

# A Global Intellectual Property Waiver is Still Needed to Address the Inequities of COVID-19 and Future Pandemic Preparedness

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**Note from the Section Editor:** With mortality from the COVID-19 pandemic at over one million dead alone in the U.S., policy experts have raised questions about how the developed world can ensure that less resourced countries have access to vaccines, diagnostics, and therapeutics. In this setting, patent rights and the overall intellectual property framework underlying life sciences development and innovation has been brought into question. Here, INQUIRY hosts a balanced debate regarding policy solutions to balance access, innovation, and economic opportunity.

## Abstract

In October 2020, India and South Africa submitted a proposal to the World Trade Organization (WTO) to suspend IP on all COVID-19 vaccines, therapeutics, and diagnostics until widespread vaccination could help achieve immunity among people in low- and middle-income countries. After 18 months, the final WTO Decision substantially watered down the original text proposed by India and South Africa, limiting it only to patents on vaccines and the use of protected clinical trial data for regulatory approval. We address why an IP waiver under TRIPS consistent with the one originally proposed by India and South Africa is still needed to not only meet the ongoing inequities of COVID-19, but also to ensure the right precedent for future equitable pandemic preparedness and other crises affecting the global South. To meet the multilateral goals of the WTO, an IP waiver as proposed by India and South Africa is still needed to increase manufacturing capability for vaccines, therapeutics, and other COVID-19 health-related technologies.

## Keywords

patent, TRIPS, COVID vaccine, intellectual property, Paxlovid

### What do we already know about this topic?

In October 2020, India and South Africa submitted a proposal to the World Trade Organization (WTO) to suspend IP on all COVID-19 vaccines, therapeutics, and diagnostics until widespread vaccination could help achieve immunity among people in low- and middle-income countries, but the final WTO Decision significantly watered down the originally proposed by India and South Africa, limiting it only to patents on vaccines and the use of protected clinical trial data for regulatory approval.

### How does your research contribute to the field?

We address why an IP waiver under TRIPS, such as the one originally proposed by India and South Africa, is still needed to not only meet the ongoing inequities of COVID-19, but also to ensure the right precedent is set for future equitable pandemic preparedness and other crises affecting the global South.

### What are your research's implications toward theory, practice, or policy?

If the WTO is to remain a relevant multilateral forum, a IP waiver as proposed by India and South Africa is still needed to increase manufacturing capability for vaccines, therapeutics, and other COVID-19 health related technologies.

In October 2020, India and South Africa submitted a proposal to the World Trade Organization (WTO) requesting a waiver of member states' obligations with respect to all intellectual property (IP) rights—patents, copyrights, industrial

designs, and trade secrets (undisclosed information)—as required under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>1</sup> The proposed TRIPS waiver was in response to the hoarding of essential medical



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equipment by the global North countries at the beginning of the pandemic and specifically sought to suspend IP on all COVID-19 vaccines, therapeutics, and diagnostics until widespread vaccination could help achieve immunity among people in low- and middle-income countries.

Since the original TRIPS waiver was proposed, officially more than 6 million people globally have lost their lives,<sup>2</sup> although the figure could be over 3 times that based on alternative modeling estimates.<sup>3</sup> Out of the nearly 12 billion doses that have been administered globally, only 16.2% of people in low-income countries received at least one dose by June 2022.<sup>4</sup>

The original TRIPS waiver proposal was co-sponsored by more than 60 developing countries and supported by more than 170 former heads of government and Nobel laureates.<sup>5</sup> But any movement on the proposal was stalled as a result of the US, EU, and other wealthy countries that have ample access to vaccines and treatments, and pharmaceutical companies that control supplies and the knowledge to make them, not pushing hard enough to make the waiver happen or blocking the suggestion outright.

