Insight

Another TRIPS Waiver for COVID-19?

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Executive Summary

- The World Trade Organization is considering whether to extend its partial waiver of intellectual property (IP) protections commonly known as the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), on COVID-19 vaccines to cover COVID-19 therapeutics and diagnostics.
- While proponents of extending the waiver claim it would lower barriers to producing these therapeutics and diagnostics, an extension would do nothing to increase COVID-19 treatment production as it is based on the misconception that IP rights prevent access and cause supply shortages.
- Extending the partial TRIPS waiver is unnecessary—there is already overproduction of vaccines—and could weaken the very incentives that drove the successful and rapid rollout of COVID-19 vaccines and treatments.

Introduction

The World Trade Organization (WTO) is considering whether to partially waive certain intellectual property (IP) protections for COVID-19 diagnostics and therapeutics in order to increase production of, and access to, COVID-19 treatments. This decision would follow the WTO's June 16 grant of a partial waiver of IP on COVID-19 vaccines used to accomplish a similar goal. These IP protections are part of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The June 16 decision specifically removed the requirement that foreign vaccine manufacturers apply for a voluntary license before applying for a compulsory license in an effort to make it easier for a foreign manufacturer to receive a compulsory license. The WTO is now considering an extension of this partial TRIPS waiver to COVID-19 diagnostics and therapeutics.

A partial TRIPS waiver for COVID-19 therapeutics and diagnostics is unnecessary for a host of reasons, and largely for the same reasons the June waiver for vaccines was unnecessary:

- It is based on the misconception that IP protections serve as barriers to production, when in reality the relevant barrier involves scaling up production.
- By October 2021, the five world's largest COVID-19 vaccine manufacturers had secured over 300 voluntary partnerships with manufacturers across the globe.[1] Through these partnerships, manufacturers produced over 11 billion COVID-19 vaccine doses in 2021, well before the TRIPS waiver was finalized. [2] [3] There have been numerous similar voluntary agreements to produce therapeutics and treatments.[4]
- The supply of COVID-19 treatments currently outpaces demand.[5] [6]

What's more, COVID-19 treatments and therapeutics use complex and emerging technologies, many of which have uses in other fields besides medicine.[7] IP protections such as TRIPS preserve markets by, among other things, enforcing patents, thereby allowing innovators to see returns on their investments.

TRIPS Provisions, Compulsory Licensing, and the June Waiver

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 and the General Agreement on Trade in Services. The purpose of the TRIPS agreement is to unify trade and increase certainty in international economic relations by codifying and standardizing IP protections shared among all WTO members. TRIPS establishes patent standards, which prevent the immediate copying of new products and technologies, allowing innovators to see returns on their investments, thereby solidifying incentives and facilitating innovation. For more information on TRIPS provisions, visit here.

TRIPS Waiver on Diagnostics and Therapeutics: Unnecessary for the Same Reasons as the Partial Waiver on Vaccines

A TRIPS waiver on vaccines and treatments is unnecessary for the reasons outlined below.

Scaling up Production

The primary justification cited for the WTO's June 16 decision on COVID-19 vaccines is that IP protections have led to underutilized manufacturing capacity. By allowing more compulsory licenses and the exportation of vaccines produced under such licenses, proponents of the decision reason, developing nations could copy patented drugs, use their own manufacturers to produce them, and export those drugs to other countries, thereby increasing access. This rationale is flawed. The primary challenge in manufacturing COVID-19 vaccines is the effort and time it takes to scale up production.[8] The issue is not necessarily that a factory lacks the instructions needed to manufacture COVID-19 vaccines due to TRIPS' IP protections, but rather that following these instructions to produce on a large scale is difficult. Receiving a compulsory license would not facilitate the considerable task of scaling up production.

