



## Removing the Roadblocks in Equitable Global Access to COVID-19 Vaccine through IPR Waiver

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In October 2020, South Africa and India proposed a plan to protect developing nations' interests and ensure a seamless supply of COVID-19 vaccinations. While rich countries have made rapid progress with their immunization programmes, many poor and underdeveloped countries have been left behind to fend for themselves due to patent protection. With the frightening rate at which COVID-19 cases have been emerging, the global population requires immediate and equitable access to life-saving vaccines. In this paper a methodological systematic review of IPR waiver related journal papers and newsletters published from 2019-2021 was performed. Search was conducted through significant scientific databases for relevant publications for this systematic review. This paper discusses to waive IPR in the COVID-19 pandemic, which has received both criticism and praise. Some opponents oppose the IPR waiver because it eliminates rewards for pharmaceutical corporations' R & D efforts. Vaccine development necessitates specialized requirements which cost a lot of money. Along with this, pharmaceutical corporations will be hesitant to take the lead in the future if a situation similar to COVID-19 arises. However, those in favour believe that an IPR waiver can reduce the barriers to countries producing their own vaccines, particularly for the lowest-income nations. Whether the reasoning is correct or incorrect, the timely & equitable distribution of COVID-19 immunizations is critical to the abolition of this pandemic.

**Keywords:** COVID-19, TRIPS, Vaccines Patent, Relaxation, WTO, Waiver, Emergency Use Authorizations

The arrival of the Corona Virus SARS-CoV-2 (Severe Acute Respiratory Syndrome Corona Virus 2) that causes Corona Virus Disease 2019 (COVID-19) has led the world to make imperative progress in developing an effective and safe vaccine.<sup>1</sup> An international movement to waive IPR's of COVID-19 vaccines towards ending this global pandemic has been discussed in this article. India and South Africa floated the idea that the intellectual property waiver could benefit middle-income countries by allowing for "emergency use authorisations (EUA)" production. The term "Intellectual Property" protects inventions relevant to vaccines.<sup>2</sup> Companies don't have to worry about their ideas being stolen when they collaborate because they have intellectual property.<sup>3</sup> In order to produce vaccinations, intellectual property is also important. In spite of having so many benefits, IPR's also serve as an obstacle to affordable and expeditious global access to vaccines and treatments.<sup>4</sup> Intellectual property detractors, on the other hand, see it as a roadblock at every turn. Sceptics believe that because intellectual property owners have the ability to prevent others

from exploiting their property, they will do so. Opponents of IPRs have urged the suspension of IPRs at every stage of the attempt to produce COVID-19 vaccines, from early R&D through bringing treatments to market to ramping up manufacturing. South Africa and India have proposed to the WTO that all IP rules for COVID-19 technologies be waived.<sup>5</sup> The goal of the IPR waiver is to reduce the barriers to countries particularly for the lowest-income nations.<sup>6</sup>

According to WHO 'Equitable access to safe and effective vaccines is critical to ending the COVID-19 pandemic.'<sup>7</sup> Vaccines are needed against a rapidly mutating virus as SAR Cov-2 because persons who have been vaccinated can clear out the virus faster in re-infection and breakthrough instances. Vaccines aid in the development of immunity against a virus or other germ. The immune system of the body produces antibodies that fight the pathogen and prevent the person from becoming ill.<sup>7</sup> Even a fifth of the population in many nations is still not properly vaccinated. The majority of these countries are in Africa, and the world has mostly ignored their vaccine needs. Thus, COVID-19 vaccinations are critical for bringing the pandemic to a conclusion. From a

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humanitarian, moral, and pragmatic standpoint, countries must band together to ensure that these vaccines are distributed fairly and quickly around the world.<sup>3</sup> In this situation of crisis, as WHO has said, "Vaccine equity is the key to ending the COVID-19 pandemic, together." Waiver of IPR, on the other hand, may lead to loss for the manufacturer and patent holders. The WHO's plan to combat the pandemic is to get 70 percent of the population of each country vaccinated by the middle of 2022. Wealthier countries have reached this goal, while the vast majority of poorer countries have not. Vaccine equity will eventually emphasise a balanced approach, reaching a centre ground for all stakeholders.<sup>9</sup>

