the existence of international or regional influence that spreads bring the influence of norms in the international world to occupy positions that are more important than domestic politics. At this stage, the mechanism in the form of active international socialization is expected to encourage norm breakers to form norm followers.

In addition, there are three motivations for the state to submit to norms: legitimacy, respect, and conformity. This legitimacy affects the role of wishing in the behavior of the state, for example, international organizations as labelers accept or reject, or when the state builds a domestic perception of its citizens, whether the country is better than other countries in making a decision. In contrast, the motivation of respect and conformity is in the form of an assessment in building relations between countries in a community. The conformity in a community can be interpreted as a state's social evidence in adopting norms, while respect concerns legitimacy and conformity, respect itself can show that a country's leaders adopt norms to want to be judged well by other countries and also, they want to assume that their country is doing an image the good one.

3) The third stage: internalization.

This cycle is marked by the norms that have been accepted and taken for granted. Thus, this condition is considered to no-longer debate the norms socialized by the international community. According to (Finnemore & Sikkink, 1998), norms that have been internalized then institutions appear that aim to perpetuate the truth of these norms.

METHOD

The method used to explain the problems in this research is descriptive qualitative. The descriptive method describes the dynamics and challenges of the TRIPS Waiver Proposal at the WTO. Meanwhile, the approach uses qualitative, which is used to focus observations on the phenomenon of the emergence of the TRIPS Waiver as a new form of international norms depth to produce a more comprehensive study of a phenomenon.

The data collection method in this research comes from secondary data, namely books, journal articles, special reports from official websites, official documents, and news. The selected data is searched for its relevance to the topic discussed by analyzing it before use.

The data analysis technique used by the author in analyzing the data obtained from this research is descriptive qualitative. Describing the problem based on the facts that exist and then connecting the facts. In contrast, the writing method that the author uses are the deductive method, where the author begins the discussion by describing the problem in general and then explicitly describing the consequences of the previously described problems.

RESULT AND DISCUSSION

TRIPS Agreement in the Context of COVID-19

The creation of the WTO TRIPS agreement in 1995 has provided minimum standard rules, which include trademarks, geographical indications, copyrights, and trade secrets (Titievskaja, 2021). The TRIPS agreement

also regulates the flexibility of deviations from the IPR protection requirements regulated therein, including in a health emergency. The WTO agreement has enabled WTO members to waive obligations in extraordinary circumstances by making consensus-based decisions (Titievskaja, 2021).

The existence of the COVID-19 pandemic that has hit the global world has prompted pharmaceutical companies to carry out Research and Development (R&D) to develop vaccine products and other health products as a response to tackling the spread of the coronavirus. Governments and non-profit organizations fund and coordinate the R&D. From the start of the pandemic, there has been a global concern, namely limited access to and unequal distribution of the COVID-19 vaccine in low and middle-income countries (LMICs). This is what has become an international debate in the context of the global health crisis during a pandemic because of the problem of the role of IPR in responding to trade policies in the conditions of the COVID-19 pandemic (Akhtar, 2022).

The Emergence of the TRIPS Waiver Proposal

India and South Africa, on 2 October 2020, made and submitted a proposal regarding wavering several parts contained in the TRIPS agreement to handle the prevention, containment, and treatment of COVID-19 (Titievskaja, 2021). In the TRIPS Waiver proposal submitted, a waiver has been proposed for members not to enforce patents (article 5) or regarding other Intellectual Property (IP) obligations on copyright (article 1), industrial design (article 4), and regarding the protection of confidential information related to COVID-19 products and technology (article 7) (Titievskaja, 2021). These regulations have provided for the determination of lengthy procedural requirements regarding export and import activities of pharmaceutical products and also have limited access to several countries in carrying out these activities to take action to control the spread of COVID-19 in their countries. It should be realized that most of the vaccines, medicines, and medical equipment used in handling COVID-19 are protected by Intellectual Property Rights. Of course, this requires permission from the right holder if a party wants to produce, sell, import, or export.

Based on data recorded by (IGJ, 2021) on 10 December 2020, the TRIPS Waiver proposal received much support from developing countries such as Eswatini, Kenya, Bolivia, Mongolia and Venezuela. Apart from that, the TRIPS Waiver proposal also received support from various parties, such as the Director General of WHO, Dr. Tedros Adhanom Ghebreyesus; UNITAID international organization; MSF; UN AIDS Agency; senators from Pakistan, the Philippines, Malaysia, and Colombia; more than 400 civil society organizations worldwide, 900 thousand people who provide personal support, and more. However, this support has yet to reach the $\frac{3}{4}$ majority of WTO members' support needed to approve the proposal.

