

The TRIPS Waiver is Necessary, but it Alone is not Enough to Solve Equitable Access to COVID-19 Vaccines

Introduction

High-income countries have dominated the limited supply of COVID-19 vaccines, leaving low and middle-income countries (LMICs) with limited, if any, supplies of these life-saving countermeasures.¹ The cause of this is two-fold: 1) insufficient doses of vaccine to meet the global demand, and 2) procurement of those limited doses which do exist has been dominated by a small number of high-income countries. The result is a deep and growing inequality in access to vaccines for COVID-19. A potential solution is to empower manufacturers, particularly those based in LMICs, to begin making COVID-19 vaccines, to expand global supply. However, intellectual property rights create a clear barrier to this solution. A dense web of intellectual property exists over the vaccines and the manufacturing platforms used to make them.² This web is both formal and informal; the manufacturing platform used to manufacture a vaccine is protected by numerous patents, while manufacturing methods and techniques (know-how) are protected informally as trade secrets.

In October 2020, India and South Africa proposed that members of the World Trade Organization (WTO) should “work together to ensure that intellectual property [IP] rights such as patents, industrial designs, copyright and protection of undisclosed information *do not create barriers to the timely access to affordable medical products* including vaccines ... or to scaling-up of research, development, manufacturing and supply of medical products essential to combat Covid-19.”³ They further proposed that an IP

“waiver should continue until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity” on the basis that “exceptional circumstances exist justifying waivers from the obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).”⁴ Since then, a number of WTO members have agreed with this position, including, recently, the United States of America. The changing position of the United States on this issue has led many commentators to hope that the waiver stands a genuine chance of passing, and passing faster than the previous WTO IP waiver, which took ten years to negotiate.⁵ This *Insight* will highlight that while promptly passing the TRIPS waiver is a vital step in ensuring equitable access to COVID-19 vaccines for the world’s poorest populations, it is not itself a sufficient step, as it does not oblige the transfer of associated technology or know-how.

Waiving TRIPS Obligations

Membership in the WTO is contingent upon parties acceding to TRIPS and incorporating its provisions into domestic law.⁶ TRIPS attempts to harmonize IP standards around the world, in an effort to provide consistency and certainty for rights holders.⁷ It is relevant to expanding COVID-19 vaccine manufacturing by requiring that WTO member states provide minimum IP protections and standards,⁸ and outlining enforcement actions that countries must have in place to remedy violations of the above standards.⁹ WTO members must offer patents for a minimum of 20 years, including in the field of pharmaceuticals.¹⁰ WTO members cannot, for example, refuse to register or recognize a patent on a COVID-19 vaccine, or associated technology.¹¹

TRIPS also outlines procedures for the granting of compulsory licenses to mitigate the potential harm caused monopolistic IP rights during a national emergency.¹² Compulsory licensing does not eliminate any IP rights. Rather, it allows a national government to grant permission to a third party to use the patent-protected technology, even if it is against the wishes of the patent holder. Compensation must be paid to the patent holder, and attempts at prior licensing negotiations must have failed prior to a compulsory license being granted.¹³ Compulsory licenses have been used during HIV epidemics by WTO members to expand access to antiretrovirals in LMICs.¹⁴ They disrupted the exclusive monopolies of the patent holders, allowing generic manufacturers to enter the marketplace, priced significantly lower than the patent holder, and expand access. Millions of lives were saved as a result. The IP waiver proposed by India and South Africa hopes to achieve something similar, by authorizing WTO members to bypass the bottlenecks caused by IP and authorize generic manufacturers in their territories to begin producing COVID-19 vaccines.

Crucially, the proposed waiver (if passed) could represent an important efficiency gain in COVID-19 vaccine manufacturing. The current arrangement is such that a potential vaccine manufacturer must survey the patent landscape, identify all of the relevant patents that apply to the manufacture of a particular COVID-19 vaccine, negotiate a license for each of these technologies, and only then can they begin manufacturing a COVID-19 vaccine. Given the expansive range of patent protections over COVID-19 vaccine technologies,¹⁵ this is a deeply inefficient process to undertake while millions of lives are lost to a vaccine preventable disease. Furthermore, there is a high likelihood of not obtaining appropriate licenses from the IP holders and no guarantee that some relevant IP has not been missed in the process, opening the manufacturer up to expensive litigation. The waiver would empower countries like India and South Africa to promise legal certainty to any manufacturers in their territory that produce COVID-19 vaccines: the manufacturers will not be held legally liable for patent infringement. While the TRIPS waiver would significantly reduce red-tape and provide much needed legal certainty to manufacturers in LMICs, it alone is not enough to expand manufacturing capacity.

Transfer of Technology and International Law

Unlike chemical pharmaceuticals (most drugs), vaccines are large-molecule biological products requiring a great deal of information and know-how to manufacture—information that is not disclosed through patents.¹⁶ Thus, waiving patent rights alone will not enable new manufacturers to come online. The initial text of the proposed waiver by India and South Africa recognizes the crucial role that know-how plays in vaccine manufacturing capacity. However, unlike with patent rights, there is no clear, easy fix contained within the proposed waiver, and pharmaceutical companies will likely strenuously resist such technology transfer. Without knowledge transfer, it will be extremely difficult for LMICs to start COVID-19 vaccine manufacturing, regardless of the removal of patent barriers from the TRIPS waiver.

