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# The Dilemma in COVID-19 Pandemic: The Protection of Intellectual Property Rights or A Life?

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Keywords:	Abstract
Bankruptcy;	Access to medicines and health facilities is a form of fulfillment of the right to health
Insolvency Test;	which, if not fulfilled, will result in the loss of the right to life. During the time of
Principle of	COVID-19 that hit the whole world, data released by WHO stated that 4,592,934 people
Balance.	had died from COVID-19, and the number was growing globally every day. However,
	only 5,352,927,296 doses of vaccines have been administered worldwide, with most going
	to developed countries. Experts predict the global population will be fully vaccinated by
	at least September 2023. WHO research shows that through vaccination, the rate of
	transmission of the disease can be reduced, and even if the subject is infected, vaccination
	can still reduce mortality and severity. However, its manufacture and distribution
	are protected by several intellectual property rights (IPR) legal instruments, which
	have resulted in several Global South countries, especially Indonesia being late in the
	vaccination process. This article aims to criticize how vaccine distribution is hampered
	due to regulations related to IPR, namely patents and trade secret. The author uses
	normative juridical research methods to answer the problems in this study by focusing on
	literature research and secondary data related to vaccination and the right to health which
	have implications for the right to human life. Comparison with other countries, especially
	South Africa fighting HIV/AIDS for years using the flexibilities of TRIPs, is also the
	subject of this research. This research describes how the Global North countries have a
	significant role in distributing the COVID-19 vaccine to the Global South. The delay in
	allotment due to regulations related to Intellectual Property Rights causes violations of
	several fundamental rights.

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## Introduction

Incorporating developments in the pharmaceutical sector, especially vaccines and drugs to be protected by Intellectual Property Law, provides two different views in the realm of human rights. On the one hand, the guaranteed patent and the other intellectual property rights embedded with it show how the state protects its innovator. However, what is often forgotten is that such protection makes a more significant group suffer since they cannot access it. The inaccessibility of consuming certain medicines and vaccines creates some fundamental rights of a person being abused. First is the right to health, which, if not handled thoughtfully, will result in the second non-derogable rights being violated, which is the right to life.

Presently, there is an urgent need to revise and amend existing laws that allow better access to medicine. As the COVID-19 pandemic ravages on, vaccines that can help combat the disease are now more in demand than ever. However, the creation and distribution of the object are protected by several legal instruments that govern the process of its use and trade. This paper shall focus on the intellectual property rights that – while paved with good intentions – are presently a hindrance to effective vaccine distributions in order to combat the virus successfully.

One of the intellectual property rights attached to the manufacturing and distribution of vaccines is patent, an exclusive right given to the vaccine developers and their pharmaceutical sponsors for the discovery, innovation, and development of the vaccine.<sup>1</sup> The law ascribes that potential distributors require permission from the innovator or inventor to make, use, sell, rent, or import objects concerning their findings. Should the parties with patent rights refuse to provide their authorization, then the trade will not proceed, and any trade of the object happening without explicit consent from the patent holders shall be deemed illegal and may be penalized by the law.<sup>2</sup>

Granting patent rights is the highest form of appreciation that can be given to an inventor or innovator, as it acknowledges and puts value on their hardships in creating their invention. However, in the context of COVID-19 vaccines and its growing demand to successfully combat the pandemic worldwide, patent rights might hinder the fulfilment of collective human rights, precisely the right to life and the right to access healthcare. To add, there is a concern that countries and/or affiliates who are unable to obtain permission from the vaccine's patent holder will not be able to provide their demographic with vaccines and therefore are forced to prolong the unprotected exposure of their citizens to the deadly COVID-19 virus.

<sup>&</sup>lt;sup>1</sup> Article 27 Agreement on Trade-Related Aspects of Intellectual Property Rights as Amended by the 2005 Protocol Amending the TRIPS Agreement.

<sup>&</sup>lt;sup>2</sup> Article 28 Agreement on Trade-Related Aspects of Intellectual Property Rights as Amended by the 2005 Protocol Amending the TRIPS Agreement.