The paper reviews the IPR rights and the role of patents for vaccine monopolies and idea protection rights. It briefly sketches the different types of vaccine developed for COVID-19 and how IPR waiving can be done to ensure its equitable distribution all over the globe. Many philanthropic approaches have been developed, like COVAX, C-TAP, patent pool, patent pledges, and vaccine nationalism for delivering vaccines to LMIC's, but despite that, there is a persistence of vaccine shortages.<sup>7</sup> It seems that the TRIPS flexibilities are insufficient in dealing with the present pandemic, particularly for nations lacking pharmaceutical manufacturing capacity.<sup>9</sup> So, for this reason, India, South Africa, and many other countries led a call at the WTO to temporarily waive protections under the TRIPS Agreement in order to speed up access to affordable medical products for the prevention, containment, or treatment of COVID-19 to all member countries.<sup>8</sup> There are debates over the consequences of IPR waving. However, forced technology transfer and other forms of IP abrogation, such as those proposed by India and South Africa at the WTO TRIPS Council, will wreak havoc on manufacturing supply chain planning, financing, and distribution networks for little gain (Fig. 1).<sup>5</sup>

IPR's are the rights given to the person for the innovation and development of new ideas from their own mind. They generally provide the creator with an exclusive right over the use of his/her creation for a particular period of time.<sup>10</sup> IPR consists of many exclusive permits such as patents, copyright, trademarks and industrial design that are the foundation for a consumer society and necessary economic growth. It is the engine that can be used to resolve the global corona virus pandemic situation.<sup>11</sup>

Intellectual properties all over the world have been protected under WIPO (World Intellectual Property Organization). WIPO provides a readily accessible source of knowledge to scientists, engineers, public health policymakers, and other members in order to improve COVID disease detection, prevention, and treatment.<sup>12</sup> The WTO regulates the international trade of vaccines all over the globe and emphasizes successful immunization programs required to eradicate the pandemic by building a functional, end-to-end supply chain and logistic system.<sup>13</sup> A COVID-19 vaccine that is both safe and effective is regarded as a nirvana for our generation, critical to resurrecting our society and saving millions of lives. Patent protection is a preliminary legal mechanism for ensuring tediously developed vaccine efforts. It is necessary to promote human knowledge, grant exclusive rights to inventors, authorizing them to charge supreme competitive cost.<sup>14</sup> Patent laws offer inventors a legal monopoly in their ideation and gives the patentee a period of around 20 years especially for product like vaccine in the market.<sup>15</sup> Another standard included is TRIPS, an Agreement on Trade Related Aspects of IPRs, which came into force on 1 January 1995. This stipulate minimum standard for protection rights in many countries intended to reduce distortion to international trade.<sup>16</sup> The TRIPS Agreement accelerates access to affordable medical products for the prevention, containment or treatment of COVID 19.<sup>8</sup> In these circumstances of the COVID-19 crisis, the G7 also announced a pledge of 1 billion doses by February 2021 (Table 1). G7 works with COVAX to share doses rapidly and equitably.<sup>17</sup>

### IPR Waiver

A vaccine patent guards on innovation by excluding competitors from copying a company's discovery and launching its product. An anomaly to

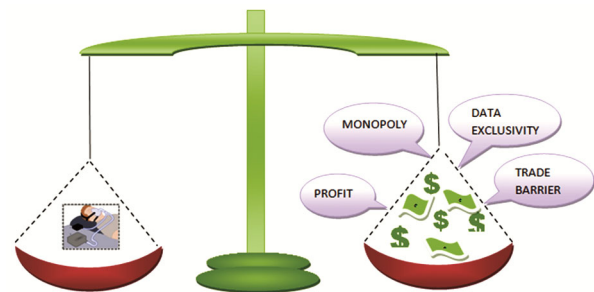


Fig. 1 — Striking a balance between patient needs and IPR importance is need of the hour

