



Insight

Intellectual Property, COVID-19 Vaccines, and the Proposed TRIPS Waiver

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Executive Summary

- In October 2020, India and South Africa proposed to waive certain intellectual property (IP) protections under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for COVID-19 related drugs and products.
- Over 100 countries, mostly developing, have signed on in support of waiving TRIPS while a handful of developed countries signaled their opposition.
- Waiving TRIPS will do nothing to increase vaccine production, represents poor policy toward IP, and will create new trade policy challenges.

Introduction

In October 2020, India and South Africa requested the World Trade Organization (WTO) suspend certain intellectual property (IP) protections for COVID-19 vaccines and related products. Both countries claim these IP protections, part of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), have slowed production of and access to COVID-19 vaccines. As of May 2021, over 100 countries, mostly in the developing world, have joined India and South Africa in calling for a waiver of TRIPS for COVID-19 vaccines and related products. At the same time, a handful of developed nations—specifically the European Union, Switzerland, Norway, Australia, Canada, Japan, and the United Kingdom—have signaled their opposition to a waiver.

In the United States, the Biden Administration recently [announced](#) that it will support the TRIPS waiver request after intense pressure from progressive activists and Democratic lawmakers in Congress—over 100 of whom have signed a series of letters calling on President Biden to support the proposed TRIPS waiver.^[1] The pressure campaign clearly had an impact on the administration, as its actions conflict with the recent [statement](#) of White House Chief of Staff Ron Klain, who argued “really, manufacturing is the biggest problem. We have a factory here in the U.S. that has the full intellectual property rights to make the vaccine. They aren’t making doses because the factory has problems.”^[2] Also being ignored in the IP debate are logistical distribution challenges and lack of sufficient frontline workers, which contribute to a slow rollout.^[3]

Public posturing aside, the Biden Administration surely knows that a TRIPS waiver for COVID-19 related IP will likely be futile. Scaling up production, as Klain alluded to, has proven to be the main challenge to manufacturing larger quantities of vaccine.^[4] Waiving TRIPS would do nothing to address this constraint. Waiving TRIPS would instead encourage IP abuse and distort market forces and innovation.

TRIPS Provisions

The TRIPS agreement is an international trade agreement among all 164 members of the WTO. It is one of three founding and central components of the WTO, along with the General Agreement on Tariffs and Trade (GATT) and the General Agreement on Trade in Services (GATS).

The purpose of the TRIPS agreement is to unify trade and provide increased certainty in international economic relations. Among other things, TRIPS specifically:

- Provides minimum IP protections and standards that apply to all WTO members;
- Outlines enforcement actions that countries can undertake to remedy violations of the above standards; and
- Establishes dispute settlement procedures to allow countries to negotiate an end to disagreements.

TRIPS does, however, allow for compulsory licensing where in a public health emergency, a country may copy patented drugs without the permission of the original manufacturer with WTO approval.

Proposal to Waive TRIPS

The recent proposal submitted by India and South Africa and signed on by over 100 developing countries would waive four specific protections of COVID-19 vaccines and related medical products and services:

- Copyrights;
- Patents;
- Trademarks; and
- Undisclosed information procedures.

The first three protections allow companies to prevent foreign companies from copying their products. They require the original company to disclose information about the product, however. Foreign companies are free to study the disclosed information of the patent but cannot copy it unless given a licensing agreement from the original company. Contrarily, companies can choose not to get patents for their products and instead keep their information secret. The fourth protection prevents the theft of trade secrets of foreign companies. While TRIPS has been waived previously, if approved, this would be the broadest waiver since the agreement's enactment in 1995.^[5]

TRIPS and Manufacturing Capacity

The primary justification for waiving TRIPS is that IP protections cause underutilized manufacturing capacity. By removing TRIPS, developing nations could copy patented drugs and use their own manufacturers to produce vaccines, thereby increasing access. This rationale, however, is flawed. Adar Poonawalla, CEO of the Serum Institute of India—currently the largest producer of COVID-19 vaccine doses in the world—has argued that access to IP is not limiting vaccine production, rather it is the time involved in scaling up manufacturing capacity.^[6] It should also be noted that Moderna has already pledged not to enforce its own COVID-19 vaccine patents during the pandemic.^[7]

In addition, COVID-19 vaccines such as those produced by Pfizer and Moderna use emerging and very complex

technologies and processes. These technologies and processes are essential to producing and increasing scale of COVID-19 vaccines. They are not published in patents but rather kept as trade secrets. The fourth protection mentioned above only prevents theft of trade secrets; it does not allow or disallow a company from keeping trade secrets. Waiving TRIPS therefore does nothing to speed up vaccine production even if there were excess manufacturing capacity, as manufacturers would not receive the essential trade secrets they would need. The issue at present is not underutilized manufacturing capacity, rather scaling up production has been the largest difficulty of vaccine manufacturing. It takes anywhere from 60 to 120 days to produce a single batch of vaccines. Even with manufacturing challenges, between 9.5 and 13.5 billion doses of COVID-19 vaccines are projected to be produced in 2021. Eleven billion doses would be sufficient to vaccinate 70 percent of the world population and reach herd immunity, assuming 2-dose vaccinations.[8]

TRIPS and Compulsory Licensing

Separate from a broad IP waiver, TRIPS includes a compulsory licensing process. Foreign manufacturers are free to ask a patentee for a voluntary licensing agreement to manufacture a product. This process can be long, however, and the patentee can ultimately refuse. When this happens, TRIPS allows the manufacturer through its national government to grant a compulsory license provided the manufacturer has first sought a voluntary licensing agreement. This compulsory license is issued by that national government to the manufacturer to produce a patented drug without the original patentee's permission. Each compulsory license must apply to a specific product. It is important to note that TRIPS does not have a governing body which oversees this process. At the same time, if a country grants an internationally unpopular compulsory license, it will face economic, political, and retaliatory ramifications from other governments and private firms, so governments must weigh these costs.