It should be noted that rich countries represent as much as 13% of the world's population and have purchased nearly 51% of global vaccines. At the same time, the fact needs to realize that inequality exists between rich and poor countries that do not have as strong authority as rich countries in accessing medical products.

However, there were also the cons of rich countries such as Japan, Canada, Switzerland, Singapore, and Australia, which had rejected the TRIPS Waiver Proposal submitted and stated that they needed further evidence against insufficient TRIPS flexibility. The reason is that opposing countries believe the TRIPS agreement has provided enough flexibility to allow countries to carry out licenses in producing, exporting, or importing needed to handle the COVID-19 pandemic. Besides, countries such as the European Union, Japan, and the United States are staunch opponents of any consensus on the waiver of intellectual property rights (Zhu, 2021). They consider IPR very important and necessary in driving future innovation and collaboration. In addition to objections from developed countries, large pharmaceutical companies also gave their opinion, based on a New York Times article written by Thomas B. Cueni, director general of the International Federation of Pharmaceutical Manufacturers and Associations, writing that there was strong opposition to the statement about the importance of IPR in the medical field because pharmaceutical companies take risks in developing vaccines and drugs. After these medical discoveries succeed, the consequence is that these inventions have the right to be protected by IPR (Zhu, 2021).

Moreover, there is a condition that article 31 is considered inflexible, this is because its implementation must be determined case by case, this indicates that there will be many applications and licenses that must be submitted and taken care of by developing countries so that they can receive drugs related to the conditions of handling COVID-19.

In addition, proponents of the TRIPS waiver proposal stated that the existing flexibility of TRIPS was only used successfully once and that there were significant pressures directed at developing countries that would make it difficult for their license applications to be successful. From these conditions it is still not possible to effectively grant mandatory licensing for developing countries, this is because it is based on the TRIPS provisions which require countries to only use licenses for domestic supplies. Therefore, if a country is only allowed to carry out domestic supplies, it will result if neighboring countries need medical equipment and vaccines, and countries with excess supply are not allowed to import/export products that country needs. Proponents of the waiver proposal argue that this will hinder global collaboration and access to needed medical

supplies. Therefore, the state strongly supports the TRIPS Waiver Proposal, emphasizing good global affordability and accessibility for all countries.

The critical point is that TRIPS did not address safety issues and affordability of access to medicines and medical products in the face of a global pandemic. Thus, TRIPS's provisions and legal process are complicated to apply, especially for countries that cannot fund medical research and develop their own vaccines at home. So, it needs to be realized that the human right to access affordable medicines in a global health crisis due to the pandemic needs to be fought. However, injustice occurs when essential medicines are restricted to the profits of the big pharmaceutical companies. This is where the struggle of countries lacking medical products can be found, and non-governmental organizations are taking a significant role in increasing awareness of prioritizing humanity, meaning there are many supporters in promoting the TRIPS Waiver against capitalism.

On January 25, 2021, it was noted that the TRIPS Waiver proposal had been supported by more than 100 developing WTO member countries. Supporters of this proposal have the hope that this proposal can provide accessibility and affordability for medicines and essential equipment (Zhu, 2021). However, it should be remembered that decision-making in the WTO must be based on consensus, meaning that more votes are needed for proposals to be approved. As of January 2021, supporters are still trying to campaign to secure the $\frac{3}{4}$ majority of the votes needed at a TRIPS board meeting for the waiver proposed in the proposal to be approved and realized.

Support from the US and Submission of Revision Proposal

After being rejected for so long, finally, on May 5, 2021, the US Trade Representative (USTR) has announced the government's position that it has offered limited support to text-based negotiations at the WTO regarding a vaccine (Yu, 2022).

Then, after the announcement from USTR, India and South Africa, with the support of 63 co-sponsors, submitted a revised TRIPS Waiver proposal. Three points distinguish the revised proposal from the original proposal namely; first, it focuses on ignoring more specificity on the products and technologies covered, namely Health-to-Health products and technology, which also includes diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, materials, or components thereof, including methods and means of manufacture used in the prevention, treatment, or containment of COVID-19. Second, even though the original proposal stated an open time, the revised proposal proposes that the waiver is valid for a minimum

of 3 years. Alternatively, it will be reviewed again by the General Council regarding extraordinary circumstances. If such circumstances no longer exist, the General Council will determine the date of dismissal of the waiver. Third, the original TRIPS Waiver proposal (October 2020) and the revised proposal (May 2021) include four types of IPR based on the TRIPS Agreement: patents, copyrights, undisclosed information, and industrial designs (IGJ, 2021).