Table 1 — COVID-19 vaccines<sup>18</sup>

S. No	Vaccine	Type of vaccine	Organization/ Company	Country
1.	Comirnaty (BNT162b2)	mRNA	Pfizer, BioNTech	Europe
2.	Moderna COVID-19 Vaccine	mRNA-1273	Moderna, Barda, Niaid	USA
3.	AstraZeneca (AZD1222)/ Vaxzevria and Covishield	Adenovirus	AstraZeneca	UK
4.	Sputnik	Recombinant adenovirus	Gamaleya Research Institute, Acellena Contract Drug Research and Development	Russia
5.	Janssen (JNJ-78436735; Ad26.COV2.S)	Non-replicating viral vector	Johnson and Johnson	Netherlands
6.	CoronaVac and BBIBP-CorV	Inactivated	Sinopharm	China
7.	Convidicea (Ad5-nCoV)	Recombinant (adenovirus type 5 vector)	CanSino Biologics of China	China
8.	Covaxin (BBV152)	Inactivated	Bharat Biotech and ICMR of India	India
9.	ZyCov-D	DNA based	ZyDus Cadila	India
10.	Covovax	Protein subunit	Serum Institute of India (Novavax)	India

the WTO's TRIPS rule that would allow manufacturers in developing countries to access big pharma's intellectual property to produce cost-effective versions of these patentee companies' vaccines.<sup>19</sup> This will facilitate low-income countries to manufacture COVID-19 vaccines through a technology transfer agreement. This will act as a shot in the arm for the global inoculation drive, which has been slacking. A patent waiver would fundamentally decentralize COVID-19 vaccine manufacturing and increase the production of generic drug-equivalent of COVID-19 vaccines.

Even though the United States, France, and many other nations are now in support of it, still the decision is up to the 164-member countries at WTO, which directs complex trade rules between countries. For an IPR waiver, all of them have to give permission. A single 'no' would result in the rejection of this proposal. So, the decisions to either waive the vaccine-related patent or not have to be consensual. If a waiver is approved, the patentee would then have to share their knowledge of vaccine manufacturing. This type of waiver has never been approved before. A very similar decision was made two-decades ago when WTO members passed a temporary waiver for poor countries allowing them to import cheap generic drugs for tuberculosis, HIV, and malaria amid health crisis. This temporary waiver, later was made permanent.<sup>20</sup>

### Vaccine Nationalism and International Efforts

Historically, it is evident that pandemics are responsible for the emergence of many global health problems. As a result of these circumstances, vaccines and vaccination programs have been developed.<sup>21</sup>

Likewise, for COVID-19 'vaccine nationalism' was initiated which is defined as 'efforts to influence the allocation of newly developed vaccines or the first batch thereof, to the detriment—often the exclusion—of other, generally poorer countries.'<sup>22</sup> During the early days of the COVID-19 pandemic, many rich countries reserved a large number of vaccines for their domestic populations.<sup>23</sup> For this, countries enter into contractual agreements, commonly referred to as pre-production orders, with pharmaceutical companies.<sup>23</sup> The TRIPS Agreement states that countries must adopt mandatory measures to protect public health and promote public interests in sectors critical to their socioeconomic and technological development. TRIPS allows the transfer of licenses with an appropriate agreement signed between the countries concerned along with the terms of the transaction in detail.<sup>24</sup> Under such a provision, a compulsory license can be transferred to the country where the patent is registered. A compulsory license is a type of tool that allows the state to modify the exclusionist influence of royalty pricing.<sup>25</sup> The government can grant manufacturing rights to other producers without the consent of the owners using a compulsory license.<sup>26</sup> There are three main actors, who play role in issuance of compulsory license that is government, third-party licensee and the patentee.<sup>27</sup> An international union called COVAX has taken certain steps to increase the supply of vaccines to poorer countries.<sup>26</sup> COVAX was established in April 2020, a type of ongoing vaccine nationalism and charitable effort that focuses on the global and equitable distribution of COVID 19 vaccines.<sup>21</sup> COVAX is sponsored by many philanthropic funders and wealthy countries. Its main motive include