After over 18 months, in March 2022, a “compromise text” emerged.<sup>6</sup> The text was believed to be the result of high-level consultations between the EU, India, South Africa, and US—coordinated by the WTO Director-General Ngozi Okonjo-Iweala—and became known as the WTO DG text. Other than the EU, none of the quartet of sponsoring countries publicly expressed official support of the text.<sup>7</sup> By contrast, civil society, public health advocates, and academics criticized the WTO DG text as largely reflecting the negotiating positions of the EU and US and as being too narrow and insufficient to address the inequities of COVID-19.<sup>8,9</sup> Indeed, many in India and South Africa advocated that the “compromise text,” be rejected on the grounds no deal is better than a bad deal.<sup>10</sup>

Despite these concerns, the WTO DG text became the basis for negotiation and the final text agreed by member states on 17 June, known as the Ministerial Decision on the TRIPS Agreement (WTO Decision).<sup>11</sup> The announcement of the agreement was lauded by the WTO, member states, and many in the media that an IP waiver had been agreed and proof that multilateralism still works.<sup>12</sup> However, the final WTO Decision significantly watered down the original proposal by India and South Africa, limiting it only to patents on vaccines and the use of protected clinical trial data for regulatory approval. The end result was not a broad IP waiver of the kind imagined and needed, but a clarification of existing flexibilities already available under the TRIPS Agreement.<sup>13</sup>

In this article, we address why an IP waiver under TRIPS, such as the one originally proposed by India and South Africa, is still needed to not only meet the ongoing exigency of COVID-19, but also to ensure the right precedent is set for future equitable pandemic preparedness and other crises affecting the global South. In making the case for this IP waiver, we will also touch on the insufficiency of the agreed WTO Decision and how it represents the status quo of the last 27 years of the TRIPS Agreement related to addressing global public health goals.

## A History of TRIPS and Broken Promises

To better understand the case for a global IP waiver in the case of COVID-19 products, it is necessary to revisit the history around the creation of the WTO in 1995 and how it has functioned. This important context is often left out of the discussions around IP and its impact on the global South—especially when it comes to global public health and matters of trade policy.

The issue of IP and technology transfer between the global North and South is not a new one. As many new nation-states started gaining independence in the 1950s from disintegrating European empires, the need to catch up technologically with the industrialized global North as a means of economic transformation and to develop self-sufficiency was a priority. However, agreements for the transfer of technology from multinational corporations to countries in the global South were one-sided. Ultimately, very little technology was transferred or indigenous capacity developed, resulting in these countries falling victim to a form of “technological colonialism.”<sup>14</sup>

As these emerging economies came to terms with the technological gap and insufficient technology transfer, some sought to repeal patent laws remaining from their times as part of the empires. For example, after a 20-year investigation of its patent laws between 1948 and 1970, India realized it had among the highest drug prices in the world and was over-dependent on multinational pharmaceutical companies.<sup>15</sup> As a result, it removed patent protection on medicine products and food in 1970, only allowing process patents. This decision helped India develop its modern pharmaceutical industry.

It was also around this time that a group of countries from the South, also known as the G77, turned to the UN General Assembly for help in their quest to close the technological gap and challenge the IP systems that stood in the way of

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their development. In 1974, the UN General Assembly adopted the resolution known as the Declaration on the Establishment of a New International Economic Order (NIEO), in which the North would help formerly colonized countries become more self-reliant through the transfer of technology.<sup>16</sup> But the global North rejected the call for a NIEO, with the US in particular unwilling to abandon enforcement of patent laws and taking up the policy that “the best thing northern governments could do for the third world is to establish stable, continuous growth in their own, northern economies.”<sup>14</sup>

And focus on the growth of the northern economies is what the global North did. Edmund Pratt, then-CEO of Pfizer, feared that manufacturers from the global South would compete with companies like his for these new markets. Along with other business leaders from the copyright industries (software and entertainment), he encouraged US officials in the 1970s and early 1980s to integrate the defense of IP into US trade policy. Pushed by the pharmaceutical and copyright industries, the Reagan administration persuaded the European and Japanese governments to join the cause, helping place IP at the heart of the General Agreement on Tariffs and Trade.<sup>17</sup> Thus was born the WTO and the TRIPS Agreement.