On May 22, 2021, India, South Africa, and co-sponsors submitted a revision of the waiver proposal based on deliberation. After four weeks of submitting the revised TRIPS Waiver proposal, the EU continues to be a challenger in making its proposal.

On June 4, the EU's proposal was submitted to the WTO General Council. The proposal was entitled Draft General Council Declaration on the TRIPS Agreement and Public Health in a Pandemic. The contents of this proposal are similar to the TRIPS Agreement, which is inadequate for developing countries. The proposal addresses the EU's response to the urgent trade policy response to the COVID-19 crisis. It calls for export restrictions, supports the expansion of vaccine production, and facilitates using the mandatory licensing provisions in the TRIPS Agreement. However, in its declaration, the EU does not allow producers from other countries to violate IPR to produce vaccines domestically (Ferris, 2021).

Proponents of the TRIPS Waiver proposal heavily criticized the EU proposal. The EU still maintains its position as a challenger, believing that the main barriers to vaccine production relate to access to raw materials and limited production capacity. The EU proposal submitted on June 4 attempts to weaken the TRIPS discussion. Switzerland pushed this EU proposal because of its position as a country opposing the TRIPS Waiver Proposal (IGJ, 2021).

Despite persistent disagreements and the US position that strikes a balance, WTO members agreed to start text-based negotiations on the TRIPS Waiver proposal in June 2021. The forum will also consider the EU proposal at the same time. However, what is unfortunate is that the negotiations at the TRIPS Council remain general, namely focusing on the waiver's need, suitability, and effectiveness. This is contrary to the parameters used in the textual waiver proposals, namely the most debated issues related to the products covered, IPR, and the abandonment duration (Yu, 2022).

Text-Based Discussion

In the text-based discussion in July 2021, the TRIPS Council is still involved. In this discussion, countries meet in smaller forums to discuss various texts in developing draft proposals that will be brought to the

WTO Council of Ministers. This is due to decision-making regarding whether a waiver will require a consensus from the Council of Ministers or if a vote is held, a $\frac{3}{4}$ majority is required as stipulated in Article IX of the WTO Agreement (Ferris, 2021).

After the TRIPS Council meeting, countries agreed to continue discussing both proposals (the Waiver Proposal and the EU's Proposal), but the positions remained different. Based on the statement by the TRIPS Council that the agreement of the temporary delegation remains committed to providing timely and safe access to vaccines and medicines. However, disagreements remain on the fundamental questions regarding the effective means of overcoming shortages and realizing equitable access to vaccines and medical products in other COVID treatments (Ferris, 2021).

In the following months, WTO members were busy trying to negotiate a way out of accommodation of their different positions. Even though developed and developing countries hoped to resolve the dispute before MC12, originally scheduled for November 2021, the TRIPS Council negotiations did not produce a breakthrough. Then, after experiencing a delay in the implementation of the 12th Ministerial Conference, which was supposed to be held on 30 November-3 December 2021 due to the emergence of an omicron virus variant, discussions continued at the WTO, and there is still uncertainty about whether the TRIPS Waiver proposal will be adopted or not.

Quad's Outcome Document

Since there was no solution yet at the TRIPS Council, in December 2021, the EU, US, India, and Africa launched a quadrilateral consultation with support from the WTO. The WTO Director General and Deputy Director General took a compromise initiative using the QUAD process. These discussions are confidential, consultations are carried out to reduce differences between the main supporters and opponents of abandonment (Yu, 2022).

The results of the informal consultations were announced by the Director General of the WTO in March 2022, Ngozi Okonjo-Iweala announced that the countries had reached a consensus on the outcome document. Overall, the Quad outcome proposals in this document are more aligned with the negotiating positions put forward by developing countries than the EU proposals or the provisions contained in TRIPS. However, this is still very far from the entire TRIPS waiver proposal.