To examine further the problems in this paper, a normative juridical approach will be used by the author on researching primary data, such as international treaties and national laws, and combine it with empirical method by compelling the secondary data related to the victim of human rights abuse of health from the respective international organisation annual report.

# **Intellectual Property Rights and TRIPS Agreement**

After the second world war, the United States changed the orientation of several businesses in the pharmaceutical field to a Research and Development (R&D) culture. This later became one of the reasons why patent and brand protection were attached to these products.<sup>3</sup> This R&D then became a growing trend in the United States and received much sponsorship in both the public and private sectors. So it is not surprising that many substances or chemical compounds supporting drugs are found in the United States.<sup>4</sup> Then other developed countries such as France, the UK, Japan, and Germany<sup>5</sup> also began to follow the trend of R&D in their pharmaceutical companies. Several giant pharmaceutical companies emerged, which are commonly referred to as "Big Pharma". Some of them are Pfizer, Merck, Johnson&Johnson, AstraZeneca, and Bristol-Myers Squibb<sup>6</sup> which are also the leading factories or companies for the production of COVID-19 Meanwhile, the Global South countries, which are low-income countries and still under development, do not provide adequate patent protection for pharmaceuticals.<sup>7</sup> This fact later became the trigger for the negotiation of The General Agreements on Tariffs and Trade (GATT) by the delegates of the US, European Union, and

<sup>&</sup>lt;sup>3</sup> Gary Gereffi, *The Pharmaceutical Industry and Dependency in the Third World* (Princeton University Press 1983).[169].

<sup>&</sup>lt;sup>4</sup> T. Walley, 'Monitoring Financial Flows for Health Research Geneva: Global Forum for Health Research' (2002) 96 Transactions of The Royal Society of Tropical Medicine and Hygiene.[57].

<sup>&</sup>lt;sup>5</sup> World Health Organization, 'The World Medicines Situation 2nd Ed' (2004) WHO/EDM/ PAR/2004.5.[5].

<sup>&</sup>lt;sup>6</sup> ibid.[16].

<sup>&</sup>lt;sup>7</sup> Mohamed Omar Gad, 'TRIPS Dispute Settlement and Developing Country Interests' (2008). [344–345].

Japan.<sup>8</sup> In 2014, at The Uruguay round of GATT, remarked the enactment of Trade-Related Aspects of Intellectual Property Rights (TRIPs).<sup>9</sup>

The WTO, which is an international organization that accommodates trade between nations, adds protection for Intellectual Property Rights at the international level. TRIPs provide a high standard for patent protection in the pharmaceutical industry, including process and product patents, a 20-year protection period, and the use of limited required licensing based on particular standards.<sup>10</sup> Many controversies arose over this agreement because, according to Global South countries, this would only foster a monopoly over the Global North countries in the economic and technological fields. Nevertheless, in the end, these low-income countries agreed to comply with the international standards set under this international agreement.<sup>11</sup>

These concerns are then accommodated in Article 8 of TRIPs, namely:

"Members may, in formulating or amending their laws and regulations, 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, provided that such measures are consistent with the provisions of this Agreement".<sup>12</sup>

The WTO Member States are required to "take measures necessary to preserve public health" under this article. As a result, how this flexibility is implemented, including the interpretation of this mandate, differs between each WTO Member States, particularly between developing and industrialized countries.<sup>13</sup> Some of them have been applied to handling the pandemic in Africa, which will be discussed further in this paper.

<sup>&</sup>lt;sup>8</sup> Kirsten Peterson, 'Recent Intellectual Property Trends in Developing Countries' (1992) 33 Harvard International Law Journal.[1].

<sup>&</sup>lt;sup>9</sup> Naomi A. Bass, 'Implications of the Trips Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century' (2002) 34 The George Washington International Law Review.[3].

<sup>&</sup>lt;sup>10</sup> Nadia Natasha Seeretan, 'The Negative Impact of Intellectual Property Patent Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industry' (2017) 3 St. Mary's Law Review on Race and Social Justice.[13].