reaching 20% of the populations in countries that have funded it, as well as distributing 1 billion doses to 92 low-income countries.<sup>28</sup> In December 2020, the COVAX mission was about to fail due to insufficient funding, but then the Biden administration gave its support, which improved the chance of success.<sup>29</sup> COVAX, which was supported by HICs, failed to offer timely and equal access to COVID-19 vaccinations, according to the proponents of the patent waiver proposal. It aims to buy 2 billion doses of vaccine and distribute them equally across HICs and LMICs. The HICs have reserved 6 billion doses, despite the fact that the LICs, with a combined population of 1.7 billion people, have yet to sign bilateral vaccine agreements. Even after launching the COVAX charity, it was unable to remove the global vaccine injustice.<sup>30</sup> It has been seen that there were many intellectual collaborations formed during the pandemic. Some of these collaborations, such as patent pools and patent pledges, have ended most issues to some extent. The patent pool negotiates voluntary licenses with pharmaceutical companies on behalf of middle and low-income countries.<sup>31</sup> One such case was in March 2020, in which the government of Costa Rica submitted an approach to WHO for the creation of a patent pool.<sup>32</sup> Then the COVID 19 technology access pool (C- TAP) was upraising in late May 2020.<sup>33</sup> Its purpose was to encourage and accelerate the public disclosure of information about COVID 19 research and development.<sup>34</sup> It also promotes licensure for both large and small manufacturers and distributors. Patent pools, such as C-TAP, are designed to reduce risk costs and accelerate research and development.<sup>35</sup> Along with this, the WHO has also developed access to the COVID 19 tools (ACT) accelerator, known as "global and time-limited collaboration to accelerate the development, production and equitable global access to new COVID 19 essential health technologies."<sup>36</sup> Other private sector initiative includes the cooperation between Gavi, Bill and Melinda Gates foundation to procure COVID 19 vaccine for lower income countries as soon as they are available.<sup>24</sup> One more pathway to voluntarily promote the use of patent inventions is the patent pledge. The open COVID 19 pledge was launched in March 2020 as a commitment by holders of intellectual property to share their intellectual property for the purpose of ending and mitigating the COVID 19 pandemic.<sup>37</sup>

### **Removing Roadblocks with IPR Waiver**

Relinquishing patent rights will not solve the global pandemic problem on its own, but it will remove some roadblocks.<sup>38-39</sup> By relaxing the enforcement of patent rights, one can increase access to vaccines. This execution can be settled in various ways, including voluntary licenses and reducing the duration of patents.<sup>39</sup> Patent sharing can contribute to the quick development of vaccines that help to make sure the entire universal vaccination of individuals against the virus at the earliest.<sup>40</sup> Vaccine access is crucial for establishing global immunity against COVID 19.<sup>41</sup> As in the case of the second wave of COVID-19, which had devastating consequences in many aspects of life. The question now is how to keep the pandemic under control and combat it. The solution is for everyone to be fully vaccinated. However, due to a variety of factors, the current arrangement of vaccines is epidemiologically unfair and inequitable. Furthermore, IPR's are emerging as a barrier to global vaccine access. By ensuring widespread global access to COVID 19, many cases and deaths can be avoided, and the global population's immunity can be improved.<sup>42</sup> At present, only certain patent holding pharmaceutical companies are authorized to manufacture the COVID 19 vaccine. As a result, many folks around the world are struggling to obtain vaccines, and a shortage has been reported in several countries. Multilateralism has resulted in the grouping of countries into three tiers: developed, developing, and least developed. The institutional setting, in particular, aids developed countries in reinforcing collective arguments and lowering costs. Developed countries with more wealth and resources tend to invent more and have more patent protection. Developing countries, on the other hand, lack a local political position for patent protection due to a lack of resources and money. The least developed countries face a delay in access and implementation. In this case, it has become a requirement to make vaccines available in an equitable and distributed manner.<sup>43</sup> Inequities in vaccines distribution result in limited vaccinations, extending the pandemic, increasing the risk, and causing social and economic disruption.<sup>42</sup> So there's an urgency to vaccinate the entire population at the earliest. One of the challenges lies in the demand and supply mismatch due to a lack of vaccine production. As most of the countries are suffering, relaxation of patents by the WTO could act as a saviour in view of the crisis, on the condition that vaccines are used for domestic purposes and can't be exported without the approval of the patent holder

