

# **The Operation of International Trade-Related Intellectual Property Barriers in the Context of Human Rights and Access to Medicines During the COVID-19 Pandemic**

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## **Research Article**

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**Abstract** - The worldwide COVID-19 outbreak has re-ignited the discussion over people's ability to get their hands on necessary medications. To achieve public health indicators, it is necessary to ensure that drugs may be freely obtained. A feature of the Indian health system is the availability of affordable and effective medications for a broad range of requirements, despite the fact that public investment on health is very low in India. India became known as the "pharmacy of the world" because to the low costs charged by pharmaceutical businesses like Serum Institute of India, Biological E, Dr. Reddy's, etc., which produced and provided critically important medications. This manufacturing business had significant expansion because to a favorable intellectual property climate that prohibited product patents for medications until 2005. The present worldwide health crisis, together with the implementation of TRIPS responsibilities after 2005, has created an enormous demand for the production and distribution of therapeutic and diagnostic equipment. Some nations are considering removing TRIPS protections from medical devices and pharmaceuticals as the globe looks to South Africa, India, and Brazil to fulfill its demands. Public health and medication access are the primary foci of the WTO/TRIPS system, which is examined in the first section of this article. This article will analyze how the TRIPS provisions have affected public health, focusing on the potential "waiver" or "flexibilities" of TRIPS duties. The emphasis on "flexibilities,"

such as compulsory licensing, relies heavily on the case law established by the Doha Declaration on TRIPS and Public Health, even if the "waiver" of TRIPS duties is a fundamental aspect of the WTO system as acknowledged in the Marrakesh Agreement. The second section of the article will compare and contrast the World Trade Organization's regulations on pharmaceutical access with the broader body of human rights law pertaining to the right to health, as well as the outcomes of this collision of standards.

## **INTRODUCTION**

An ongoing global health disaster, the COVID-19 epidemic continues to rage. Vaccine formulations and treatment regimens are the medical community's greatest shot for getting life back to "normal" in the near future, since emergency solutions range from social immunizations to cutting-edge scientific breakthroughs. Vaccines that aim to lessen the severity of the pandemic have entered the market over the last year or so, with approval from both international and national authorities based on emergency use standards. Even in India, the vaccination front looked promising for 2021. The licenses enabling limited emergency use for Covishield (produced by an Oxford-AstraZeneca cooperation) and Covaxin (developed indigenously by BharatBiotech in conjunction with ICMR) were granted by the Drugs Controller General of India on January 2, 2021. During the initial round of vaccinations in



February 2021, priority was given to frontline health professionals, police officers, and municipal employees. Vaccines were made accessible for those over the age of 60 and those over the age of 45 with co-morbidities by March of 2021. Governments and policymakers were preoccupied with worries over vaccination reluctance throughout the first few months. Vaccine shortages and their availability were hardly touched upon. Accordingly, it came as no surprise that India has also exported 58 million doses of vaccine to over 65 nations under its so-called "Vaccine Maithri" program by March 10, 2021. <sup>4</sup>When the second wave of the epidemic struck Maharashtra and Delhi in April of 2021, vaccine supply became a major worry. Vaccine equity was obstructed by international and national patent regimes, the Indian government was evidently sluggish in increasing manufacturing capacity, and the idea of placing advance orders on vaccines was not given enough consideration. Other developed countries had done this as early as June 2020.

However, in light of the current vaccine scarcity, a topic that had been discussed a few months ago—the potential waiver of intellectual property ("IP") rights over Covid-related drugs and equipment—has been brought up again. In a joint submission to the TRIPS Council, South Africa and India requested a derogation from certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19 on October 2, 2020. This communication emphasized the importance of WTO members working together to ensure that people fighting the pandemic have faster and easier access to life-saving medications, vaccines, and medical products, as well as new opportunities for medical research and development.<sup>5</sup> We revisited the subject in November 2020 and provided more instances to back up our claims. Patents acted as a barrier to medication availability, as South Africa pointed out, since pharmaceutical companies Regeneron and Eli Lilly had locked up production capacity in bilateral agreements for monoclonal antibody treatments. South Africa further exemplified how Pfizer's patent on the pneumococcal vaccine, an inoculation recommended by the World Health Organization to prevent pneumonia in children, hindered its broad adoption in low- and middle-income nations. By the way, Médecins Sans Frontières (MSF) has petitioned the Delhi High

