

VIEWPOINT

Protecting Public Health through Technology Transfer: The Unfulfilled Promise of the TRIPS Agreement

ELLEN 'T HOEN

The scrambling for access to COVID-19 vaccines by developing countries has reignited the debate on the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and its effects on public health and health-related rights.

In such debates, the TRIPS Agreement is often cast as “the big evil.” There is no denying that when the TRIPS Agreement was adopted in 1995, it ushered in intellectual property (IP) norms and standards derived from wealthy nations with robust industries. These norms and standards were suitable to expand the global protection of the IP assets of these industries. However, TRIPS was ill-suited to the needs of developing and least-developed nations, representing the majority of the WTO's membership. In 2002, the World Bank estimated that the implementation of the TRIPS Agreement by developing countries would amount to more than US\$20 billion in income transfers from developing countries to technology-creating nations—particularly the United States, Germany, and France.¹ The promised trade-off from the TRIPS Agreement was that the higher levels of IP protection would lead to technology transfers from high-income to lower-income countries and that the benefits of this technology transfer, creating research and industrial activities in lower-income countries, would outweigh the cost of expanded levels of IP protection. Article 66.2 of the TRIPS Agreement stipulates that high-income countries “shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.”

Disputes around access to HIV medicines in the late nineties and early 2000 first called the TRIPS promise into question: medicines were accessible in wealthy countries, but IP protection meant that treatment prices were often several times the per capita income if they were available at all in the lower-income countries hardest hit by the disease. It was not until patent barriers were cleared away that low-cost generic medicines became widely available where they were needed most. More recently, the unsuccessful attempts by vaccine producers—most of them in developing countries—to access the intellectual property, manufacturing know-how, and technology needed to produce COVID-19 vaccines may have confirmed the view that the TRIPS Agreement primarily serves the rich to the detriment of the poor.²

The right to health, including access to medicines and vaccines, is firmly rooted in international human rights law and some domestic constitutional law.³ However, this right is hard to realize and enforce

ELLEN 'T HOEN, PhD, is a lawyer and public health advocate with a focus on pharmaceutical and intellectual property policies, and director of Medicines Law & Policy, Amsterdam, the Netherlands.

Please address correspondence to the author. Email: ellenthoe@medicineslawandpolicy.net.

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when medicines and vaccines are predominantly available from private corporations that hold monopoly rights to those products. As a result, those companies determine when, where, and at what price the products are made available.

While this is the reality of today, the stated objective of the TRIPS Agreement in fact focuses on creating societal benefits for all and supporting the transfer of technologies. In particular, articles 7 and 8, which lay out the objectives and principles of the TRIPS Agreement, deserve more attention.

Article 7 acknowledges that the protection and enforcement of IP should benefit society as a whole, not only rights holders. It describes the IP system as a social policy tool rather than a means to gather and hold on to assets. It refers explicitly to technology transfer and dissemination of technology. Article 8 acknowledges countries' rights to take measures to protect the public interest and specifically public health. It further states that measures may be needed to prevent abuse by IP holders and to prevent practices that restrain trade or adversely affect technology transfer.

The Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference in 2001, confirmed this right and spotlighted compulsory licensing (the authorization to use patents without the consent of the patent holder against an adequate remuneration) to ensure access to medicines for all, further strengthening the hand of governments to intervene when patents are a barrier to accessing medical products.⁴

While TRIPS articles 7 and 8 and the Doha Declaration do not explicitly refer to human rights, they are crucial provisions for the realization of the right to health.⁵ For example, the Doha Declaration states that the TRIPS Agreement “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.” This paragraph echoes article 12 of the International Covenant on Economic, Social and Cultural Rights, which requires that states take steps necessary for the full realization of the right to health. The importance of taking the Doha Declaration into account when interpreting the

TRIPS Agreement was confirmed by a WTO panel in the *Australia – Tobacco Plain Packaging* case.⁶ This ruling offered important encouragement for pro-public health interpretation and implementation of the TRIPS Agreement.

The TRIPS Agreement provides ample scope for WTO members to intervene in private IP rights on public interest grounds, to protect public health, or to respond to an emergency in international relations such as a pandemic.⁷

In the past, countries have resorted to compulsory licensing, including government use of patents, to allow the supply of generic antiretroviral medicines for the treatment of HIV. Since 2001, the TRIPS Flexibilities Database—a resource that tracks when TRIPS flexibilities are proposed or executed—has documented 80 instances of compulsory licensing for public health in 43 countries.⁸ Thirty-four least-developed country (LDC) members of the WTO have used the special provision for LDCs that allows them not to grant or enforce pharmaceutical product patents.⁹ The WTO has 35 LDC members.

In 2021, all of the 10 new instances of compulsory licenses concerned products to prevent or treat COVID-19. This underlines the value of being able to get around IP protection when public health is at risk. Of course, compulsory measures come into play only when voluntary measures are not sufficient, which was the case for COVID-19 vaccines. Collaboration with the World Health Organization’s COVID-19 Technology Access Pool, a voluntary mechanism for sharing IP related to pandemic countermeasures established in May 2020, was rejected by COVID-19 vaccine companies.

Compulsory licensing is also at the core of the WTO Ministerial Decision of June 17, 2022, on the TRIPS Agreement in the context of the COVID-19 pandemic, often referred to as “the TRIPS waiver.”¹⁰ The decision reiterates members’ rights to authorize the use of the subject matter of patents needed for the production and supply of COVID-19 vaccines, without the consent of the patent holder. The decision further waives the TRIPS requirement that a compulsory license of vaccine technology be predominantly for the supply of the domestic mar-

ket, so that equitable access can be achieved across countries. But since compulsory licensing extends only to patents and not to other forms of IP that are essential in vaccine production, such as manufacturing know-how, the utility of the decision for vaccines will likely be limited. Discussions are now ongoing at the WTO to extend the decision to COVID-19 therapeutics and diagnostics, which are more suitable technologies for compulsory licensing.