The Quad proposal only focuses on patents, while the proposals submitted by India and South Africa focus on four types of IPR, namely patents, copyrights, industrial designs, and confidential information protection (Yu, 2022). In addition, the Quad proposal also provides

limitations that apply to the eligibility of developing country members who have exported COVID-19 vaccine doses of less than 10% in 2021, thus developing country members who have the capacity to export vaccines are encouraged to leave this decision, and countries other developing companies that do not export vaccines are still allowed within the objectives of the decisions made. The Quad results document was officially released by the WTO on 3 May. "Quad results", is a document resulting from informal discussions between four parties (EU, US, India, and South Africa). This text is a frame of reference to WTO decisions and not a waiver (Thambisetty, McMahon, McDonagh, Kang, & Dutfield, 2022)

Ministerial decision

Implementation of the 12th Ministerial Conference (MC12) is based on the adoption of the Ministerial Decision on the TRIPS Agreement which was developed from the results of the Quad proposal. In the forum, there is a decision stated in Paragraph 1 that explicitly permits WTO members who meet the requirements to authorize the use of patented products needed to carry out the production, manufacture, and also supply of the COVID-19 vaccine without the need for approval from the right holders as long as it remains in the context for tackling the COVID-19 pandemic. As cited in (Yu, 2022), there are seven specific changes to the Ministerial Decision compared to the Quad proposal:

- 1) The Ministerial Decision removes the rules that allow countries to opt-out, and the exception of developing countries that have exported at least 10% of vaccines by 2021. Instead, it is written in footnote 1 that all developing country members are eligible members. Developing countries with the ability to produce a COVID-19 vaccine are encouraged to make commitments not to take advantage of this decision. This commitment includes statements made by eligible members of the General Council, such as at the General Council meeting on 10 May 2022. It will then be recorded by the TRIPS Council and compiled and publicly published on the WTO website.
- 2) Replacement of the phrase "patented subject matter" in the Proposal Quad to become "subject matter of a patent". In the MC12 deliberation forum, there is still debate about whether coverage should focus on finished COVID-19 vaccine products and the mandatory requirements that must be maintained.
- 3) In MC12, there is the removal of the entire paragraph 3(a), which is considered very controversial and has requested countries the inclusion all patents involved in the authorization. This decision guarantees that there will be no use of provisions to prevent trade

diversion and other unnecessarily complicated procedures.

- 4) Added a new footnote to soften requirements with humanitarian and non-profit purposes, namely that WTO members who meet the requirements can still re-export the COVID-19 vaccine to eligible members. This softening applies as long as eligible members still have to communicate the re-export to the TRIPS Council (footnote 3)
- 5) The softening of the Quad Proposal in Ministerial Decisions modified to read: "Recognizing the importance of timely availability of and access to COVID-19 vaccines, it is understood that Article 39.3 of the Agreement does not prevent eligible Members from enabling rapid approval for the use of COVID-19 vaccines. Vaccines produced under this decision". In this case, article 39.3 has become the focus of developing countries since pharmaceutical companies increasingly claim protection in tests or other data to provide a substitute or additional protection.
- 6) The results of the Ministerial Decisions are more in favor of the position of developing countries concerning the duration of the waiver release, namely by setting it for five years. However, negotiators and commentators are still questioning whether the duration is still too short considering the time needed to develop vaccine production facilities or complete the necessary regulatory approval process.
- 7) There are additions to Paragraph 9, where this decision is without prejudice to the flexibility that Members have under the TRIPS Agreement, including the flexibility outlined in the Doha Declaration on the TRIPS Agreement and Public Health, and without prejudice, to their rights and obligations under the TRIPS Agreement unless otherwise provided in paragraph 3(b). For the sake of greater certainty, this decision without prejudice to the interpretation of the flexibility, rights, and obligations mentioned above is beyond the scope of this decision.

This addition implies flexibility over the pre-existing TRIPS Agreement.

Above are the results of the Ministerial Conference (MC-12), which has slightly improved the EU and Quad proposals. However, all the decision is still very far from the overall waiver proposals submitted by India and South Africa as so far, the decisions have only been to agree on a waiver for the vaccine and grant permission to take direct action to diversify the production of COVID-19 by clarifying the existing flexibility and also the waiver set for the next five years (WTO, 2022).

The decision to waive IP on vaccines, agreed upon in June 2022 at the WTO MC forum, led the WTO to conduct further reviews to focus on other treatments within six months until December 2022. Until December 2022, the discussion of neglecting the diagnosis and treatment of COVID-19 had stalled. As announced on the website (WTO, 2022), WTO members agreed to recommend to the General Council to extend the deadline for a decision on expanding the focus on diagnostics and therapeutics for COVID-19, which had previously been implemented, listed in paragraph 8. However, since the last MC12, although many meetings have been held, the members have not reached a consensus on the substance of the problem.