The TRIPS Agreement recognizes the importance of technology transfer through its Objectives,¹⁷ and Article 66.2 of TRIPS states that “developed country Members 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.”¹⁸

The WHO has set up a mRNA technology transfer hub to provide a mechanism to facilitate the sharing of know-how related to manufacturing mRNA vaccines, but none of the technology holders have thus far engaged with the hub.¹⁹ This is reflective of wider

efforts by the WHO to facilitate the transfer of technology from established vaccine manufacturers to new manufacturers in developing countries. In recent history this was most notably attempted through the WHO's Pandemic Influenza Preparedness Framework (PIP Framework),²⁰ where the WHO has attempted to use multilateral access and benefit-sharing arrangements to negotiate the sharing of technology in the field of pandemic vaccine manufacturing. To this end, pandemic influenza vaccine manufacturers who wish to receive influenza virus samples from the WHO's network of specialized laboratories must sign a contract with the WHO called a Standard Material Transfer Agreement, committing to at least two of the following options:

A1. Donate at least 10% of real time pandemic vaccine production to WHO.

A2. Reserve at least 10% of real time pandemic vaccine production at affordable prices to WHO.

A3. Donate at least X treatment courses of needed antiviral medicine for the pandemic to WHO.

A4. Reserve at least X treatment courses of needed antiviral medicine for the pandemic at affordable prices.

A5. Grant to manufacturers in developing countries licenses on mutually agreed terms that should be fair and reasonable including in respect of affordable royalties, taking into account development levels in the country of end use of the products, on technology, know-how, products and processes for which it holds IPR for the production of (i) influenza vaccines, (ii) adjuvants, (iii) antivirals and/or (iv) diagnostics.

A6. Grant royalty-free licenses to manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of pandemic influenza vaccines, adjuvants, antivirals products and diagnostics needed in a pandemic. WHO may sublicense these licenses to manufacturers in developing countries on appropriate terms and conditions and in accordance with sound public health principles.²¹

Most notably absent from contracts concluded under the PIP Framework to date is any commitments from manufacturers regarding transfer of technology. This is despite the fact that the importance of technology transfer for pandemic preparedness and

procurement was stressed in the reports of the PIP Framework's Advisory Group and the WHO Director-General during negotiations of the PIP Framework.²²

It is clear, therefore, that developed country Members of the WTO need to provide a strong commitment to share know-how and/or provide economic incentives to pharmaceutical companies based within their territories to actively engage in transfer of technology for COVID-19 vaccines. Doing so would satisfy their Article 66 TRIPS obligations and demonstrate a clear commitment to fair and equitable vaccine access for LMICs. A significant amount of the research and development funding for COVID-19 vaccines was paid for with public monies—either directly by developed country governments, or through public initiatives such as COVAX.²³ This fact alone highlights the limitations of arguments that the TRIPS waiver and associated measures would destroy free-market incentives for R&D investment. Yet, it appears no government, while agreeing to heavily subsidize the COVID-19 vaccine R&D, sought to negotiate IP ownership, or impose obligations on manufacturers receiving this funding to actively engage in transfer of technology to other manufacturers in order to expand any future manufacturing base.

Ideally, access to information and know-how ought to occur through the WHO hub system (which could be expanded beyond mRNA technology), rather than on a direct bilateral manufacturer-to-manufacturer basis, to ensure maximum efficiency and maximum utility from the transfer. If we are to make progress on equitable access to vaccine, the TRIPS waiver must be promptly passed by WTO Members, but until a workable solution to facilitate technology transfer on vaccine technology can be found, we remain at an impasse on equitable access to medicines.

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¹ Mark Eccleston-Turner & Harry Upton, *International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility*, THE MILBANK QUARTERLY (2021).

² Mario Gaviria & Burcu Kilic, *A network analysis of COVID-19 mRNA vaccine patents*, 39 NATURE BIOTECHNOLOGY 546–548 (2021).

³ WTO Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19: Communication From India And South Africa*, IP/C/W/669 (Oct. 2, 2020).

⁴ *Id.*

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- ⁵ Amy Maxmen, *In shock move, US backs waiving patents on COVID vaccines*, NATURE (2021).
- ⁶ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].
- ⁷ Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 1867 U.N.T.S. 14, 33 I.L.M. 1143 (1994)
- ⁸ TRIPS Agreement § 5.
- ⁹ *Id.* Part III.
- ¹⁰ *Id.* art. 33.
- ¹¹ *Id.* art. 27.
- ¹² *Id.* art. 31.
- ¹³ *Id.* art. 31(b).
- ¹⁴ Gorik Ooms & Johanna Hanefeld, *Threat of compulsory licences could increase access to essential medicines*, 365 BMJ I2098 (2019).
- ¹⁵ See e.g. Mario Gaviria & Burcu Kilic, *A network analysis of COVID-19 mRNA vaccine patents*, 39 NATURE BIOTECHNOLOGY 546 (2021).
- ¹⁶ Mark Eccleston-Turner, *The Economic Theory of Patent Protection and Pandemic Influenza Vaccines: Do Patents Really Incentivize Innovation in the Field?*, 42 AM. J.L. & MED. 572–597 (2016); M. Eccleston-Turner, *Beyond patents: Scientific knowledge, and access to vaccine*, 3 ETHICS, MED. & PUB. HEALTH 64 (2017).
- ¹⁷ “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”
- ¹⁸ TRIPS Agreement, art. 66.2.
- ¹⁹ WHO, *Establishment of a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing* (2021), <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing>.
- ²⁰ WHO, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework)* UN Doc. A64/VR/10, 24 May 2011 [hereinafter PIP Framework].
- ²¹ PIP Framework, Annex 2, SMTA2, art. 4.4.1.A.
- ²² WHO, *Pandemic influenza preparedness: Sharing of influenza viruses and access to vaccines and other benefits: Report of the advisory group report by the director-general* (2012), http://www.who.int/influenza/pip/A65_19_en.pdf.
- ²³ Eccleston-Turner & Upton, *supra* note 1.