Court in India to nullify Pfizer's drug patent, arguing that the vaccine's formulation is merely an improvement upon an earlier one and citing the fact that Pfizer's patent had already been nullified by the European Patent Office.<sup>7</sup> Not only do the governments of low- and middle-income nations spearhead the need for an IP waiver, but so do international organizations like MSF and the WHO. A briefing paper on the potential benefits of IP waiver has been presented by MSF. The main point raised by MSF is that the use of WTO flexibilities and a case-by-case approach would not provide positive results. The main reason for this is that the pharmaceutical sector is known to take advantage of license arrangements.<sup>8</sup> A patent waiver would be much appreciated by WHO during the epidemic, according to the Chief Scientist of WHO.<sup>9</sup>

Within the framework of the COVID-19 public health emergency, this article analyses the arguments surrounding the potential abolition of intellectual property rights. Because of the significant expenses of research and development, the pharmaceutical business has a history of being monopolistic and self-serving; as a result, it is very unlikely that the industry would agree to a waiver request. The availability of vaccinations and medications is an important topic of discussion in both academia and business, regardless of the political result of the request for a waiver. Public health and medication access are the primary foci of the WTO/TRIPS system, which is examined in the first section of this article. This paper will analyze how the provisions of the TRIPS Agreement, which deal with trade-related aspects of intellectual property rights, affect public health. Specifically, it will look at how the TRIPS regime's "flexibilities" or the possibility of a "waiver" of TRIPS obligations could affect public health. As acknowledged in the Marrakesh Agreement, the 'waiver' of TRIPS obligations is a fundamental aspect of the WTO system. However, the emphasis on 'flexibilities,' such as compulsory licensing, is heavily influenced by the case law established by the Doha Declaration on TRIPS Agreement and Public Health (the 'Doha Declaration'). This paper's second section will examine the interplay between human rights law on the right to health and the World Trade Organization's regulations on access to pharmaceuticals, as well as the ramifications of this relationship.

## **TRIPS OBLIGATIONS AND ACCESS TO HEALTH CARE**

TRIPS is a multilateral agreement on intellectual property brought into being on the understanding that a uniform and basic level of intellectual property protection is necessary to reduce distortions to international trade. TRIPS came into effect on January 1, 1995. The Agreement sets standards on protections that extend towards all types of intellectual property including copyrights, trademarks, patents, geographical indicators, industrial designs, layout and designs of integrated circuits, and trade secrets. Even though the Agreement places paramount importance on protecting intellectual property, it does in certain circumstance accommodate a waiver of its provisions or alternatively flexibility in the implementation of its provisions. A detailed discussion on waivers and flexibilities is provided in subsequent sections but before that an overview of TRIPS and its relation to public health and access to medicines is first provided.

The TRIPS Agreement make a mention of public health or health in the following provisions, Article 8 (Principles), Article 27 (Patentable subject matter), and Article 31bis (Other use without authorization of the right holder). In addition to the above, Article 7 (Objectives) of the TRIPS Agreement is inferred to have direct relation with discussions on TRIPS and public health.

It is the fundamental commitment of the TRIPS agreement that promoting technological innovation, the transfer and dissemination of technology while ensuring the benefit of producers and users of such knowledge, shall also promote socio-economic welfare. It emphasizes the need to strike a balance between competing interests.<sup>10</sup>

Article 8 of the Agreement acknowledges that it is the undeniable right of Member States to take requisite measures necessary for public health and in the interest of the general public while

simultaneously protecting intellectual property rights. It also stresses the need for such measures to confirm to the provisions of the TRIPS Agreement. Article 8 therefore authorizes Member States to design laws and regulations with due regard to public health concerns.