The USTR has announced its support for extending the deadline for decisions on diagnostics and therapeutics for COVID-19. The USTR even asked the US International Trade Commission (USITC) to carry out further investigations regarding the diagnosis and therapy of COVID-19 (Heilprin, 2022). Other developed countries such as the EU, Singapore, Japan, Switzerland, the United Kingdom, and South Korea are also still proposing an extension of the decision to collect evidence to show that intellectual property regulations have slowed down global access to treatment and tests (diagnostic and therapeutic) (Heilprin, 2022).

Case Implementation on The Concept of The Norm Life Cycle

Based on the theory of the norm life cycle by Martha Finnemore and Kathryn Sikkink, shifts in norms can affect system changes. If implemented in the TRIPS Waiver Proposal case in the COVID-19 pandemic, India and South Africa will become reporting actors for bringing new norms to the international community.

In the concept of the norm life cycle, there are three stages, namely norm emergence, norm cascade, and norm internalization (Finnemore & Sikkink, 1998).

1) Stage 1: the norm emergence

In this first stage consist of the synergy between norm entrepreneurs and organizational platforms.

(1) Norm Entrepreneur

A norm entrepreneur can be interpreted as an actor who triggers and seeks the emergence of new norms with consideration of the logical consequences in looking at old norms that are developing (Finnemore & Sikkink, 1998). The emergence of the norm entrepreneur is usually followed by making alternative proposals that lead to the development of a new norm which will then be introduced to the system after being adjusted so that it can

finally be accepted by the system where the norm is promoted.

If implemented in the TRIPS Waiver Proposal case, then India and South Africa will be the originators of the new norm by submitting the TRIPS Waiver Proposal to the WTO. Submission of this proposal is based on the logical consequences that are occurring during the ongoing COVID-19 pandemic, namely the occurrence of conditions of inequality between developing countries and developed countries or rich countries in accessing Health products and Health care that are protected by IPR required in responding to the spread of COVID-19.

Since the TRIPS Agreement emerged, it has brought a controversial debate about the role of IP and public health (Mercurio & Upreti, 2022). It should be realized that most of the vaccines, medicines, and medical equipment used in handling COVID-19 are protected by IPR, and of course, this requires permission from the right holder if other parties want to produce, sell, import, or export. This reason encouraged India and South Africa as norm entrepreneurs to propose a new form of the norm in the TRIPS Waiver Proposal on 2 October 2020, namely regarding the waiver of the application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement, which in that section discusses copyrights, industrial designs, trade secrets, and patents.

India and South Africa in fighting for support for the waiver proposal, have used diplomatic channels either bilaterally, regionally, or globally (Singh, et al., 2022). India and South Africa have also used the issue of public health as part of their foreign policy soft diplomacy at the individual level. India has done this by providing the COVID-19 vaccine to more than 100 countries through "Vaccine Maitri" diplomacy (Singh, et al., 2022). In addition, patent diplomacy has received support from many parties, such as developing countries, Nobel laureates, academics, more than 350 civil society organizations, activists, and international organizations such as the Joint United Nations Program on HIV/AIDS (UNAIDS), Unitaid, and MSF. UNCTAD also provided its support and even participated in urging the WTO to accept the waiver proposal. WHO is also very supportive of the proposal. India and South Africa also collaborated in leading communications and debates before the TRIPS Council.

To reach the next stage, the new norm brought by norm entrepreneurs must reach a tipping point. This critical mass refers to the power of countries willing to adopt the new norms. According to (Finnemore & Sikkink, 1998), critical mass can occur in at least 1/3 of the number of countries in the system that have started to adopt this norm. Tipping points are marked by the existence of

several societies or countries that can accept these norms.