<sup>&</sup>lt;sup>11</sup> H.S. Kartadjoemana, GATT WTO Dan Hasil Uruguay Round (UI Press 2007).[253].

<sup>&</sup>lt;sup>12</sup> Look Article 8 Agreement on Trade-Related Aspects of Intellectual Property Rights as Amended by the 2005 Protocol Amending the TRIPS Agreement.

<sup>&</sup>lt;sup>13</sup> Carlos Correa, Integrating Public Health Concerns into Patent Legislation in Developing Countries (South Centre 2000).[3].

# Covid situation globally and at the national level

To date, the WHO states that 5,020,204 people<sup>14</sup> have died from COVID-19 and the number continues to grow globally by tens of thousands each day. However, only 7,027,377,238 doses<sup>15</sup> have been administrated worldwide out equals with 51% world population<sup>16</sup>, with most of it going to developed countries. Experts estimate that the global population will be fully vaccinated by at least September 2023.<sup>17</sup> In Indonesia, by the end of October 2021 there were t have died because of COVID-19.<sup>18</sup> As one of the most populated nations in the world, currently there were only 73.798.983 people<sup>19</sup> is fully vaccinated out of 270,20 million,<sup>20</sup> it means that approximately 70% of the them are being in risk.

It will be an enormous sacrifice until it reaches that year, considering that COVID-19 has taken millions of lives in the short course of its existence. Until now, no specific medicine has been found to cure this infectious disease. However, WHO research shows that through vaccination, the transmission rate of this disease can lessen, and even if subjects do get infected, vaccination can still reduce mortality and severity.<sup>21</sup> Despite these benefits, vaccine distributions remain slow, especially within a developing country, and one contributing factor to this lagging is patent and intellectual property laws.

<sup>&</sup>lt;sup>14</sup> World Health Organization, 'WHO Coronavirus (COVID-19) Dashboard' (*World Health Organization*, 2020) <a href="https://covid19.who.int/">https://covid19.who.int/</a> accessed 28 May 2021.

<sup>&</sup>lt;sup>15</sup> *ibid*.

<sup>&</sup>lt;sup>16</sup> Josh Holder, 'Tracking Coronavirus Vaccinations Around the World' (*The New York Times*, 2022)<https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> accessed 5 November 2021.

<sup>&</sup>lt;sup>17</sup> Anthony McDonnell and et.al, 'COVID-19 Vaccine Predictions: Using Mathematical Modelling and Expert Opinions to Estimate Timelines and Probabilities of Success of COVID-19 Vaccines' (2020) 183 CGD Policy Paper.[5]. <a href="https://www.hrw.org/news/2021/05/06/covax-enhance-transparency-share-intellectual-property">https://www.hrw.org/news/2021/05/06/covax-enhance-transparency-share-intellectual-property>.</a>

<sup>&</sup>lt;sup>18</sup> Satuan Tugas Penanganan COVID-19, 'Beranda' (*Covid-19.go.id*, 2020). <sup>19</sup> *ibid*.

<sup>&</sup>lt;sup>20</sup> Badan Pusat Statistik, 'Hasil Sensus Penduduk 2020' (*Badan Pusat Statistik*, 2021) <a href="https://www.bps.go.id/pressrelease/2021/01/21/1854/hasil-sensus-penduduk-2020.html">https://www.bps.go.id/pressrelease/2021/01/21/1854/hasil-sensus-penduduk-2020.html</a> accessed 31 October 2021.

<sup>&</sup>lt;sup>21</sup> Immunization; Vaccines; and Biological Team of World Health Organization, 'Evaluation of COVID-19 Vaccine Effectiveness' (2021) WHO/2019-nCoV/vaccine\_effectiveness/measure-ment/2021.1.

Data shows that COVID-19 transmission in Global South countries is prolonged, corresponding to the fact that the Global South contributes many casualties throughout the pandemic. For the low-income, developing countries, requests for patent waiver of vaccines and other health products related to COVID 19 are the only way to have easy and low-cost access to vaccines.<sup>22</sup> However, the Global North countries rejected the proposal made by the communication from India and South Africa to waive several provisions of the TRIPS Agreement for the prevention, containment and the treatment of COVID-19.<sup>23</sup>They were arguing that patent suspension and the other TRIPS waiver would only hinder researches and innovations in handling COVID-19. Global South countries and the WHO argued that the patent waiver<sup>24</sup> could be conducted at a time of crisis like this until WHO confirms the pandemic has ended.

