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June 16, 2021

Potential WTO TRIPS Waiver and COVID-19

The Coronavirus Disease 2019 (COVID-19) pandemic has spurred biopharmaceutical companies to conduct costly and risky research and development (R&D) to develop vaccines and other products to respond to COVID-19. Firms have relied on intellectual property rights (IPR) to commercialize these products. Governments and nonprofits have funded and coordinated some of the underlying R&D. Some groups have voiced concerns over the impact of IPR on affordable access to these products for low- and middle-income countries (LMICs). An active debate is unfolding in the World Trade Organization (WTO) on the role of IPR in the pandemic response. On May 5, U.S. Trade Representative Katherine Tai announced the Biden Administration's support for the concept of a waiver of the 1995 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for COVID-19 vaccines, and pledged to "actively participate in text-based negotiations at the [WTO] to make that happen." Many consider this notable, given the United States' history of advancing stronger IPR standards globally. Members of Congress have varying views on the issue.

Background on TRIPS Agreement

TRIPS incorporated IPR obligations into the multilateral rules-based trading system. It requires most WTO members to adhere to minimum standards to protect patents, copyrights, trademarks, and other rights, and to enforce these protections domestically. TRIPS also has certain limitations to and flexibilities for these obligations.

> *The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.* – TRIPS Article 7 (Objectives)

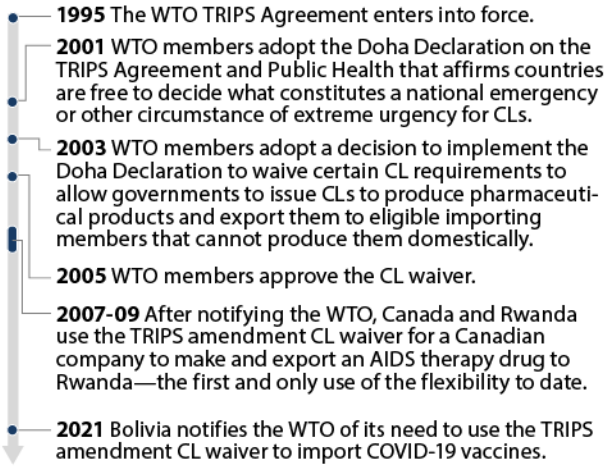
Since the agreement's inception, some WTO members and stakeholders have debated the balance that TRIPS struck to promote innovation and other societal aims. This debate intensified during the HIV/AIDS epidemic in the 2000s over access to anti-retroviral drugs, and more recently over access to COVID-19 treatments. Some of the relevant TRIPS flexibilities are summarized below.

Transition. Least-developed countries (LDCs) are exempt from meeting substantive TRIPS obligations generally until July 31, 2021, and pharmaceutical patent obligations until January 1, 2033. The WTO has extended the time limits on these exemptions several times in the past.

Patentability Exclusion. A government can exclude certain inventions from patentability, including if necessary to protect human health or life, and if they are diagnostic, therapeutic, or surgical methods of treatment.

Compulsory Licenses (CLs). A government may issue a CL 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 get a voluntary license; giving adequate remuneration to the patent owner; and using the CL mainly to supply the domestic market. These requirements may be waived in "situations of national emergency or other circumstances of extreme urgency…." The WTO has sought to address obstacles to using CLs for members with limited domestic manufacturing capacity (see **Figure 1**).

Figure 1. TRIPS Timeline: Selected Developments



Source: CRS, based on WTO documents.

Essential Security Interests. A member can take measures in derogation of TRIPS if it is "necessary for the protection of its essential security interests… taken in time of… other emergency in international relations."