Sponsors* and supporters			Opposing members	Undetermined members
Algeria*	Guinea-Bissau*	Saint Lucia	Austria	Albania
Angola*	Guyana	Saint Vincent and the Grenadines	Belgium	Armenia
Antigua and Barbuda	Haiti*	Samoa	Bulgaria	Bahrain
Argentina	Honduras	Senegal*	Croatia	Brazil
Australia	India*	Seychelles*	Cyprus	Brunei Darussalam
Bangladesh*	Indonesia*	Sierra Leone*	Czech Republic	Canada
Barbados	Jamaica	Solomon Islands*	Denmark	Chile
Belize	Jordan*	South Africa*	El Salvador	Costa Rica
Benin*	Kenya*	Sri Lanka*	Estonia	Ecuador
Bolivia*	Lao People's Democratic Republic*	Suriname	European Union	Georgia
Botswana*	Lesotho*	Tanzania*	Finland	Guatemala
Burkina Faso*	Liberia*	Thailand	France	Hong Kong (China)
Burundi*	Madagascar*	Togo*	Germany	Iceland
Cabo Verde*	Malawi*	Tonga	Greece	Israel
Cambodia*	Malaysia*	Trinidad and Tobago	Hungary	Kazakhstan
Cameroon*	Maldives*	Tunisia*	Ireland	Kuwait
Central African Republic*	Mali*	Turkey	Italy	Kyrgyzstan
Chad*	Mauritania*	Uganda*	Japan	Liechtenstein
China	Mauritius*	Ukraine	Latvia	Macao (China)
Colombia	Mongolia*	United States (vaccines only)	Lithuania	Mexico
Congo*	Morocco*	Vanuatu*	Luxembourg	Moldova
Côte d'Ivoire*	Mozambique*	Bolivarian Republic of Venezuela*	Malta	Montenegro
Cuba	Myanmar*	Viet Nam	Netherlands	North Macedonia
Democratic Republic of the Congo*	Namibia*	Yemen*	Poland	Norway
Djibouti*	Nepal*	Zambia*	Portugal	Oman
Dominica	New Zealand	Zimbabwe*	Romania	Panama
Dominican Republic	Nicaragua		Singapore	Paraguay
Egypt*	Niger*		Slovakia	Peru
Eswatini*	Nigeria*		Slovenia	Qatar
Fiji*	Pakistan*		Spain	Saudi Arabia
Gabon*	Papua New Guinea		Sweden	South Korea
Gambia*	Philippines		Switzerland	Tajikistan
Ghana*	Russia		Taipei (China)	United Arab Emirates
Grenada	Rwanda*		United Kingdom	
Guinea*	Saint Kitts and Nevis		Uruguay	

In the TRIPS Waiver Proposal, the majority of the full supporters of the proposal are developing countries. During the process until now, rich countries have still not fully supported the entire contents of the TRIPS Waiver Proposal.

Based on the data on WTO members who have provided their support and who have not yet provided their support as of June 2022. Approximately 59% of members support the TRIPS waiver from direct sponsors or countries that ratify the TRIPS Waiver Proposal. About 21% of WTO member countries are opponents of the proposal (with 28 of these 35 opposing member countries being from the European Union). The remaining 20% are unspecified member positions. These positions either do not comment publicly on the TRIPS waiver or provide comments withholding the definitive position concerning the waiver proposal (Kohler, Wong, & Tailor, 2022). From this data, support for the TRIPS Waiver is already great. It is just that the next challenge is regarding governance at the WTO, which requires an entire decision from all member countries. Because remembering that if there is resistance from a big or rich country, the impact will be more significant on the final decision because it cannot be denied that big countries also carry significant power in spreading influence.

Table 1. WTO Member Position Regarding the TRIPS Waiver Proposal

As cited in (Kohler, Wong, & Tailor, 2022), there are four main reasons given to members supporting the waiver of TRIPS, namely:

- 1) A waiver of TRIPS is required to remove barriers to the existence of IPs in accessing the existing voluntary and mandatory licensing systems
- 2) TRIPS Abandonment is an essential tool in promoting consistent solutions to the presence of COVID-19 with the implementation of human rights to health
- 3) The scope of the TRIPS Waiver must cover vaccines, therapies, and diagnostics. Because if neglect is limited to vaccines, it will not be enough to adequately and comprehensively address the impact of COVID-19
- 4) Abandonment of TRIPS as a legal trade policy instrument following existing WTO regulations. As stated by the WTO Secretariat, the Ministerial Conference is the forum in the WTO that can decide on waiving the obligations imposed on Members by the Marrakesh Agreement or any of the WTO agreements.

Meanwhile, there are four reasons for WTO member groups oppose the waiver of TRIPS, which have been mentioned (Kohler, Wong, & Tailor, 2022), namely:

- 1) The TRIPS Agreement is not a barrier to access, and agreeing to a TRIPS waiver would not be effective in helping increase global supply due to patents
- 2) Access to the required COVID-19 health technology can be done through a nominal modification using a mandatory licensing system
- 3) Neglecting TRIPS is considered to damage licensing partnerships which are essential in expanding health access
- 4) Ignoring TRIPS is considered to be detrimental to the growth of the IP-dependent Health technology sector

(2) Organizational Platforms

Organizational platforms are an organizational mechanism aimed at promoting these new norms. WTO is a member-driven, consensus-based organization. Thus, the decision of the proposal to be approved or not is based on the decision in the WTO forum which is very dependent on the overall decision of WTO members. To gather support for the TRIPS Waiver Proposal, there is the role of organizational platforms to voice or support and invite countries that have not yet accepted the proposal.