# Relevancy between business and human rights in COVID-19 pandemic situation

Human rights are interdependent with one another.<sup>25</sup> Once one rights are unable to be fulfilled, it will give a domino effect towards the other.<sup>26</sup> This could be seen from the number of deaths due to contracting COVID-19. The probability of mortality rate can be reduced by distributing the vaccine quickly and evenly first. This unfulfilled access to health results in a person's right to life is violated, leading to death.

In every part of the world, the right to health is protected under Article 25 of the Universal Declaration of Human Rights asserts that,

"Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing, and medical care and necessary social services".

<sup>&</sup>lt;sup>22</sup> World Health Organization, 'Waive Covid Vaccine Patents to Put World on War Footing' (*World Health Organization*, 2021) <a href="https://www.who.int/news-room/commentaries/detail/waive-covid-vaccine-patents-to-put-world-on-war-footing">https://www.who.int/news-room/commentaries/detail/waive-covid-vaccine-patents-to-put-world-on-war-footing</a>> accessed 6 June 2021.

<sup>&</sup>lt;sup>23</sup> IP/C/W/669

<sup>&</sup>lt;sup>24</sup> Human Rights Watch, 'COVAX: Enhance Transparency, Share Intellectual Property' (*Human Rights Watch*, 2021).

<sup>&</sup>lt;sup>25</sup> Christian Tomuschat, *Human Rights : Between Idealism and Realism* (Oxford University Press 2008).[32].

<sup>&</sup>lt;sup>26</sup> OHCHR, 'What Are Human Rights?' (*United Nations Human Rights*) <https://www.ohchr. org/en/issues/pages/whatarehumanrights.aspx> accessed 17 December 2020.

Subsequently, this right was granted by the International Covenant on Economic, Social, and Cultural Rights. Under Article 12, the right to access standards of physical and mental are comprehensively explained. Moreover, other international human rights instruments assured the fulfillment of these rights. Such as the International Convention on the Elimination of All Forms of Discrimination 1965, the International Convention on the Elimination of All Forms of Discrimination against Women 1979, and the Convention on the Rights of the Child 1989.

In CESCR General Comment No. 14, it is explained that the state's responsibility for fulfilling the right to health must fulfill the element of accessibility.<sup>27</sup> In this element, it is stated that the state must fulfill its obligations on four dimensions, specifically:

- 1. Non-discrimination<sup>28</sup>: This is one of the implementations of fulfilling human rights as regulated in all human rights conventions. Namely, everyone has the right to access health regardless of their background, such as sexual orientation, race, religion, political, social or another status, national and opinion.
- 2. Physical accessibility: Health access and services must be accessible to everyone wherever they live. For instance, an indigenous group who lives far from the city can also access hospital services without going far to the city. Health access provided must also be friendly to people with disabilities. For example, there are toilets or lifts that people with disabilities can use.
- 3. Economic accessibility: This is the core of the discussion in this paper, how GC 14 explicitly and in detail requires that access and health services, including medicines and vaccines, be affordable for all humankind.<sup>29</sup> The original intent in article 12 also includes how wealthier households should be burdened with the health expenses of the poorer households. Of course, this is in stark contrast to the administration of vaccines and other medical devices related to COVID-19 in Global North countries compared to Global South countries.
- 4. Information accessibility: This is another crucial dimension, especially in a pandemic. The public has the right to know and obtain, seek and obtain health information. This is also related to the confidentiality of information for each patient receiving Health treatment.<sup>30</sup>

<sup>&</sup>lt;sup>27</sup> Para. 12 E/C.12/2000/4.

<sup>&</sup>lt;sup>28</sup> Common article 2 Bill of Rights.

<sup>&</sup>lt;sup>29</sup> Para. 12 E/C.12/2000/4.

