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INSIGHT

Potential WTO TRIPS Waiver and COVID-19

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On May 5, 2021, the Biden Administration announced its support for a proposed waiver of intellectual property rights (IPR) obligations in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for Coronavirus Disease 2019 (COVID-19) vaccines. This is significant, given the United States' history of advancing stronger IPR protections and enforcement globally.

WTO TRIPS Agreement

Entering into force in 1995, TRIPS requires most WTO members to adhere to minimum standards to protect various types of IP, and to enforce these protections through domestic procedures and remedies, as well as provides for certain limitations and flexibilities to these obligations. Least-developed countries are exempt from meeting substantive TRIPS obligations generally until July 31, 2021, and pharmaceutical patent obligations until January 1, 2033. The balance struck in TRIPS to promote innovation and other societal aims faces ongoing debate.

Some of the relevant flexibilities are that a WTO member can:

- Exclude certain inventions from patentability, including if necessary to protect human health or life, and diagnostic, therapeutic, or surgical methods for the treatment of humans.
- Issue a compulsory license (CL) for a patented invention, to authorize a third party to use a patented product or process without the patent owner's consent under certain conditions, which may be waived in "situations of national emergency or other circumstances of extreme urgency…." A 2005 TRIPS amendment permits a CL for the export of a patented product; the amendment aims to address situations in which countries need the product but do not have the domestic manufacturing capacity. One prior instance of the amendment's use exists, although Bolivia announced it may use it for COVID-19 vaccine imports.
- Take measures in derogation of TRIPS if "necessary for the protection of its essential security interests… taken in time of… other emergency in international relations."

First proposed by India and South Africa in October 2020, a potential TRIPS waiver for the COVID-19 response subsequently attracted support from many low- and middle-income countries (LMICs) seeking greater access to vaccines and other health products. The proposed waiver prompted skepticism largely from a number of high-income countries concerned about its adverse effects on innovation incentives and drug quality and safety. The debate intensified amid worsening COVID-19 outbreaks in South Asia and Latin America.

On May 21, India, South Africa, and 60 other countries, seeking greater support, submitted a revised proposal that would waive the same IPR obligations as originally proposed—copyrights, patents, industrial designs, and undisclosed data (e.g., test data and trade secrets. The revised proposal specifies

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that the waiver would be for an initial three-year period and "in relation to health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment, or containment of COVID-19."

While the United States changed its position to generally support an IP waiver for COVID-19 vaccines, a number of other high-income countries appear to remain opposed or uncertain. On June 4, the European Union proposed a global trade initiative for equitable access to COVID-19 vaccines and therapeutics that would include facilitating the use of CLs under TRIPS.

WTO members may enter text-based negotiations on these issues. The WTO Director-General voiced support for members to make progress on a text by July and reach agreement by the 12th WTO Ministerial Conference (November 30 – December 3) on a "pragmatic framework that offers developing countries near automaticity in access to health technologies, whilst also preserving incentives for research and innovation."

Debate

Countries and stakeholders supporting the waiver argue that the large-scale morbidity (illness) and mortality (deaths) caused by the pandemic and its disproportionate impact on LMICs require a more comprehensive response than allowed under the existing TRIPS flexibilities. They contend that the conditions for invoking a CL, or the process for countries without manufacturing capabilities to obtain patented products, is too lengthy, costly, and cumbersome to be a viable strategy for addressing domestic manufacturing shortfalls. By contrast, suspending IPR obligations may allow countries to authorize producers to manufacture generic COVID-19 products and technologies likely without facing the threat of a WTO dispute or other negative WTO consequences. U.S. advocates of the waiver also argue that since the U.S. government, through taxpayer-funded R&D, played a key role in the development of some COVID-19 vaccines, the IPR should be shared publicly.

Conversely, other countries, industry, and some other stakeholders argue that IPR facilitate innovation and access to COVID-19 treatments. They point to the unprecedented speed in the development of COVID-19 vaccines and claim that the waiver would constrain their current production ability and discourage future advances. U.S.-based stakeholders also argue the waiver would cause the United States to lose a competitive advantage to countries such as China, which may reap the economic rewards of U.S.-developed technology. They further claim little evidence exists to show that IPR is delaying vaccine production and distribution, which they argue is due to other barriers such as supply chain disruptions; lack of manufacturing capacity, know-how, and financing; and inadequate distribution networks in many LMICs. (See this CRS In Focus on global COVID-19 vaccine distribution.)

Some stakeholders debate whether the waiver would actually help accelerate the production and deployment of vaccines and therapeutics. The pharmaceutical industry claims that ongoing voluntary licensing agreements and technology transfer of COVID-19 treatments are sufficient to ensure that enough vaccines will be available globally by the end of 2021. Companies also doubt the ability of third-party manufacturers to produce the vaccines. For instance, if the waiver applies only to patents, a patent holder would not necessarily be under any obligation to transfer technological or manufacturing know-how, which is especially critical for the mRNA vaccines. Waiver advocates counter that voluntary licenses are too costly and inefficient and, in some cases, rights-holders have been unwilling to license their IPR to vaccine-producing companies. For example, firms in Bangladesh, Canada, and Israel state they are willing and able to make the vaccine save for the IPR. It is difficult to evaluate these claims, as most licensing agreements and their terms are not public.

Issues for Congress

Some Members of Congress voiced support and opposition to the waiver proposal in the months ahead of and after the Administration's announcement. Among Members, proponents may press the Administration to negotiate an IPR waiver for COVID-19 vaccines as expeditiously as possible and/or to advocate for a broader waiver. Opponents may encourage the Administration to consider alternative responses, such as stronger voluntary technology transfers or increased U.S. production for export. Members may consider proposals to require additional notifications, consultations, or explicit congressional approval before the Administration agrees to a waiver, or impose other restrictions on the Administration's ability to agree to a waiver (see, for example, S.Amdt. 1975 (not adopted) to S. 1260; H.R. 3035 and companion bill in the Senate; and H.R. 3236). They may examine related legal issues as well (see this CRS Legal Sidebar). Congress also may examine how a waiver could affect U.S. economic interests. In addition, Congress may consider a potential waiver's implications for future U.S. trade agreements, and whether it would represent a unique position for an unprecedented pandemic, or a general shift in U.S. trade policy on IPR as it relates to public health tools.

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