The Private Sector Has Already Signed Manufacturing Licensing Agreements

As of October 2021, well before the June 2022 partial TRIPS waiver, the world's five largest COVID-19 vaccine manufacturers had already created over 300 manufacturing partnerships across the globe. These voluntary partnerships were largely responsible for the production of over 11 billion vaccines in 2021.[9] [10] There have been many similar agreements to produce COVID-19 diagnostics and therapeutics.[11] [12] According to Reuters, "'COVAX has called for manufacturers to acknowledge the global oversupply situation, and support collective efforts to meet the timing of countries' needs and avoid unnecessary wastage,' said a spokesperson for Gavi, the Vaccine Alliance, which runs the initiative alongside WHO." [13] It should be noted this statement was made in June, the same month the WTO elected to grant the partial TRIPS waiver on COVID-19 vaccines.

Treatment Supply Outpaces Demand

The supply of COVID-19 treatments is currently outpacing demand for them. According to Airfinity data, Pfizer has the capacity to produce over 120 million doses of Paxlovid, a three-pill dose oral antiviral treatment specifically for COVID-19, in 2022. As of August 2022, the contracted supply is at only 41.5 million doses, 35 percent of full production capacity. Similarly, with Merck & Co., Inc, Kenilworth, NJ, USA, and Ridgeback Biotherapeutics' Molnupiravir, an antiviral medication that prevents the reproduction of RNA viruses like COVID-19, demand amounts to just 45 percent of full production capacity.[14]

IP Protections and Future Innovation

The TRIPS agreement and its IP protections promote research and development in, and innovation of, complex and new technologies. These endeavors commonly come with large costs and uncertainty. TRIPS, among other things, enforces patents, which prevents competitors from immediately copying new technologies, and therefore allows innovators to see returns on their investments. IP protections like TRIPS preserve market forces and countries' comparative advantages in high-tech endeavors. Removing IP protections weakens incentives and the market forces that encourage innovation, which have led to the rapid creation of COVID-19 vaccines and treatments. Since COVID-19 vaccines and treatments use complex and emerging technologies that have uses in multiple fields, a TRIPS waiver extension to treatments jeopardizes future research and development in many other fields and sectors, not just in health care.[15]

Conclusion

The WTO's consideration of extending its partial TRIPS waiver to cover COVID-19 diagnostics and therapeutics is unnecessary for two key reasons. First, there is not a shortage of COVID-19 treatments, and second, IP protections are not a significant obstacle to their production. Moreover, extending the waiver would likely disincentivize the very innovation that drove the successful and rapid rollout of COVID-19 treatments.

[1] COVID-19 Vaccine Supply Chain: How We Are Vaccinating the Globe – BIO

[2] https://www.ifpma.org/resource-centre/11-billion-covid-19-vaccines-produced-in-2021-has-resulted-in-the-biggest-immunization-campaign-in-human-history-and-2022-will-require-more-and-better-vaccine-redistribution-and-innovation/

[3] https://www.census.gov/popclock/

[4] Brochure-MPP licenses for therapeutics.indd (who.int)

[5] https://www.reuters.com/business/healthcare-pharmaceuticals/covid-19-vaccine-scheme-worlds-poorest-pushes-delivery-slowdown-2022-06-22/

[6] https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W693.pdf&Open=True

[7] https://www.efpia.eu/news-events/the-efpia-view/blog-articles/a-fact-based-analysis-of-the-trips-waiver-extension/

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

[9] https://www.ifpma.org/resource-centre/11-billion-covid-19-vaccines-produced-in-2021-has-resulted-in-the-biggest-immunization-campaign-in-human-history-and-2022-will-require-more-and-better-vaccine-redistribution-and-innovation/

[10] https://www.census.gov/popclock/

[11] Brochure-MPP licenses for therapeutics.indd (who.int)

[12] https://www.efpia.eu/media/676659/factsheet-covid19-therapeutics.pdf

[13] https://www.reuters.com/business/healthcare-pharmaceuticals/covid-19-vaccine-scheme-worlds-poorest-pushes-delivery-slowdown-2022-06-22/

[14] https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W693.pdf&Open=True

[15] https://www.efpia.eu/news-events/the-efpia-view/blog-articles/a-fact-based-analysis-of-the-trips-waiver-extension/