<sup>&</sup>lt;sup>30</sup> Para. 12 E/C.12/2000/4.

The failure of accessing the right to health as mentioned above is death or a violation of the right to life. Based on UN Guiding Principles on Business and Human Rights, it is indeed a global standard for every entity to be responsible for respecting and protecting human rights.<sup>31</sup> It means that whether it's a State actor or non-State actor, which is in this paper related to the "Big Pharma" company, is responsible for not interfering with the enjoyment of human rights. Should the rights be interfered with by the non-State actor, then the State is obliged to stop such interference and ensure that the fulfilment of such rights is not jeopardized. The obligation to protect means that the States should take steps to ensure that human rights are not violated by any parties.

On this matter, "Big Pharma" as the developers of COVID-19 vaccines should approve and cooperate with the solidarity call made by the WHO.<sup>32</sup> The purpose of this campaign is to persuade the vaccine's developers to expedite the open sharing of knowledge<sup>33</sup> on the intellectual property for conquering COVID-19 through medicines, specifically the vaccine. More importantly, the States need to take immediate action to prevent and combat COVID-19 by establishing a legal framework as a ground for providing effective and affordable medicines and vaccines.<sup>34</sup> As stated earlier, there are some measures that can be taken and are still in line with the TRIPs Agreement. To add, this has been practised before when the endemic hit Africa.

## The practices of TRIPs flexibility in the South Africa

Flexibility over patent protection within the scope of TRIPS is not unprecedented. An example exists in the HIV / AIDS epidemic that hit the African region from 1990 until 2005, which shook the country's social stability and

<sup>&</sup>lt;sup>31</sup> Andreas Rasche and Sandra Waddock, 'The UN Guiding Principles on Business and Human Rights: Implications for Corporate Social Responsibility Research' (2021) 6 Business and Human Rights Journal 227.[31].

<sup>&</sup>lt;sup>32</sup> 'Solidarity Call to Action,' accessed October 31, 2021, https://www.who.int/initiatives/ covid-19-technology-access-pool/solidarity-call-to-action.

<sup>&</sup>lt;sup>33</sup> A/RES/74/274.

<sup>&</sup>lt;sup>34</sup> *ibid*.

economy – even the continent – affected. In South Africa, more than 200.000 people<sup>35</sup> with HIV / AIDS experience difficulties accessing antiretroviral drugs because the price is costly, around US\$ 12,000 for one year.<sup>36</sup> Meanwhile, the average national income of the South African population did not even reach US\$ 3,000.<sup>37</sup> For this humanitarian crisis, the Government passed The Medicines and Related Substance Control Amendment Act, No. 90 of 1997, which serves as the basis for granting parallel importing and compulsory licensing for pharmaceutical products.<sup>38</sup> The regulation of parallel importing in this law is intended to permit the importation of drugs from the cheapest international sources regardless of whether the pharmaceutical industry that holds the patent in question approves that source to import or not. Meanwhile, compulsory licensing is intended to provide opportunities for local companies to produce their drugs whose patents are held by foreign companies at lower prices through the manufacture of generic drugs.<sup>39</sup>

The adverse reactions that then arose were demands from 42 pharmaceutical industries against the Government for issuing policies that violated Article 27 of the TRIPS regarding Patents.<sup>40</sup> Nevertheless, Government argued that this is in line with TRIPS because of the urgency of the situation at hand, namely the increasing number of people living with HIV / AIDS in the country, which is recorded as the highest number in the world.<sup>41</sup> Data showed that more than 3 million people of South Africa would die because of this disease.<sup>42</sup> In 1998, the US Government

<sup>&</sup>lt;sup>35</sup> Tshimanga Kongolo, 'Public Interest versus the Pharmaceutical Industry's Monopoly in South Africa' (2001) 4 Journal of World Intellectual Property.

<sup>&</sup>lt;sup>36</sup> Anna Lanoszka, 'The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries' (2003) 24 International Political Science Review.[181].

<sup>&</sup>lt;sup>37</sup> ibid.[190].