In addition, if a country declares a national emergency or other circumstances of extreme urgency, TRIPS allows a foreign manufacturer to immediately apply for a compulsory license, skipping the process to apply for a voluntary license. A TRIPS waiver, like the one suggested for COVID-19-related IP, is therefore entirely unnecessary—even if IP protections were an obstacle to vaccine access. In the case of COVID-19, compulsory licensing would not, however, address the real issues related to scaling manufacturing capacity.

The Vagueness of the Proposed TRIPS Waiver

Under the broad language of the proposed TRIPS waiver, any drugs that have use for patients with COVID-19, including those that predate the pandemic, could lose patent protection. Thus, a foreign company could produce a specific drug under the auspices of COVID-19 but sell it for another disease. Moreover, the foreign company would not have to provide any financial compensation to the company from whom they took the IP. The proposal's language is so broad that other patented medical products beyond pharmaceutical drugs such as masks, non-pharmaceutical chemical compounds, and respirators would also be subject to the waiver.

It is also noteworthy that the vaccines developed by Pfizer, Moderna, and Johnson & Johnson are not currently approved by the Indian government for use in India, due to regulatory obstacles related to localized clinical trials. Effectively then, India is pointing to IP protections as an obstacle to obtaining vaccines they have not even approved for use in their country.[9]

At the same time, a concerted global effort is underway to ensure access to COVID-19 vaccines in all countries. The WHO, Gavi (previously the Global Alliance for Vaccines and Immunization), and the Coalition for Epidemic Preparedness Innovations have partnered to establish the COVAX initiative, designed specifically to

distribute vaccines to the developing world. COVAX is projected to distribute at least 2 billion vaccines by the end of 2021.[10] Johnson & Johnson has further announced plans to distribute 500 million vaccines to developing nations starting in mid-2021, in addition to those it already allocated to other nations.[11]

TRIPS and Innovation

The TRIPS agreement and its IP protections were created to increase unity and certainty in the global economy. The economic certainty provided by IP protections preserve competitiveness and increase value—i.e., IP protections provide incentives to companies to create new and groundbreaking technologies. In terms of the COVID-19 pandemic, perhaps it is these incentives that encouraged companies to produce vaccines quickly and successfully. Without IP protections, companies could not reap the rewards of their efforts. Waiving TRIPS would weaken the market forces that encourage innovation. Combined with the broad language of the TRIPS waiver, the loss of innovation would happen in many industries and sectors of the global economy.

Conclusion

The proposal to waive TRIPS is based on the misperception that IP protections serve as barriers to COVID-19 vaccine production. In fact, the difficulty of scaling up production is the key challenge. Waiving TRIPS will do nothing to increase vaccine production, represents poor policy toward IP, and will create a whole new set of trade policy challenges.

A better approach is to build upon current global vaccine partnerships while ensuring that companies can secure their supply chains. Such efforts would increase access to vaccines while avoiding the potentially widespread and long-term problems associated with waiving IP protections provided by TRIPS.

[1] <https://www.tribuneindia.com/news/nation/over-100-us-lawmakers-urge-biden-to-support-trips-waiver-proposal-of-india-247244>

[2] <https://www.cbsnews.com/news/transcript-ron-klain-on-face-the-nation-may-2-2021/>

[3] <https://www.care.org/news-and-stories/health/our-best-shot-women-frontline-health-workers-around-the-world-are-keeping-you-safe-from-covid-19/>

[4] <https://www.theguardian.com/global-development/2021/feb/14/we-took-a-huge-risk-the-indian-firm-making-more-covid-jobs-than-anyone>

[5] <https://www.un.org/ldcportal/wto-drugs-patent-waiver-for-ldcs-extended-until-2033/>

[6] <https://www.theguardian.com/global-development/2021/feb/14/we-took-a-huge-risk-the-indian-firm-making-more-covid-jobs-than-anyone>

[7] <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19>

[8] <https://launchandscalefaster.org/sites/default/files/documents/Speedometer%20Issue%20Brief-COVID%20Manufacturing%20Landscape%2019%20March%202021.pdf>

[9] <https://www.reuters.com/world/india/pfizer-says-it-told-india-there-no-safety-concern-with-its-covid-19-vaccine-2021-05-03/>

[10] <https://www.gavi.org/vaccineswork/covax-supply-forecast-reveals-where-when-covid-19-vaccines-will-be-delivered>

[11] <https://www.jnj.com/johnson-johnson-announces-advance-purchase-agreement-with-the-african-vaccine-acquisition-trust-for-the-companys-covid-19-vaccine-candidate>