TRIPS was formalized in 1995, when the global North countries pushed it through over the objections of many Southern countries. While the deal protected the investments of the global North countries and their corporations, it also prevented countries from the global South competing on an even footing in the growing knowledge economy. The Agreement required WTO member states to provide a minimum level of protection and enforcement for all types of IP, even when they may not have previously. Indeed, when many countries in the global North were developing their economies and technological capabilities, they did not always allow patents on pharmaceutical products. For example, Germany and Switzerland, home to some of leading pharmaceutical companies today, only introduced protection for pharmaceutical patents in 1968 and 1977, respectively.<sup>18</sup> Since TRIPS was signed into existence, the global North and the companies based in it have shifted forums to pursue bilateral free trade deals with Southern countries to further strengthen IP protections.<sup>19</sup>

Those advocating against the IP waiver consistently point to the flexibilities within the agreement, claiming the existing framework offers enough space for countries to manage any IP issues, such as through issuing compulsory licenses for patents, when faced with a public health emergency. Indeed, this has been the negotiating position of the EU, Germany, Switzerland and the UK throughout the TRIPS waiver discussions and largely reflects the final text of the WTO Decision. Despite these flexibilities and the objectives and principles of the TRIPS Agreement (Articles 7 and 8) that were supposed to provide policy space for countries to meet their national interests and public health needs, the 27-year history of the TRIPS Agreement is a story of

continual broken promises related to technology transfer to the global South.<sup>20</sup>

Whenever countries in the South have attempted to use these flexibilities during epidemics or other urgent public health needs, whether it be HIV, hepatitis C, tuberculosis, or non-communicable diseases, the US and EU, with lobbying from their pharmaceutical industries, have responded with opposing political pressure.<sup>21</sup> The consequence of such pressure over time has resulted in countries in the global South becoming more and more reluctant to use the TRIPS flexibilities to their fullest to address access to medicines.<sup>22</sup> Even in this pandemic—although the US supported a waiver of IP on vaccines only—the 2022 Special 301 Report of the US Trade Representative still admonishes a number of countries for using the flexibilities permitted by TRIPS in their domestic IP laws.<sup>23</sup> The global North’s pharmaceutical companies have followed suit. Pfizer is currently attempting to thwart the Dominican Republic from issuing a compulsory license on patents covering its COVID-19 drug nirmatrelvir/ritonavir (Paxlovid), arguing that its IP is a human right.<sup>24</sup>

These constant trade threats and pressures have squeezed the policy space within which Southern countries can serve their national needs, something that the global North countries never had as they developed technologically. As a result, the only way for local manufacturers in these countries to survive is to enter into heavily restricted voluntary licensing agreements with multinational pharmaceutical companies. These licenses not only undermine any flexibilities a country may have used, they also manage the competition by restricting the territories where products can be sold.<sup>25</sup> For example, the Paxlovid licenses that Pfizer recently established have excluded many middle and upper-middle income countries in need of affordable access to the drug.<sup>26</sup>

Relying solely on flexibilities such as compulsory licenses on patents—which the current WTO Decision re-confirms—and not a broad IP waiver is not enough. This is because compulsory licenses are only available for patents and not all IP, such as trade secrets, that are key to unlocking vaccine manufacturing. Also, compulsory licenses have to be applied for on a product-by-product basis, which is too slow and cumbersome for addressing a pandemic. Paradoxically, the current WTO Decision could be most useful in relation to COVID-19 therapeutics, especially given the existing ability of manufacturers in the global South to make such products without the need for trade secrets and transfer of technologic know-how. However, given how long it took to reach the WTO Decision, it is likely the EU, Germany, Switzerland, US, UK, and pharmaceutical companies will resist or delay any efforts to expand it to therapeutics and diagnostics when this issue is revisited in the coming months.<sup>27</sup>

It is this history of inequity that explains the rationale for a TRIPS waiver that covers IP for vaccines, therapeutics, and diagnostics. The failure to agree a broad waiver on IP and COVID-19 related health products sets the wrong precedent for future pandemics. A broad IP waiver could help to change

the fundamental workings of TRIPS and the WTO. Instead, the global South countries can expect the same treatment it has been receiving over the past 27 years of an inequitable trade system that continues to put IP before lives.