<sup>&</sup>lt;sup>38</sup> Medicines and Related Substances Control Amendment Act 1997.

<sup>&</sup>lt;sup>39</sup> James J. Wheaton, 'Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984' (1986) 35 Catholic University Law Review. [437].

<sup>&</sup>lt;sup>40</sup> The High Court of South Africa, *Pharmaceutical company lawsuit (forty-two applicants) against the Government of South Africa (ten respondents),* 1998.

<sup>&</sup>lt;sup>41</sup> Sara M. Allinder and Janet Fleischman, 'The World's Largest HIV Epidemic in Crisis: HIV in South Africa' (*Center for Strategic & International Studies (CSIS)*, 2019) <a href="https://www.csis.org/analysis/worlds-largest-hiv-epidemic-crisis-hiv-south-africa">https://www.csis.org/analysis/worlds-largest-hiv-epidemic-crisis-hiv-south-africa</a> accessed 28 June 2021.

<sup>&</sup>lt;sup>42</sup> Naomi A. Bass (n 9).

criticized this policy and froze South African concessions until an increase in IP Law protection can be ensured. However, in 2000, from Executive Order 13155, "*Access to HIV/AIDS Pharmaceuticals and Medical Technologies,*" the US government retracted a 1998 statement,<sup>43</sup> reasoning that TRIPS is here to enable member states to guarantee access to medicines that can protect their people's health.<sup>44</sup> This strong statement initially provided a bright spot that medical companies must also respect human rights, namely the right to health.

This opinion was then strengthened through The Doha Declaration, related to interpreting the provisions of Article 31 TRIPs. Based on this declaration, Article 31 of TRIPs can and must be interpreted and implemented in a manner that supports the rights of WTO member countries to protect public health, and in particular, to seek all access to medicines.<sup>45</sup> TRIPs must be interpreted in this sense. Therefore, each member country has the right to determine what is meant by the urgent need for the national interest. There are 7 points of this Declaration clearly stated that:

- 1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics.<sup>46</sup>
- We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) to be part of the wider national and international action to address these problems.<sup>47</sup>
- 3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on price.<sup>48</sup>
- 4. We agree that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health.<sup>49</sup>
- 5. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner

<sup>&</sup>lt;sup>43</sup> William J. Clinton, 'Executive Order 13155–Access to HIV/AIDS Pharmaceuticals and MedicalTechnologies' (*The American Presidency Project*, 2000) <a href="https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/a-new-strain-of-coronavirus-what-you-should-know">https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/a-new-strain-of-coronavirus-what-you-should-know</a> accessed 28 May 2021.

<sup>&</sup>lt;sup>44</sup> Naomi A. Bass (n 9).

<sup>&</sup>lt;sup>45</sup> Carlos Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health' (2002) WHO/EDM/PAR/2002.[3].

<sup>&</sup>lt;sup>46</sup> Number 1 Declaration on the TRIPs Agreement and Public Health 2001.

<sup>&</sup>lt;sup>47</sup> Number 2 Declaration on the TRIPs Agreement and Public Health 2001.

<sup>&</sup>lt;sup>48</sup> Number 3 Declaration on the TRIPs Agreement and Public Health 2001.

<sup>&</sup>lt;sup>49</sup> Number 4 Declaration on the TRIPs Agreement and Public Health 2001.

supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPs Agreement, we recognize that these flexibilities include:

- a. In applying the customary rules of interpretation of public international law, each provision of the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- b. Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
- c. Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- *d.* The effect of the provisions in the TRIPs Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.<sup>50</sup>
- 6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council for TRIPs to find and expeditious solution to this problem and to report to the General Council before the end of 2002.<sup>51</sup>
- 7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least development country Members pursuant to Article 66.2. We also agree that the least developed country Member will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPs Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPs Agreement. We instruct the Council for TRIPs to take the necessary action to give effect to this pursuant to Article 66.1. of the TRIPs Agreement.<sup>52</sup>

Through this Declaration, it is only proper that when a viral outbreak has hit the entire country the TRIPs flexibility policy on patents can and should be pursued. Number 4 within this Declaration also clearly states that there are valid

<sup>&</sup>lt;sup>50</sup> Number 5 Declaration on the TRIPs Agreement and Public Health 2001.