company.<sup>44</sup> Moreover, the waiver could encourage pharma companies with patents to increase their production supplies. So, granting a compulsory license seems to pay off in terms of provoking patent owners to share their technology.<sup>38</sup> Another concern is the risk of high price, affordability and financial status of the COVID 19 vaccine.<sup>45</sup> In the case of the COVID 19 pandemic, demotivating impact of exclusivity on access to vaccines has been seen, like an increase in price because of more demand for production capacity. This has resulted in a vigorous promotion of open licensing, technology transfer of COVID 19 vaccines and medicines to conform economical, equal and affordable distribution.<sup>45</sup> The TRIPS waiver aids in the termination of monopoly criteria on production and provides vaccines that facilitate the scale up of production by several manufacturers. This step allows biotech, generic and diverse manufacturers to rescale assembly of vaccines under authorized voluntary approval by the patent owner.<sup>46</sup> Currently, low income and middle income countries LMIC face substantial hurdles for vaccine access. Various philanthropic programs launched by various organizations do not appear to be delivering vaccines to LMIC quickly enough and deform the purpose of IPR at the expense of access injustice, which is why a stronger approach to IPR is required to make global vaccine access a reality.<sup>27</sup> The waivers would reduce the cost of vaccines and make it easier for poorer countries to purchase and acquire adequate quantities of vaccines.<sup>43-47</sup>

The relaxation of patent rights provides enormous benefits to the human population, particularly those who have not yet received the primary vaccine jab. Human rights, according to the 'UN Guiding Principles on Business and Human Rights' guidelines for Pharmaceuticals should not be tainted by business, third parties, or jurisdiction. Some medicines have been designated by the WHO as essential medicines, which must satisfy the priority health care needs of the entire population and be available in adequate quality and quantity. It is a phase when countries should approach the WHO with a humanitarian attitude and request that the IPR provisions for the COVID 19 vaccine be relaxed. Waiver in patent rights can perform to shield humanity across the world.<sup>39</sup>

### **Roadblocks to the IPR Waiver**

Those against the waivers say that a waiver is a red herring that will do little improvement in the global vaccine distribution while eliminating incentives for

innovation. If a waiver is approved, there are chances that ample manufacturers will not take up production. Therefore, setting aside the intellectual protection for production can be dangerous, particularly if does not work. Instead of this, voluntary licenses can be issued in which the patentee provides manufacturers with the know-how to produce their vaccines.<sup>49</sup> Understanding the practical limitations of lifting a waiver would be better approach. It is not like following a recipe, it is far more complex. It requires factories with specialized technology, high skilled manpower, and stringent quality control.<sup>20</sup> Therefore, a waiver temporarily unsays the exclusionary rights but does not bridge the vaccine scarcity problem. Briskly lifting IP bottlenecks results in millions of ineffective and perilous doses, which could potentially harm the receiver and encourage scepticism.<sup>19</sup> One of the disquiet about the IP waiver is that it may provide a crosscut to competitors gazing to acquire expensive technology.<sup>6</sup>