From a public policy perspective and from the viewpoint of Member States of WTO representing the South, Article 7 & 8 highlights their concerns within TRIPS. These provisions impress upon the reader of the TRIPS Agreement that it is not a pure IP legal framework but one that recognizes **social and economic welfare** of populations impacted by IP regimes and their application in trade. In other words, Article 7 & 8 emphasizes that IP regimes should serve the larger public good rather than be an end in itself.<sup>11</sup>

An examination of the drafting history of Article 7 & 8 discloses that they were brought into being at the instance of developing countries that had to concede to a master draft advanced by developed countries to all types of intellectual property that they owned and had an interest in protecting.<sup>12</sup> Commentators in particular pointed out that it was achievement for the developing countries to have placed these articles as part of body of the treaty and not its Preamble. Scholars have also pointed out that Article 7

& 8 strengthen the operative provisions of TRIPS, and has to be read in the light of General Comment 17 to the ICESCR, which states that "intellectual property is a social product... [with] a social function" and that "the private interests of authors should not be unduly favoured and the public interest in enjoying broad access to their productions should be given due consideration."<sup>13</sup>

Even though there are no expansive interpretation guidelines for Article 7 & 8, the recent decision of the WTO Dispute Settlement Panel in the case of Australia – Tobacco Plain Packaging as well as the Doha Declaration has advanced the general understanding of these two provisions. Incidentally, paragraph 4 of the Doha Declaration on TRIPS Agreement and Public Health states that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access

to medicines for all” (paragraph 4, Doha Declaration).<sup>14</sup>

### WAIVER OF TRIPS OBLIGATIONS

The Marrakesh Agreement Establishing the WTO (the "WTO Agreement") specifies in Article IX that the organization would carry on the GATT regime's practice of reaching decisions by consensus. This provision applies to the organization's scope, structure, and operations. A vote will only be taken in cases when a consensus cannot be reached. Since TRIPS is a Multilateral Treaty within the framework of the World Trade Organization, the exclusive authority to approve interpretations of TRIPS, upon proposal by the TRIPS Council, rests with the WTO Ministerial Conference and the General Council. There is a different procedure for waiving TRIPS or comparable WTO multilateral treaties, in addition to the power of the WTO Ministerial Conference to choose interpretations to TRIPS, as provided for in Article IX sub clause 3. To initiate a waiver, a WTO Member State must first submit a waiver request to the TRIPS Council. The TRIPS Council has 90 days to review the request and report back to the WTO Ministerial Conference on the waiver's validity. In cases where the Ministerial Conference is unable to reach a unanimous decision about the waiver, the topic will be settled by a majority of three-quarters. The extraordinary circumstances that warranted the waiver must be detailed in the Ministerial Conference's resolution. The Ministerial Conference may extend a waiver once a year or until the conditions that prompted it no longer exist. Straight out of the Doha Declaration came the most egregious TRIPS waiver. In 2001, the Doha Round of trade talks began with the goal of reducing economic obstacles between nations. This round of talks focused on the critical problem of trade barriers based on intellectual property. This led to the adoption of the Doha Declaration on Public Health and the TRIPS Agreement in November 2001; its specifics are detailed below. The execution of the Doha Declaration was anticipated, since it was a soft legislation. There was an unsuccessful attempt to propose a waiver in August 2002 that was based on the Doha Declaration. The decision to waive was approved by the TRIPS Council in August 2003.<sup>15</sup> Under the terms of the

waiver, pharmaceuticals produced after a compulsory license agreement are not limited to distribution to domestic markets but may reach international markets as well. Additionally, the need that right holders be adequately compensated when forced licenses are given was waived. For the exporting country member, "Article 31(f) of the TRIPS Agreement is waived on the condition that an eligible importing member notifies the TRIPS Council that it has insufficient or no manufacturing capacity in the pharmaceutical sector for the product in question." This was the practical interpretation of the waiver.<sup>16</sup> This waiver was eventually included into the TRIPS Agreement as an amendment. The protocol of 6 December 2005, which added Article 31bis to the TRIPS Agreement, went into force on 23 January 2017. This article completes the process for the export of medicines to developing and least developed countries, where they are manufactured as a result of a mandatory licensing agreement. In October 2020, the present patent waiver request for COVID-19 equipment and medicament was filed. The matter was deliberated by the TRIPS Council in May 2021, and it is anticipated that a report would be presented to the WTO ministerial Conference in November 2021. According to experts, this plan would not have an immediate impact as intended by the WTO Agreement and TRIPS since the TRIPS Council has ignored the 90-day timeframe after India and South Africa's request for a waiver. <sup>17</sup> Indian public health advocates have long argued that a patent waiver would be beneficial; citing Remdesivir as an example, they say that the drug's price would drop in India and that it would be available for export if patent holder Gilead Sciences were to waive their rights to sell the drug.<sup>18</sup>