<sup>&</sup>lt;sup>51</sup> Number 6 Declaration on the TRIPs Agreement and Public Health 2001.

<sup>&</sup>lt;sup>52</sup> Number 7 Declaration on the TRIPs Agreement and Public Health 2001.

reasons for using the flexibility of TRIPs,<sup>53</sup> such as compulsory licenses and parallel imports. To add, Article 8 TRIPs states that member states can establish or change their laws and regulations to determine the protection measures needed for public health.<sup>54</sup>However, the treatment and the way of pandemic handling quite differs with the endemic circumstances. Those flexibilities, especially the compulsory licensing can only be given country-by-country and product-by-product and will primarily be used to fulfil the demands of its own nationals. Hence, the needs of TRIPs waiver at these times is the most reasonable manner to carry with.

### **TRIPs waiver in COVID-19 situation**

In April 2020, the United Nations (UN) Committee on Economic, Social and Cultural Rights stated on the coronavirus disease (COVID-19) pandemic and economic, social and cultural rights:

"The COVID-19 pandemic is a global crisis, which highlights the crucial importance of international assistance and cooperation, a core principle enshrined in the Covenant. Such international assistance and cooperation include the sharing of research, medical equipment and supplies, and best practices in combating the virus; coordinated action to reduce the economic and social impacts of the crisis; and joint endeavours by all States to ensure an effective, equitable economic recovery. The needs of vulnerable and disadvantaged groups as well as fragile countries, including least developed countries, countries in conflict and post-conflict situations, should be at the centre of such international endeavours".<sup>55</sup>

It can be concluded that IP is a product that can be used as broadly as possible for the benefit of humans in this world so it has become an obligation for each country, especially here in the country where "Big Pharma" is located, to overcome the problem of disparity in the distribution of vaccines and other health equipment related to the handling of COVID-19 due to the high cost that is set. The inconsistency can be seen from the statement of European Union representatives

<sup>&</sup>lt;sup>53</sup> 'In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose.' Look Number 4 Declaration on the TRIPs Agreement and Public Health 2001.

<sup>&</sup>lt;sup>54</sup> Article 8 Agreement on Trade-Related Aspects of Intellectual Property Rights as Amended by the 2005 Protocol Amending the TRIPS Agreement.

<sup>&</sup>lt;sup>55</sup> Economic and Social Council, 'Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights' (2020).

that the vaccination program is a universal common good. Nevertheless, they also consistently reject the TRIPs waiver proposals India and South Africa submitted at WTO meetings.<sup>56</sup> Even though the offer requested by India and Africa will facilitate the distribution of the COVID-19 vaccine to countries in the Global South, particularly Indonesia. This waiver proposal aligns with the reasoning of the US Government in 1998 formulated TRIPS mentioned in the previous section.

One of the reasons often given by "Big Pharma" countries is that IP is not an obstacle to accelerating the procurement of COVID-19 vaccines and appropriate health equipment. Because even though the IP can be used freely, it is not possible to accelerate the procurement. This was later broken by statements submitted by several factories in Bangladesh and India that their inability to produce vaccines was due to the absence of licenses.<sup>57</sup> Thus, the IP is indeed the barrier to producing effective and efficient COVID-19 medicines and vaccines.

Number 8 of the TRIPs waiver proposal stated that:

"To meet the growing supply-demand gap, several countries have initiated domestic production of medical products and/or are modifying existing medical products for the treatment of COVID-19 patients. The rapid scaling up of manufacturing globally is an obvious crucial solution to address the timely availability and affordability of medical products to all countries in need".<sup>58</sup>

By waiving certain IP rights under TRIPs agreement, it would make technology transfers easier, allowing producers all around the world to produce Covid-19 medical items, including vaccinations, swiftly and affordably.<sup>59</sup> For example, with extensive human resources, Indonesia can work together to produce vaccines and medical devices if it has received training or transfer of knowledge

<sup>&</sup>lt;sup>56</sup> Steve Cockburn, 'WTO: A Missed Opportunity to Put People before Patents' (*Amnesty*, 2020) <a href="https://www.amnesty.org/en/latest/news/2020/10/wto-states-waiver-trade-rules-for-covid19-vaccine/">https://www.amnesty.org/en/latest/news/2020/10/wto-states-waiver-trade-rules-for-covid19-vaccine/</a> accessed 30 June 2021.

