Tom Lee

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The "Limited" TRIPS Waiver, COVID-19 Vaccines, and Intellectual Property

Executive Summary

- On June 16, the World Trade Organization waived certain intellectual property (IP) protections for COVID-19 vaccines commonly known as the Agreement on Trade-Related Aspects of Intellectual Property Rights.
- This decision will do nothing to increase vaccine production since it is based on the misconception that IP rights have prevented manufacturers in developing nations from producing COVID-19 vaccines.
- Developed nations have the comparative advantage in producing highly innovative medical products and therapies such as COVID-19 vaccines; attempting to shift production to developing countries is counterproductive and will likely fail.
- The June 16 decision will weaken the very forces that have encouraged the rapid and successful rollout of COVID-19 vaccines.

Introduction

On June 16, at the conclusion of the 12th Ministerial Conference (MC12), the World Trade Organization (WTO) members agreed to waive certain intellectual property (IP) protections for COVID-19 vaccines. These IP protections are part of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In October 2020, India and South Africa originally proposed suspending TRIPS for COVID-19 vaccines. WTO members based the proposal on the misconception that IP protections act as barriers to producing COVID-19 vaccines when, in fact, the difficulty of scaling up production has proven to be the main obstacle.

The American Action Forum has found that waiving TRIPS would have done nothing to increase the production and access to COVID-19 vaccines and instead would have encouraged future IP abuse, distorted market forces, and hampered future innovation in vaccines and other medical products. The TRIPS waiver in the June 16 decision is more modest than the original proposal, but it is still based on the same misconception that IP protections serve as barriers to producing COVID-19 vaccines. Like the original proposal, this one will also fail to increase production and access.

COVID-19 vaccines, such as those produced by Moderna and Pfizer, use complex technologies and processes. Countries in the developed world have the greatest comparative advantages in producing these products. What's more, IP protections, such as those codified by TRIPS, allow these comparative advantages to exist. It would be more effective to encourage the production of vaccines in developed countries, and to focus

instead on efficiently *distributing* vaccines to developing ones. The June 16 decision therefore represents a large opportunity cost for the global community. Instead of attempting to increase the distribution of vaccines, an endeavor that would truly increase access in the developing world, the global community is following through on its misconceptions to expand production in the developing world. Perhaps most concerning, the June 16 decision encourages the global community to again squabble over the misconception that IP protections prevent access to vaccines, and to pursue these same ineffective policy actions during the next health crises.

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 increase certainty in international economic relations by codifying and standardizing IP protections shared among all WTO members. TRIPS discourages IP theft by creating standards and outlining enforcement, thereby increasing trust and facilitating trade.

The original October 2020 proposal submitted by India and South Africa would have waived copyrights, patents, trademarks, and undisclosed information procedure protections for all COVID-19 vaccines and related products. The primary justification cited was that these IP protections, namely patents, lead to underutilized manufacturing capacity. This rationale, however, is flawed. The main issue has not been underutilized manufacturing capacity, but rather difficulties in scaling up production. If the original October 2020 TRIPS waiver had been granted, it would have done nothing to address this barrier to greater production. It would have instead encouraged future IP abuse and discouraged future innovation. For more information on TRIPS provisions and the originally proposed waiver, read more here.

TRIPS Waiver and Compulsory Licensing

TRIPS also allows for compulsory licensing. Under this arrangement, foreign manufacturers can ask a patentee for a voluntary licensing agreement to manufacture a product. This process can be lengthy and the patentee can ultimately refuse. If this happens, TRIPS allows the foreign manufacturer to ask its own national government to grant a compulsory license, which the manufacturer can then use to produce the drug without the patentee's permission. To receive a compulsory license, the foreign manufacturer must have first sought a voluntary license. If, however, the foreign manufacturer's national government has announced a national emergency, the manufacturer can automatically apply for the compulsory license. TRIPS requires that once a compulsory license is given, its authorized use must predominantly be to supply the domestic market—in other words, a foreign manufacturer cannot, with few exceptions, export vaccines it manufactured under a compulsory license. Each compulsory license must also apply to a specific product.

The June 16 decision specifically waives the requirement for a foreign manufacturer in a developing country to seek a voluntary license before first applying for a compulsory license. As noted above, TRIPS already allows this if a government has announced a national emergency. Over 70 percent of countries in the world have announced some sort of national emergency in response to the COVID-19 pandemic.[1] The June 16 decision also waives the requirement that COVID-19 vaccines produced under compulsory licenses must predominantly be used to supply the domestic market of the foreign manufacturer that received the compulsory license. This decision applies only to developing countries for a duration of five years. It also does not apply to other kinds of products such as therapeutics and treatments.

Manufacturing Capacity and Scaling Up Production

The primary justification cited for the June 16 decision is the same as that for the original proposal: IP protections have led to underutilized manufacturing capacity. By allowing more compulsory licenses and the exportation of vaccines produced under such licenses, the rationale holds, 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 still 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, he asserts, it is the time investment necessary to scale up manufacturing capacity.[2] Put simply, the issue is not that a factory cannot receive the instructions (i.e., copy the patent) needed to manufacture COVID-19 vaccines due to TRIPS' IP protections, but rather that even if the factory can copy the instructions, following them on a large scale is difficult. Easing restrictions on compulsory licensing will allow foreign manufacturers to more easily copy patents but does nothing to facilitate the considerable task of scaling up production.

TRIPS and Comparative Advantages

The TRIPS agreement and its IP protections were created to increase cooperation and certainty in the global economy. The economic certainty provided by IP protections preserves competitiveness and increases value—i.e., IP protections provide incentives for companies to create new and groundbreaking technologies. COVID-19 vaccines are a prime example. Developed countries have the best comparative advantages in producing these kinds of products. Without IP protections, companies could not reap the rewards of their efforts. Removing IP protections weakens those comparative advantages and the market forces that encourage innovation, the very forces that have led to the rapid creation of COVID-19 vaccines.

[1] https://datastudio.google.com/reporting/1sHT8quopdfavCvSDk7t-zvqKIS0Ljiu0/page/dHMKB

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

Instead of removing IP protections to increase manufacturing, the global community should instead focus on how to effectively distribute vaccines. Even after vaccines are manufactured, they still need to be stored and transported. mRNA vaccines, such as those produced by Moderna and Pfizer, require extreme cold storage and have short shelf lives after leaving cold storage. Developing nations may not have the infrastructure in place to accommodate these distribution challenges. These are the kind of administrative and logistical issues the global community can address without harming future innovation.

Conclusion

The proposal to waive TRIPS is based on the misperception that IP protections serve as barriers to COVID-19 vaccine production. The primary challenge in producing more vaccines is scaling up production. Making it easier for vaccine manufacturers to receive compulsory licenses will not help, however. A better approach is to build on current global vaccine partnerships while easing distribution problems. This would increase access to vaccines for developing nations and would avoid the potentially widespread and long-term problems associated with waiving IP protections provided by TRIPS. The WTO is set to meet again in December to determine if it should take similar actions to waive IP protections for COVID-19 therapeutics and treatments. This is also an opportunity cost, because the global community will have the same futile debate on IP protections when it could spend that time focusing on improving global distribution. Finally, the debate over TRIPS encourages the global community to pursue the same ineffective policy actions in future health crises.