### FLEXIBILITIES UNDER TRIPS

At the Fourth Ministerial Conference at Doha (2001), the WTO had conferred upon Members States the mandate to negotiate aspects of TRIPS that posed difficulties at the implementation level. Consequently, the Doha Declaration was “designed to respond to concerns about the possible implications of the TRIPS Agreement for access to medicines.”<sup>19</sup> The Declaration affirms that governments’ have the right to





access the flexibilities provided for under the TRIPS Agreement and “clarifies some of the forms of flexibility available, in particular compulsory licensing and parallel importing.”<sup>20</sup>

Paragraph 4 of the Doha Declaration emphasizes that each provision of TRIPS Agreement is to be understood and interpreted in tune with its objectives and principles. It clarifies that every member is vested the freedom to grant compulsory licenses and also decide the circumstances in which these may be granted. Significantly it also recognizes members’ right to assess when there occurs a national/extreme emergency/public health crises including epidemics.

Paragraph 4 (a) affirms that in line with general principles of international law, the WTO and its associated agreements will be interpreted having due regard to the rule on the purposive interpretation of treaties. This rule is found both in customary international law as well as in Article 31(1)Vienna Convention on the Law of Treaties.

Paragraph 4(b) & (c) emphasis upon the right of members to exercise the flexibility of compulsory licensing and paragraph 4(d) refers to a second flexibility known as parallel importation. In this paper, the feasibility of compulsory licensing as flexibility during the time of Covid-19 pandemic is examined.

### COMPULSORY LICENSING UNDER TRIPS

It was in 1623 that the UK statute of monopolies introduced Compulsory Licensing. Thereafter it gradually evolved and in 1883 it was introduced as an integral part of patent legislation in UK. It was

primarily targeted at patents wherein public demand was unmet or where interested people were prohibited from utilizing an invention. This trend deeply influenced most of the subsequent patent legislations across countries including the International Convention for the Protection of Industrial Property, also known as the Paris Convention. Thus the question of patent waiver arose only if Compulsory Licensing failed to address the issues encountered. Thus Compulsory Licensing emerged as an efficient tool to resolve the consequences of exclusive patent rights.

A “compulsory license”<sup>21</sup> is an authorization given by a national authority to a person, without or against the consent of the title-holder, for the exploitation of a subject matter protected by a patent or other intellectual property rights.<sup>3</sup>

Article 31 of TRIPS Agreement authorizes WTO Member countries to provide for compulsory licenses in respect of certain patents.<sup>22</sup> In times of national emergency or extreme emergency or in cases of public non-commercial use member countries are directed to first negotiate or seek approval from the patentee of the vaccine or drug for the manufacture of the same to meet the demand through a voluntary license. In case of failure of such attempts TRIPS in Article 31 (b) allows members to issue Compulsory license to domestic manufacturers to produce these without the patent holder’s permission.<sup>23</sup> Despite this, a cumbersome issue with respect to Compulsory Licensing is Article 31 (g), which makes provision of the termination of a compulsory license as soon as the circumstances which led to its grant, cease to exist. This would mean uncertainty for the licensees’ right, thus discouraging the use of the mechanism of compulsory licensing, thus defeating its purpose.<sup>24</sup>

Since the adoption of TRIPS, Article 31(f) TRIPS posed a significant obstruction in access to medicines. Article 31(f) TRIPS mandatorily requires that a proposed user of compulsory license shall use the compulsory license to predominantly supply the domestic market. Member States of the WTO from the South found the provision a significant obstruction in the achievement of public health objectives, as these States relied upon cheap import of medicines to tackle health crisis. Many countries faced with ongoing epidemics such as HIV/AIDS, tuberculosis, malaria etc, which had an absence of pharmaceutical manufacturing capacities, pushed for relaxations to Article 31(f) which eventually led to the enactment of Article 31bis.