In the case of the TRIPS Waiver Proposal, there is a legal basis for non-supporting countries, that is the existence of international human rights agreements that have guaranteed the existence of basic rights and multilateral obligations to carry out international cooperation and stipulate obligations related to life-saving actions. This legal basis is contained in two instruments adopted by the UN General Assembly, namely the ICESCR which

accommodates human rights in the economic, social, and cultural fields, and the ICCPR which accommodates human rights in the civil and political fields (Seni, 2017). As contained in Article 12 of the ICESCR explains that there is a guarantee for the right of everyone to obtain the highest attainable standard of physical and mental health. More detail is explained in Article 12(2)(c) which states the creation of explicit obligations in preventing, treating, and controlling epidemic diseases; and Article 12(2)(d) which stipulates that parties to the ICESCR have an obligation to create conditions to ensure that everyone has access to adequate medical care and services.

The ICESCR also binds States Parties concerning Actions in that country, namely in Article 2(1) of the ICESCR which sets out broader obligations and also undertakes multilateral cooperation and international assistance to achieve the full realization of treaty rights. In the conditions of the COVID-19 pandemic, irrational human rights for health and life demand equal distribution of the COVID-19 vaccine and also an increase in the supply of medical products in handling the COVID-19 virus. Apart from that, Article 6 of the ICCPR also regulates rules relating to the right to life (Dugard, Sucker, Porter, & Burton, 2021).

All non-supporting TRIPS Waiver Proposal countries have ratified the ICESCR and ICCPR. Therefore, if viewed legally, these countries are bound by their obligations to uphold international human rights (Dugard, Sucker, Porter, & Burton, 2021). Thus, to defend the right to health and life, a Movement was formed, which includes the collaboration of various global, regional, and national human rights, social justice, and public health organizations. The organization is hosted by four international organizations, namely ESCR-Net, Global Movement Lawyers Network (GNML) at the Law Movement Lab (MLL), International Network of Civil Liberties Organizations (INCLO), and People's Vaccine Alliance (Dugard, Sucker, Porter, & Burton, 2021). The movement they bring wants to fight the fact that for countries party to the ICESCR and ICCPR that do not support the TRIPS Waiver Proposal for handling COVID-19, this action conflicts with their obligations to comply with IHRL enforcement. This movement is a form of advocacy work by international organizations to help increase support for COVID-19 relief in TRIPS.

Moreover, this movement has carried out several actions, such as making formal petitions before international/multilateral organizations, sending letters to governments and pharmaceutical companies, urging and requesting accountability actions to the WTO, and issuing expert legal opinions, 135 leading legal experts have signed. These actions have the primary goal of opposing countries to implement IHRL obligations in support of the TRIPS Waiver Proposal and carried out as a voice for

all countries in supporting the TRIPS Waiver proposal so that it can be approved as soon as possible as a whole (Dugard, Sucker, Porter, & Burton, 2021).

2) Stage 2: Norm cascade

This stage shows the success of the tipping point that occurred in the previous stage, specifically that there was an increase in countries receiving distributed norms. At this stage, state actors and support networks take the role. The network formed in the TRIPS Waiver Proposal case came from countries willing to become co-sponsors and other parties willing to support the proposal's success. Since the beginning of the submission of the TRIPS Waiver Proposal to the WTO, the tipping point stage has occurred rapidly in many international parties. 62 WTO Members have sponsored proposals for a temporary waiver of certain TRIPS obligations for preventing, containing, and treating COVID-19, and many other WTO Members support the proposal. This means that it has reached 1/3 of the total WTO members. However, the limited support provided by the rich member countries of the WTO is still an obstacle to accepting the new norm in full resolution in approving the TRIPS Waiver Proposal. An example of this is the position of the US, which was initially opposed to the TRIPS Waiver Proposal. In its development, the US has become a supporter of the TRIPS Waiver Proposal, but only limited to vaccine access. Even other rich countries, such as the EU, are still making it difficult to agree to the entire content of the waiver proposal.

Until the Ministerial Conference 12 on the WTO decision was made, which was agreed upon in June 2022, it turned out that the decision was only limited to the suspension of patents on vaccines, even though what was stated in the TRIPS Waiver Proposal covered the needs for handling, treatment, and prevention, which included vaccines, medicines, diagnostics, therapeutics, and medical equipment. Moreover, it has been almost two years since the proposal has been running, but the limited decisions issued that are relevant to the waiver proposal submitted are limited to vaccine access. Despite much support from most countries, civil society organizations, academics, international organizations, and Nobel laureates, rich countries still find it difficult to agree on the entire contents of the TRIPS Waiver Proposal, which includes patents, copyrights, undisclosed information, and industrial design.