After the IPR waiver is accepted, the company may conceal some information for competitive reasons; in such cases, lifting the waiver will not result in informational disclosure unless the patentee is willing to collaborate. It will not solve the informational problem that fortifies competition in vaccine manufacturing.<sup>50</sup> Furthermore, loosening vaccine patents will deter pharmaceutical companies and the industry from developing the next generation of vaccines.<sup>43</sup> There is still a long way to go before implementing the IPR waiver, and much more work is needed to improve manufacturing capacity. Only an IPR waiver will not solve the problem; proper technology transfer will be required, which will be time-consuming. It will take approximately 18-24 months to build up the manufacturing capacity from scratch. The IP waiver will not accelerate vaccine manufacturing because there is not enough infrastructure or raw materials to produce vaccines. COVID-19 vaccine manufacturers are concerned about how recipients will understand and implement the knowledge to produce vaccines of the necessary quality. Sending a skilled trainee to the recipient to set up the plant will decrease the manufacturing capacity of the original manufacturer.<sup>50</sup> Governments arguing for an IPR waiver say WHO already provides the petition for a 'compulsory license' to override IP during emergencies.<sup>6</sup> Moreover, a waiver will not immediately solve the problem of an immense shortfall in vaccine production. Finally, it is important to keep in

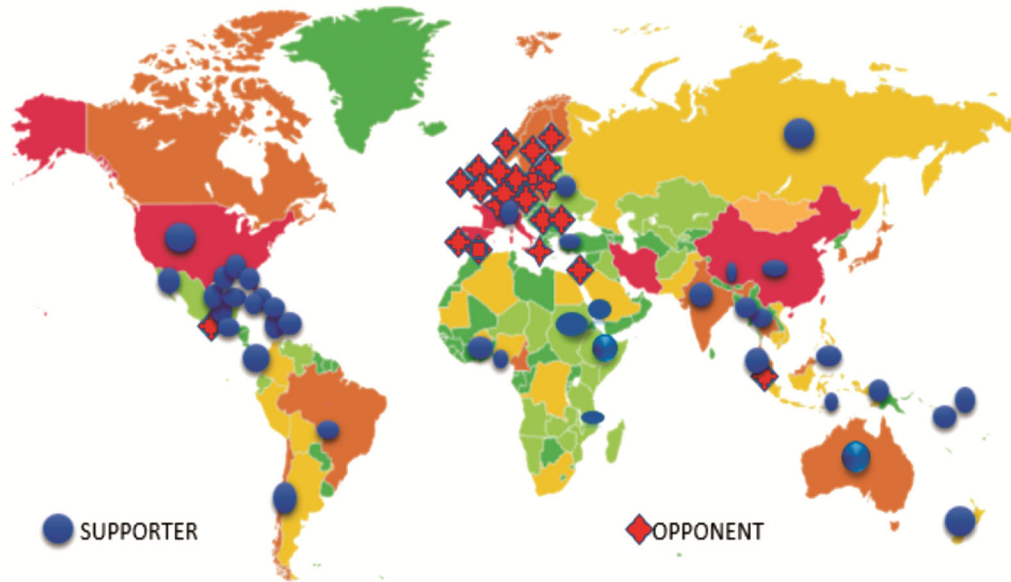


Fig. 2 — Map outlining countries in support or oppose of the move of waiving COVID-19 patents<sup>51-53</sup> (18 January 2022)

mind that waiver is temporary, countries who are supporting should consider legal and practical uncertainty that a waiver would introduce, as it is unclear how technology transfer between companies would cease or continue once waiver expires.<sup>50</sup>

### International Diplomacy and Views on Waivers

In October last year, India and South Africa had approached the WTO seeking a temporary waiver on TRIPS in COVID-19 related innovations to boost access to tests, drugs, and vaccines. This proposal has approximately 100 countries backing it. The main aim of this patent waiver is to make poor countries produce their vaccines easily. Initially, the proposal was blocked by several countries. The main opposition was from the US, EU, Switzerland, UK, Norway – and Brazil.<sup>20</sup> Then, a revised edition of this global IPR wavier was proposed by India which states that “At least a three-year-long wavier of IPR globally for COVID-19 vaccines as well as waivers for the inclusion of requisite drugs, medical equipment and all health technologies necessary for the prevention of COVID-19”.<sup>51</sup> This proposal has the unofficial backing of nearly 120 countries. Countries like Australia, Britain, Canada, the European Union, Japan, Norway, and Singapore still oppose the waiver idea.<sup>20</sup> Recently, many countries that opposed the idea, have now changed their decision. The US has agreed to the waiver idea however, it doesn’t back the IPR waiver for drugs and health technology.<sup>51</sup> Joining