Article 31bis lays down a procedure for accessing medicines through import from manufacturing countries in the event of national emergency or other circumstances of extreme urgency.

Article 31bis was created with the needs of the developing and least developed countries in mind



as certain countries in the Annex to the TRIPS Agreement (“Annex”, elaborating upon Article 31bis), such as Australia, Switzerland, United States, Norway have all agreed not to benefit from the special procedure provided for in Article 31bis.

Article 31bis states that an eligible importing member may make a notification to the TRIPS Council about the name and quantity of the product in need, establish that the importing country has ‘insufficient manufacturing capacity’ (a defined term in the TRIPS Agreement) in the pharmaceutical sector for the production of the medicine and confirm that if the drug is patented in its territory, it will grant a compulsory license in accordance with Articles 31 and 31bis of the TRIPS Agreement.

The Annex also imposes obligations on exporting countries such as caps on production (including a specification that the entire production should be exported), special labelling requirements and disclosure the TRIPS Council on the quantities of medicines being exported to meet the national emergency or situation of extreme urgency. The above-described procedure is subject to annual review for compliance by the TRIPS Council. Till date, the Article 31bis regime has only been used by Canada to export antiretroviral drugs to Rwanda.<sup>25</sup> Moreover, both Médecins sans Frontier which supported Rwanda in this endeavor as well the generic manufacturer of the drug in Canada have come out heavily against the process which in practice bureaucratic and neither expeditious or nor easily workable.<sup>26</sup>

India has domestic laws on compulsory licensing found in Sections 82-94 of the Indian Patents Act, 1970. These provisions benefit both the domestic market as well as the needs of countries that seek to import drugs from India for reasons of cost effectiveness. In the context of the current pandemic, a significant intervention that the government will have to make is to grant compulsory licenses under Section 92 of the Patent Act (Special provision for Compulsory Licenses on notification by the Central Government). Here, the government notifies a list of patents that should be subject to

compulsory licensing and allows

individuals to commercialize the same subject to an application being made to the Controller of Patents. Section 92 removes a few of the typical conditions applicable to compulsory licenses, including a hearing of the patentee, in the interest of expediency. However, remuneration as fixed by the Patents Controller will become due to the patentee. The India Patent Act, 1970 does not end with the alternative of compulsory but also goes on to provide for ‘take over’ of a patent either by authorizing its use for government purposes - under Section 100 of the Patent Act (Power of the Central Government to Use Inventions for the Purpose of Government) – or permitting for the acquisition of the patent from the patent holder under Section 102 of the Patent Act, upon a payment of reasonable remuneration.

The Supreme Court of India in a suo motto petition, *In re: distribution of essential supplies and services during pandemic* is seized of the grave situation in India where there is severe shortage in access to medicines and vaccines.<sup>27</sup> The court’s order dated April 30, 2021 has outlined the above legal framework that can be accessed by the government for addressing the shortage in medicines and vaccines and has urged the government to seriously consider the option of compulsory licensing given that countries such as Canada and Germany have already resorted to IP relaxations to facilitate access to medicines.