<sup>&</sup>lt;sup>57</sup> Human Rights Watch, 'Seven Reasons the EU Is Wrong to Oppose the TRIPS Waiver' (2021) <https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver> accessed 3 June 2021.

<sup>&</sup>lt;sup>58</sup> World Trade Organization, 'Waiver From Certain Provisions of The TRIPS Agreement For The Prevention, Containment and Treatment of COVID-19' (2021).

<sup>&</sup>lt;sup>59</sup> Human Rights Watch, 'Urgently Waive Intellectual Property Rules for Vaccine' (*Human Rights Watch*, 2020) <a href="https://www.hrw.org/news/2020/12/10/urgently-waive-intellectual-property-rules-vaccine">https://www.hrw.org/news/2020/12/10/urgently-waive-intellectual-property-rules-vaccine</a> accessed 28 May 2021.

from "Big Pharma". Low-cost production equipment and the chemical recipe secret itself will help support the production process so that the program will not reduce the transmission rate to the death rate due to COVID-19.

The fear that Global North countries often raise is that waiving the IP rights, specifically the patent ones, would end the innovation to broaden medicines and vaccines in the future. This completely misleading statement for the public because the waiver will not last forever. This waiver is needed and used only for a certain period, at least three years, at least until the transmission rate and mortality rate are below 10% and herd immunity has been created. If the protection of patents continues to be used as a shield by Global North countries, it will only worsen because it has blocked the way to combat COVID-19 on the other side of the world. With the mortality rate of the COVID-19 virus, its high infection rate, and its ability to mutate<sup>60</sup> into much more dangerous variants,<sup>61</sup> equal, non-discriminative distribution of the vaccine is needed more now than ever.

#### Conclusion

After HIV / AIDS crisis that happened in South Africa years ago, the world should not delay the patent waiver for handling COVID-19. The vaccine effectively lowers the mortality rate of COVID-19, and its distribution is essential in decreasing the infection and transmission rate of today's crisis. Having parallel importing and compulsory licenses as a form of TRIPs flexibilities are not the option for combating the COVID-19 pandemic situation. TRIPs waiver is the only action that should be conducted as soon as possible at this time. The reason behind this suggestion is how South Africa could not handle the endemic that well even though compulsory license and parallel imports have been conducted.

<sup>&</sup>lt;sup>60</sup> Robert Bollinger, Stuart Ray and Lisa Maragakis, 'COVID Variants: What You Should Know' (*Johns Hopkins Medicine*, 2021) <a href="https://www.hopkinsmedicine.org/health/conditions-and-diseas-es/coronavirus/a-new-strain-of-coronavirus-what-you-should-know">https://www.hopkinsmedicine.org/health/conditions-and-diseas-es/coronavirus/a-new-strain-of-coronavirus-what-you-should-know</a> accessed 28 May 2021.

<sup>&</sup>lt;sup>61</sup> Soutik Biswas, 'Mucormycosis: The 'black Fungus' Maiming Covid Patients in India' (*BBC*, 2021) <a href="https://www.bbc.com/news/world-asia-india-57027829">https://www.bbc.com/news/world-asia-india-57027829</a>> accessed 9 May 2021.

Apart from this, one of the essential things to do is to prepare human resources with knowledge of technology in patents so that the State is no longer dependent on other nations to transfer knowledge on technology manufacturing. This will be very useful in supporting the national health service program and easing access to medicine for the community.

The devastating loss in India has shown the global community that the new wave of COVID-19 is something that must be handled quickly. The world should learn enough from the endemic in South Africa, and the number of COVID-19 and its mutation infected dead keeps rising to date.

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