### **De-centralizing Production for COVID-19 and Pandemic Preparedness**

Throughout the pandemic, opponents of a broad IP waiver have made a variety of arguments while simultaneously moving the goalposts to further delay dissemination of life-saving medical products. One of the arguments against suspending IP has been that it would not increase supplies as there are no other manufacturers in the world that have the capacity to make vaccines – especially mRNA vaccines. This argument rehashes a tired trope that manufacturers in the global South either do not have the capability to produce complex technologies or their quality is lacking. However, over the past 2 years, enough evidence has appeared to show that this argument does not hold ground.<sup>28,29</sup> Manufacturers in China, India, Thailand, and Vietnam now have their own mRNA vaccines in development.<sup>30</sup> Local manufacturing of COVID-19 rapid tests in Africa and Latin America have been expanded through collaborations with producers in China and Brazil as a result of the World Health Organization's Access to COVID-19 Tools (ACT) Accelerator and financial support from Unitaid and the Foundation for Innovative New Diagnostics (FIND).<sup>31</sup> A broad IP waiver could help other countries and manufacturers invest in developing their own manufacturing capabilities and capacity, which would not only serve this pandemic but also future ones. It would also help remove any patent litigation risks, which are now mounting in relation to mRNA vaccines. Both Moderna and Pfizer are facing patent infringement suits with respect to their mRNA vaccines, while the Indian company Gennova is being sued for alleged trade secret theft.<sup>32-34</sup> Interestingly, Moderna tried to shield itself from patent infringement lawsuits by arguing that, as they are a government supplier, any action should be directed against the US government. Based on this logic, Moderna (and, by extension, Pfizer) moved the goalposts to benefit from its own personal patent waiver for the past few years while lobbying against a TRIPS waiver.<sup>35</sup>

Having successfully delayed a broad TRIPS waiver for over 18 months, a more recent argument from those against suspending IP is that it is now an outdated proposal given that current global production of vaccines has reached 12 billion doses and supplies are outstripping demand.<sup>36</sup> The problem with this argument is that as Moderna and Pfizer get ready to roll out the next generation of mRNA vaccines that may be more effective against the Omicron variant and future variants, they will be disseminated with priority again to the global North while the global South will be pushed to the back of queue.<sup>37</sup> It also begs the question of whether Moderna and Pfizer will continue to produce the current version of

their vaccines or whether they will only have capacity to produce the new generation—which will cause another supply problem. Perhaps the supply of older, less-effective vaccines be passed to the global South? Either way, this is not a solution that puts the public health first.

It has become abundantly clear that relying on only a few manufacturers to serve global demand has been one of the biggest failures of leadership and policy during this pandemic. The current WTO Decision makes matters worse by encouraging developing country member states with existing capacity to manufacture COVID-19 vaccines to make a binding commitment to not avail themselves of the Decision to override patents and regulatory data for vaccines made under the agreement.<sup>38</sup> Following demands from the US for the explicit exclusion of China from any WTO IP waiver, China's statement at a WTO General Council meeting on 10 May agreeing not to avail themselves of any IP waiver means the WTO now recognizes this as a binding commitment under the Decision.<sup>39,40</sup> The concern now is whether other developing countries with manufacturing capacity could follow. Only by unlocking all the IP monopolies that currently block vaccine, therapeutics and diagnostic development and production in other countries will we be able to decentralize supply and meet the global demand for this pandemic and be prepared for future ones.

### **Conclusion**

The clash between the global North and South over the right to scientific knowledge has been going on for 70 years. The creation of the WTO and the TRIPS Agreement was designed to maintain the order of power of the global North and its corporations. This pandemic has shown the dangerous effects such a system can have on public health and that it is not fit for tackling today's global crises.

If the WTO is to remain a relevant multilateral forum, a broad IP waiver as proposed by India and South Africa is still needed. The current WTO Decision will do little to increase manufacturing capability for vaccines, while excluding therapeutics and other COVID-19 health related technologies. Based on the history of TRIPS to date, perhaps that is what the global North wanted to achieve—to provide the illusion of giving something, knowing that that it will not work in practice. As it stands, the global South can expect the same treatment it has been receiving over the past 27 years of TRIPS and we will be back scrambling for solutions either during this pandemic, the next one, or as the climate crisis gets worse, while untold lives are lost. Leaders in the global North need to look past their own historical biases and economic self-interest and think of how we can build a system that promotes the collective good. The broad TRIPS waiver as proposed by India and South Africa would have met not only the current moment, but also would prepare us for future equitable pandemic preparedness. It is still not too late to take this course.



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