the Biden Administration, Australia’s Prime Minister Scott Morrison and Russian President Vladimir Putin have accepted the call to relax vaccine patents. UN Secretary-General Antonio Guterres has supported the US call too. A surprise U.S. shift earlier to support a patent waiver heaped pressure on remaining opponents like the European Union and Switzerland that are home to numerous drug makers.<sup>52</sup> Major global powers such as the European Union, the UK, and Singapore have expressed their vexation at a ‘potential blanket suspension of the terms of the TRIPS Agreement’ (Fig. 2). France was among the first to support the US call. Brazil Health Minister said he is tensed that country will not have the means to produce vaccines and patent waiver will interfere in buying doses from pharmaceutical companies.<sup>20</sup> Around 10 countries, including South Korea and Britain, continued to express doubts and asked for more time to study the new South Africa/India proposal of patent waiver. “The protection of the intellectual property is a source of innovation and must remain so in the future,” said German Chancellor Angela Merkel’s office.<sup>20</sup> Gates Foundation CEO, Mark Suzman, said, “No barriers should stand in the way of equitable access to vaccines, including intellectual property, which is why we are supportive of a narrow waiver during the pandemic. Those negotiations will occur *via* the WTO process, led by country negotiators.”<sup>54</sup> Among the companies which have licensed COVID-19 vaccines,



Pfizer, Moderna, Johnson & Johnson, and AstraZeneca, only Moderna has for long been saying that it will not pursue rivals for patent infringement during the pandemic.<sup>20</sup> Pfizer and other biotech companies are skeptical. They said the waiver will affect their target of delivering 3 billion vaccines this year as raw materials will be swamped. Biotech's CEO, Ugur Sahin, says that such a move would fail to solve the supply bottlenecks.<sup>53</sup> A waiver is the simple but the wrong answer to what is a complex problem," said the International Federation of Pharmaceutical Manufacturers and Associations.<sup>20</sup>

### Conclusion

South Africa and India, leaders of poor and medium income nations, seem to be committed to address the inequitable access to COVID-19 vaccination; they have proposed to the WTO that some TRIPS rules be waived in the case of COVID-19 vaccines, medicines, and treatments. Delaying vaccine delivery to billions of people jeopardises the pandemic's survival and the spread of new mutations. Whether the reasoning is correct or incorrect, the timely and equitable distribution of COVID-19 immunizations is critical to the abolition of this pandemic. This pandemic has rekindled a long-running debate over the appropriate balance between private profit and public health. Instead of making vaccinations freely available, IPRs prioritise industry profits over human health and well-being. COVID-19 vaccinations should be considered as global public good because current IPR protection for vaccine corporations is causing global health and socioeconomic hardship rather than improving it. However, forsaking the innovation to achieve this goal would be a short-sighted approach. Impediments to boosting production and equitable access to vaccinations include increasing institutional capacity in a number of countries, overcoming systemic barriers, raw material scarcity and implementing necessary reforms in the machinery and legal environment. IPR waivers can address substantial unfairness in the worldwide distribution of COVID-19 vaccines, as wealthier countries control the vast majority of available supplies. Although the global effort to waive COVID-19 vaccine IPRs is gathering traction, affluent countries at the WTO are opposing it. Scholars of global health must join the call for universal vaccination access. Finally, a decision

favouring the cause of humanity should prevail. The highlights of the study are:

- IPRs are a significant barrier to global vaccination availability.
- With the frightening rate at which COVID-19 cases emerged, the globe requires immediate and simple access to life-saving vaccines.
- Delaying vaccine delivery to billions of people jeopardizes the pandemic's survival and the spread of new mutations.
- The timely and equitable distribution of COVID-19 immunizations is critical to the abolition of this pandemic.
- Scholars of global health must join the call for universal vaccination access.

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