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INSIGHT

The Biden Administration Announces its Support for a WTO TRIPS Waiver

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On May 5, 2021, the Biden Administration announced its support for a waiver of intellectual property rights (IPR) obligations in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for COVID-19 vaccines. This is a significant development, given U.S. leadership historically in advancing stronger IPR protections and enforcement globally.

The COVID-19 pandemic has spurred pharmaceutical and biotechnology companies to undertake intensive, costly, and risky research and development (R&D) to create new vaccines and other products to respond to COVID-19. Certain stakeholders have expressed concerns over the impact of IPR on access to these treatments and technologies. The potential waiver was first proposed by India and South Africa in October 2020. Subsequent discussion of it in the WTO has attracted support from low- and middle-income countries (LMICs) seeking greater access to vaccines and related products, but has prompted skepticism largely from high-income countries, reflecting pharmaceutical industry and other concerns about the impact on incentives to innovate, and on quality and safety. The debate has intensified amid the recent surge in COVID-19 in certain regions. Meanwhile, India and South Africa plan to amend their waiver proposal to seek greater support. Whether other high-income countries also change their position on the waiver remains to be seen; Germany, for instance, has criticized the U.S. decision. WTO activity on the proposed waiver may enter text-based negotiations, perhaps including discussion of other issues such as technology transfer. A number of Members of Congress have issued statements in support and opposition to the waiver proposal in the months leading up to and following the Biden Administration's announcement, and are likely to continue to weigh in on the matter.

Background

The India/South Africa proposal would waive TRIPS obligations with respect to copyrights, patents, industrial designs, and undisclosed data (e.g., clinical testing data and trade secrets) for the "prevention, containment, and treatment" of COVID-19 until widespread vaccination exists. Suspending these rights would allow countries to authorize generic producers to manufacture COVID-19 vaccines, therapeutics, testing, and other items, notwithstanding IPR, likely without violating core WTO obligations.

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Entering into force in 1995, TRIPS marked the first incorporation of IPR obligations into the multilateral rules-based trading system. TRIPS sets minimum standards for the protection of various types of IP, and enforcement of these protections through domestic procedures and remedies. It also includes certain limitations and flexibilities to these protections (see **text box**). TRIPS obligations are enforceable in the WTO. The balance struck in TRIPS to promote innovation and other societal aims faces ongoing debate.

WTO TRIPS Agreement Flexibilities

TRIPS includes flexibilities related to pharmaceutical patents. For example:

- Governments 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.
- Governments can issue a compulsory license (CL) for a patented invention. A CL allows a government to authorize a third party to use a patented product or process without the patent owner's consent under certain conditions—including first trying to negotiate a voluntary license from the patent holder; providing adequate remuneration; and mainly supplying the domestic market. A 2005 TRIPS amendment permits a CL for the export of a patented product, and aims to address situations in which countries need the product but do not have the domestic manufacturing capacity, but only one instance of its use exists.
- Least-developed countries are exempt from applying substantive TRIPS obligations generally until July 31, 2021, and pharmaceutical patent obligations until January 1, 2033.

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 attached to invoking a CL, or the process for countries without manufacturing capabilities to obtain patented products, is too time-consuming, costly, and cumbersome to be effective as a viable strategy for addressing domestic manufacturing shortfalls and that voluntary licenses are too costly and inefficient. 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 with the public.

Conversely, other countries, and industry and 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 vaccine production ability and potentially 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 would reap the economic rewards of U.S. technology. They further claim there is little evidence that IPR is delaying the production and deployment of the vaccines, pointing to ingredient shortages and supply chain disruptions, as well as lack of manufacturing capacity, know-how, financing, and inadequate public health distribution networks in many LMICs as more significant barriers.

Stakeholders also debate whether the waiver would actually help accelerate the production and deployment of vaccines and therapeutics. The pharmaceutical industry notes ongoing voluntary licensing agreements and technology transfer of COVID-19 treatments and claims 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, which are mostly complex biological products, without the technological know-how. Absent additional requirements, 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 rights-holders have been unwilling to license their IPR to all the companies to make vaccines. For example, firms in Bangladesh, Canada, and Israel claim they are willing and able to

make the vaccine save for the IPR. It is difficult to evaluate these claims about the available supply of and need for additional manufacturing capability, as most licensing agreements and their terms are not public.

Issues for Congress

Members of Congress are likely to closely monitor U.S. involvement in any future WTO negotiations on a potential TRIPS waiver. Among Members, proponents may press the Administration to negotiate a waiver of IP for COVID-19 vaccines as expeditiously as possible and/or to advocate for a broader waiver. Opponents may encourage the Administration to revisit its position and consider alternatives, such as a narrower waiver of IP, stronger voluntary technology transfer mechanisms, or increased U.S. production for export. Congress may consider whether to require additional notifications from or consultations with the Administration, or explicit congressional approval, before the United States signs onto a potential waiver. Congress also may examine how a waiver could affect U.S. industry, broader economic interests, and future innovation. In addition, Congress may consider a potential waiver's implications for future U.S. trade agreements, and whether it would represent a unique event for an unprecedented pandemic, or a general shift in the U.S. trade policy approach to IPR and public health.

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