### TECHNOLOGY TRANSFER AND ITS RELEVANCE IN ACCESS TO MEDICINES

In order to make vaccinations accessible on a worldwide scale, technology transfer seems to be crucial.<sup>28</sup> One approach to make sure that vaccinations and medications are accessible to more people is via compulsory licensing. However, many critics have pointed out that this strategy won't work unless there's a transfer of technology.<sup>29</sup> Members of the World Trade Organization have a legal responsibility to assist LDCs in transferring technology. In order to fulfill their obligations under Article 66 of the TRIPS Agreement, developed member nations must incentivize their own businesses and institutions to facilitate technology transfer to



least developed nations. But it's not uncommon for middle-income nations like Brazil and India to bear the brunt of this burden.<sup>30</sup> Transferring knowledge in the pharmaceutical sector often involves one of the three main steps in the manufacturing process: formulation, packaging, or the Active Pharmaceutical Ingredient (API).<sup>31</sup> According to the World Intellectual Property Organization, technology transfer can be described as "a series of processes for sharing ideas, knowledge, technology and skills with another individual or institution (e.g. a company, a university or a governmental body) and of acquisition by the other of such ideas, knowledge, technologies and skills." This definition encompasses a broader range of activities.<sup>32</sup> The transferee is bound by a number of obligations when it comes to technology - "limits on further transfer of technology or know-how to third parties, the maintenance of trade secrets, preservation of patent monopolies for a certain period, price floors/ceilings, royalty payments and other terms may all be included in transfer agreements."<sup>33</sup> To finalize technology transfer deals, data exclusivity relaxations may be required, however this is by no means guaranteed.

<sup>34</sup> The need of developing nations being able to manufacture their own vaccinations and medications via the transfer of technology has been the subject of research by the World Health Organization and other organizations for some time. In terms of pharmaceuticals, the World Health Organization's strategy has been to compile a list of essential medications and then use technology transfer agreements to encourage the local manufacture of those treatments.<sup>35</sup> It is not always economically feasible to produce vaccinations locally. From the standpoint of national health security, however, international authorities have previously recommended domestic manufacturing.<sup>36</sup> Researching the origins of pharmaceutical manufacturing in the region reveals that emerging nations' drug production capacities were severely lacking in the 1970s. In poor and medium income nations, this often caused public health crises, which prompted the World Health Organization (WHO), the United Nations Industrial Development Organization (UNIDO), and the United Nations Conference on Trade and Development (UNCTAD) to work together on

the issue. Around this time, the world's nations tried to come up with a code of conduct for the transfer of technology, but they had to give up because of the gulf that existed between the North and the South.<sup>37</sup> India, China, Brazil, and South Africa are among the emerging nations with the most advanced industrial capacity for producing medications locally. There is a comparable tale of vaccine manufacture in the realm of vaccinations. After a precipitous decline in vaccine manufacturing in the 1970s, international organizations were forced to step in during the next several decades to ensure sufficient vaccine supplies. In contrast to pharmaceuticals, which may be easily manufactured by chemical synthesis, vaccinations are complicated biological products, making their local manufacturing more challenging.<sup>38</sup> Furthermore, patents are not seen as the main reason why local manufacture of vaccines cannot occur, since this is often dependent on the proper transfer of know-how and research and development in the receiving state.<sup>39</sup>

Despite the challenges associated with transferring vaccine production technology to underdeveloped nations, it is clear that manufacturing vaccines locally greatly improves access. Developing nations provide the United Nations with 64 percent of the EPI vaccinations purchased in 2011, according to figures.<sup>40</sup> This is most clearly shown by the fact that the three most popular vaccines—Hib, Hepatitis B, and Meningitis A—are all made in the same country. Finally, academics have speculated that rich nations aren't likely to support domestic pharmaceutical manufacture until there's absolutely little hope for the medicine's economic viability or if developed-world manufacturing capabilities are insufficient. When it comes to vaccinations, it's true that poor nations with a lot of money and people tend to have knowledge transfer agreements with big multinational vaccine manufacturers, but smaller

, lower-income countries may be not secure technology transfers unless it is with public support.<sup>42</sup>

## **I. RECONCILING HUMAN RIGHTS REGIMES ON ACCESS TO MEDICINES WITH THE WTO REGIME**

Both the international human rights framework and several domestic courts have acknowledged the right to health and the right to get necessary pharmaceuticals. The right of every individual to the best possible physical and mental health is guaranteed in Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR). According to General Comment 14 (2000) of the International Covenant on Economic, Social, and Cultural Rights, which explains the contents and extent of Article 12, nations must ensure that all citizens have safe access to medications as part of their right to health. States are obligated "to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs," according to the General Comment, which is their "Core Obligation." Further, General Comment 14 briefly mentions that Article 12 acknowledges that "[t]he right to treatment includes the creation of a system of urgent medical care in cases of accidents, epidemics and similar health hazards, and the provision of disaster relief and humanitarian assistance in emergency situations." The right to health is explicitly addressed in international human rights law as a matter of state responsibility, aid, and action in the event of a pandemic.