Tension between protecting IP and protecting the human right to health remains. The COVID-19 pandemic and the inability of developing-country manufacturers to obtain IP, know-how, and technology needed to produce COVID-19 vaccines through voluntary measures illustrates the need for a more forceful implementation of the measures the TRIPS Agreement offers to rebalance IP and human rights. If vaccine companies had agreed to collaborate with the COVID-19 Technology Access Pool to share IP, provide manufacturing know-how, regulatory information needed to obtain marketing authorization, and technical assistance, eligible producers in various countries would have been able to start producing and supplying COVID-19 vaccines. Instead, vaccines were first supplied within the wealthy nations that held the technology to produce them. The subsequent hoarding of vaccines by those nations might have cost a million lives.¹¹

In 2015, the then United Nations Secretary-General Ban Ki-moon established the High-Level Panel on Innovation and Access to Health Technologies to “review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”¹² The eight recommendations of the panel regarding the protection of intellectual property center around the use of TRIPS flexibilities, which can be implemented within the current TRIPS framework. However, the panel also warned against the pursuit of stricter levels of IP protection in bilateral and regional trade talks. Specifically, the panel recommended that countries refrain from

demanding that their trading partners implement IP obligations that go beyond TRIPS. The recently leaked draft IP chapter of the UK-India free trade agreement is evidence that high-income countries continue to seek to erode TRIPS flexibilities implemented in national law.¹³ The lack of transparency around such trade negotiations means that democratically crafted national legislation is changed in closed-door trade negotiations. Considering the important role of the Indian pharmaceutical industry in the supply of low-cost medicines, applying stricter IP rules that are not required under WTO law will have consequences far beyond India alone.

The panel further recommended that public financing for research should require that the research results be shared and that IP be licensed, including through patent pools, to promote technology transfer and enable broad access to innovations.

The pandemic treaty that is currently being negotiated at the World Health Organization is an opportunity to remind the international community about the objectives and principles underlying the TRIPS Agreement and to see them put into practice for more equitable management and sharing of IP, know-how, and knowledge needed for pandemic preparedness and response. In October 2021, Medicines Law & Policy held an expert working group meeting that formulated seven recommendations for the pandemic treaty that are consistent with international human rights law.¹⁴ One of the recommendations is to mandate technology transfer for government-funded research and to incentivize or mandate it for privately funded research on pandemic countermeasures.

The lack of equity in access to COVID-19 vaccines makes us wonder what would have happened if governments had taken measures to ensure the sharing of health innovations and the knowledge needed to make them. The World Health Organization’s pandemic treaty negotiations offer a new opportunity to put technology transfer and sharing of IP at the heart of global pandemic preparedness and response for more equitable and rights-based access to medicines for all.

References

1. World Bank, *Global Economic Prospects and the Developing Countries* (Washington, DC: World Bank, 2001).
2. G. Krikorian and E. Torrelee, "We Cannot Win the Access to Medicines Struggle Using the Same Thinking That Causes the Chronic Access Crisis," *Health and Human Rights Journal* 23/1 (2021).
3. L. Forman, "'Rights' and Wrongs: What Utility for the Right to Health in Reforming Trade Rules on Medicines?," *Health and Human Rights Journal* 10 (2008); K. Pehudoff, B. Toebes, and H. Hogerzeil, "Essential Medicines in National Constitutions: Progress since 2008," *Health and Human Rights Journal* 18/1 (2016).
4. Fourth WTO Ministerial Conference, Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (2001); E. 't Hoen, "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha," *Chicago Journal of International Law* 3 (2002).
5. C. Correa, "Interpreting the Flexibilities under the TRIPS Agreement," South Centre Research Paper 132 (2021).
6. T. Romero, "Public Health and Plain Packaging of Tobacco: An Intellectual Property Perspective," South Centre Research Paper 108 (2020).
7. Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1896 U.N.T.S. 299 (1994), arts. 27, 30, 31, 31bis, 44.2, 66, 73(b)iii; South Centre, "A Public Health Approach to Intellectual Property Rights: Public Health Related Flexibilities in the TRIPS Agreement," <https://ipaccessmeds.southcentre.int/wp-content/uploads/2018/12/Public-Health-Related-Flexibilities-in-the-TRIPS-Agreement.pdf>; F. Abbott, "The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic," South Centre Research Paper 116 (2020).
8. Medicines Law & Policy, "The TRIPS Flexibilities Database," <http://tripsflexibilities.medicineslawandpolicy.org>; E. 't Hoen, J. Veraldi, B. Toebes, and H. Hogerzeil, "Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016," *Bulletin of the World Health Organization* 96/3 (2018).
9. Fourth WTO Ministerial Conference (see note 4), para. 7.
10. World Trade Organization, *Ministerial Decision on the TRIPS Agreement* (June 17, 2022).
11. H. Ledford, "Covid Vaccine Hoarding Might Have Cost More Than a Million Lives," *Nature* (November 2, 2022).
12. United Nations, *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies* (New York: United Nations, 2016).
13. Bilaterals.org, "UK-India FTA: Draft Intellectual Property Chapter" (April 2022), https://www.bilaterals.org/IMG/pdf/uk-india_fta_ip_chapter_dated_april_2022_68_.pdf.
14. K. Pehudoff, E. 't Hoen, K. Mara, et al., "A Pandemic Treaty for Equitable Global Access to Medical Countermeasures: Seven Recommendations for Sharing Intellectual Property, Know-How and Technology," *BMJ Global Health* 7/7 (2022).