TRIPS Waiver Developments

First proposed by India and South Africa in October 2020, a broad TRIPS waiver proposal drew support from many LMICs seeking greater access to COVID-19 vaccines and other health products. The proposal 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 grew amid worsening COVID-19 outbreaks in South Asia and Latin America. On May 21, 2021, India, South Africa, and 60 other countries submitted a revised proposal. The revised proposal would waive the same IPR (copyrights, patents, industrial designs, and undisclosed data), but it now specifies that the waiver would initially span three years and would be "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 shifted its position to support generally a TRIPS waiver for COVID-19 vaccines, some other high-income countries remain opposed, such as the European Union (EU) (though it is internally divided), the United Kingdom (UK), Switzerland, and South Korea. The positions of some other countries vary and, in some cases, have shifted. The BRICS nations (Brazil, Russia, India, China, and South Africa) jointly voiced support for ongoing consideration of a TRIPS waiver and using flexibilities under TRIPS. Other developments include the Asia Pacific Economic Cooperation (APEC) group's recent support for text-based negotiations, including on a temporary waiver.

WTO text-based negotiations are expected to commence. The U.S. representative to the WTO has said that the United States "has not prejudged an outcome," and views "the most expeditious pathway toward consensus" as addressing "the supply and distribution of vaccines specifically." On June 4, the EU submitted a proposal for a global trade initiative for equitable access to COVID-19 vaccines and therapeutics, relating to trade facilitation and reducing export restrictions, expanding production, and facilitating the use of CLs under TRIPS as needed. The WTO Director-General voiced support for members to make progress on a text by July and reach agreement by the planned 12th WTO Ministerial Conference at the end of 2021 on a "pragmatic framework" offering developing countries access to health technologies while maintaining incentives for innovation. If the WTO were to adopt a potential TRIPS waiver, it would not necessarily change WTO members' domestic IP protections automatically. Each member would need to go through its relevant domestic procedures to decide whether and how to change its laws to implement the waiver.

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 fuller response than allowed under existing TRIPS flexibilities. They assert that the conditions for invoking a CL are too lengthy, costly, and cumbersome to be a viable strategy for addressing shortfalls in domestic manufacturing. By contrast, suspending IPR obligations may allow countries to authorize producers to manufacture generic COVID-19 products likely without facing the threat of a WTO dispute or other negative trade consequences. U.S. advocates also argue that since the U.S. government, with taxpayer-funded R&D, supported some COVID-19 vaccines development, the IP should be shared publicly.

Conversely, other countries, 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 production ability and discourage future advances. Some U.S.-based stakeholders also argue the waiver would cause the United States to lose a competitive advantage to countries such as China and Russia, 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 and health care systems in many LMICs.

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 knowhow, 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

Supporters may urge the Administration to negotiate a waiver as quickly as possible and/or to advocate for a waiver covering specific types of IP or to cover other COVID-19-related products beyond vaccines. Critics may press the Administration to consider alternative responses, such as related to voluntary licensing, transfer of know-how, use of existing TRIPS flexibilities, or scaling up production. Various bills have been introduced to provide congressional input or other related requirements on any agreement by the Administration to a waiver. Issues that Members of Congress may examine include:

- What should the role of Congress be in any potential U.S. agreement to modify TRIPS?
- Would a waiver, if adopted, actually promote greater global production and access to COVID-19 treatments, and if so, would it be in a sufficient period of time to respond to the urgency of the crisis? Would further steps be necessary to transfer know-how to develop COVID-19 vaccines or other products safely?
- How might a waiver affect U.S. industry, economic interests, and competitiveness in future innovation including with respect to China?
- In terms of U.S. trade agreements, does support for a waiver represent a unique position for an unprecedented pandemic, or a general shift in U.S. trade and IPR policy as it relates to public health tools?

See CRS In Focus IF10033, *Intellectual Property Rights (IPR) and International Trade*, CRS In Focus IF11796, *Global COVID-19 Vaccine Distribution*, and CRS Legal Sidebar LSB10599, *The Legal Framework for Waiving World Trade Organization (WTO) Obligations*.

Shayerah I. Akhtar, Specialist in International Trade and Finance

IF11858

Ian F. Fergusson, Specialist in International Trade and Finance

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