Since its adoption in 1966, the right to health has had very little interaction with the system of intellectual property rights. The need to establish a unique framework to safeguard traditional knowledge and the TRIPS negotiations in the 1990s brought the two fields of law and their inherent tensions to the forefront of global attention.<sup>43</sup> Academics came to the conclusion that the IP system was not really implementing human rights at that moment.<sup>44</sup> Intellectual property rights were deemed a significant obstacle to the attainment of economic, social, and cultural rights in the 2000/7 resolution of the Sub-Commission on the Promotion

and Protection of Human Rights, which highlighted the conflict between the two sets of rights.<sup>45</sup> The goal of subsequent human rights approaches to IP rights challenges was to establish IP rights as subservient to human rights norms. Scholars have argued that, in light of the tensions between IP and human rights, it would be beneficial to create more "soft law" instruments outlining IP's relationship to human rights and its boundaries, as well as to articulate IP's maximum standards (as opposed to IP's minimum standards, as in the TRIPS approach).<sup>46</sup>

The same treaty has a clause that affects the relationship between human rights and intellectual property rights, apart from Article 12 of the International treaty on Economic, Social, and Cultural Rights (ICESCR). "State Parties to the Covenant recognize the right of everyone... to enjoy the benefits of scientific progress and its application," reads Article 15 (1) (b) of the International Covenant on Economic, Social, and Cultural Rights, which is part of Article 15 (Participation in Scientific and Cultural Activities). Examining the breadth of Article 15 (1) (b), the Committee on Economic, Social and Cultural Rights notes in General Comment 17 (2006) that: Ultimately, intellectual property is a social product and has a social function. States parties thus have a duty to prevent unreasonably high costs for access to essential medicines, [emphasis added] plant seeds or other means of food production, or for schoolbooks and learning materials, from undermining the rights of large segments of the population to health, food and education.

The right to health and the right to participate in and benefit from scientific progress are inseparable rights that must be liberated simultaneously in accordance with the universality, indivisibility, interdependence, and interrelatedness of all human rights as stated in the 1993 Vienna Declaration and Programme of Action on Human Rights. Human dignity is undermined when intellectual property

rights regimes are given more weight than access to medicines, according to the international human rights regime. In retrospect, the years 2000–2006 were a time of fruitful cooperation between the international human rights regime and the WTO system, leading to the successes at Doha, even if the discussion on IP rights, medical accessibility, and human rights is far from ended.<sup>47</sup>

### **CONCLUSION**

Despite the passing of twenty years since the Doha Declaration, little has been done to improve the accessibility of medicines on a local level, either by increasing domestic drug production or by facilitating international trade in medicines to address public health emergencies. Three score and thirty-three WTO member states still need to ratify the TRIPS Agreement modification and its Protocol to Article 31bis, which would ease the trade of medications in times of national emergency or severe urgency. Except for a single instance, the World Trade Organization's protocol for the supply of inexpensive medications in times of need has not been implemented. It is obvious that people view the WTO-TRIPS mechanism with distrust because of its emphasis on compulsory licensing, and it is becoming more difficult to calm anxieties of trade conflicts in the event that this mechanism is used. In light of the present epidemic, domestically, compulsory licensing seems to be the way to go in order to address the urgent scarcity of vaccinations and medications. Medicine shortages can be advertised at local, national, and international levels, and government attention can be directed to more urgent issues like vaccine equity, but only if the international community takes action towards a WTO waiver on intellectual property rights (in whatever form that pharmaceutical companies are willing to accept) in response to this pandemic. At last, the pandemic's lessons learned should motivate governments, NGOs, and companies to resume human rights-based discussions on medication access.