The voting system in the WTO is achieved through consensus and must produce a unanimous vote (Sangal, 2021). Having majority support does not help much because all it takes is the unanimous vote of every WTO member to agree or abstain. Even a "no" from one member is enough to veto any proposal (Sangal, 2021).

3) Stage 3: Norm Internalization

This last stage is a process that shows that the state and its citizens have accepted the new norms brought by the originators. The function of this process is to perpetuate the brought norms. In this process, the country that has accepted the norm will ratify the agreement. If in the case of the TRIPS Waiver Proposal struggle at the WTO, the internalization of norms does not yet exist because it is still problematic and has not been fully accepted by WTO members because with proof that there are still developed countries that have not been able to accept all the contents of the submitted proposals. Even until December 2022, the decision on diagnostics and therapeutics is still being postponed.

However, several aspects have been decided on the vaccine. What has been decided is based on the decision of the WTO Minister adopted on June 17, 2022. The decision that has been agreed upon is to provide a waiver of certain requirements, including a compulsory license for the COVID-19 vaccine for five years (Akhtar, 2022). This decision grants permission to members who meet the requirements to use patent subjects covering the materials and processes needed to make the COVID-19 vaccine, which is done without the consent of the right holder through all kinds of instruments in the law of the members that allow such authorization (Akhtar, 2022). This decision is set on all WTO "developing country" members who are eligible to take advantage of the waiver but also encourages developing countries that can produce a COVID-19 vaccine, this relates to a commitment not to take advantage of their own country from the decision made (Akhtar, 2022).

Diagnostics and therapy need to be fought for access for all countries it becomes a vital tool for a comprehensive approach to fighting the ongoing COVID-19 pandemic. By agreeing to open diagnostic and therapeutic access, it will provide a holistic approach for developing countries in overcoming intellectual property barriers in terms of preventing the expansion and diversification of production and increasing accessibility of essential medical devices needed to save lives in the context of tackling COVID-19. With the successful expansion of intellectual property rights in diagnostics and therapy, WTO members have the opportunity to demonstrate that they can provide critical actions and responses in responding to the COVID-19 pandemic and the challenges of unequal access to therapies and diagnostics, as well as to improve critical responses to the decision about the vaccine came too late (Zuhn, 2022).

CONCLUSION AND RECOMENDATION

This research focuses on the dynamics and challenges of the TRIPS Waiver as a proposed new norm in fighting for global health equity in the context of the COVID-19 pandemic. The TRIPS Waiver Proposal proposed by India and South Africa has been running for over two years and is still problematic and debated in the WTO

forum until 2022. To see the dynamics and challenges in the progress of the TRIPS Waiver Proposal, this study uses the concept of the norm life cycle.

According to the norm life cycle concept, the TRIPS Waiver proposal has yet to be fully accepted by the international community, especially in the WTO system. This is evident because the WTO is still suspending the discussion of the entire contents of the TRIPS Waiver Proposal. Even though there is already much support for the TRIPS Waiver proposal, the other hand, big countries still find it difficult to support the contents of the proposal fully. Support from big countries has a significant impact on the final decisions because big countries also have great power in influencing the results of decisions. As a result, this proposal has yet to be fully accepted and implemented. Bearing in mind that the voting process at the WTO is a consensus, it is also an obstacle to the overall acceptance of the temporary suspension of Intellectual Property Rights for COVID-19 Health products and treatments proposed in the TRIPS Waiver Proposal.

In response to this case, there is a need for a more reliable international trade system as a means of encouraging equity in increasing access to public health products to save lives. When WTO members consider implementing the TRIPS waiver for an extended period, it will impact global spread with the emergence of new variants so that the limited waiver decision can be said to be ineffective for the proposal's success in fighting for human rights in global health equity.

With more critical international coordination, transparency, and better consideration in fighting for all citizens' health and human rights, health justice for the safety of everyone's life can be realized. Many small countries still need to prepare for future pandemics and global emergencies. Therefore, the government must continue to strive for fair solutions as a solution to significant progress in increasing global health access to essential health products. Without firm action and advanced thinking regarding the occurrence of a global health crisis, this will also impact current and future management and will continue to shape the pattern of global health disparities for every citizen in the world (Kohler, Wong, & Tailor, 2022).

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