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Updated September 13, 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). On May 5, 2021, the Biden Administration announced its support for the concept of a waiver of parts of the World Trade Organization (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 IPR standards globally. Members of Congress are divided on the issue. An active debate is underway in the WTO on the role of IPR and trade policy in the pandemic response.

Background on WTO TRIPS Agreement

TRIPS, which entered into force in 1995, incorporated IPR obligations into the multilateral rules-based trading system. It requires most WTO members to adhere to minimum rules and disciplines on patents, copyrights, trademarks, and other rights, and to enforce these commitments domestically. It also has certain limitations to and flexibilities for these obligations. Longstanding debates over the balance in TRIPS to promote innovation and other societal aims has intensified over access to COVID-19 vaccines and other treatments. Select relevant TRIPS flexibilities are summarized below.

Transition. Least-developed countries (LDCs) are exempt from meeting most substantive TRIPS obligations generally until July 1, 2034, and meeting pharmaceutical patent and clinical trial data protection obligations until January 1, 2033. The time limits on these exemptions have been extended several times using WTO waiver authority.

Patentability Exclusion. A government can exclude certain inventions from patentability, including if necessary to protect human health or life, or 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. These conditions include requiring the proposed user to first seek a license on commercial terms; 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 CL use by poorer members (see **text box**).

Additional Compulsory Licensing Flexibility

In 2003, WTO members adopted a decision to waive the TRIPS obligation generally limiting members' CL use to supply pharmaceutical products to their domestic markets. The waiver allowed members to export pharmaceutical products made under CLs to least-developed and other eligible countries that cannot make these products themselves, subject to certain requirements. In 2005, members formally amended TRIPS to make the waiver permanent. The amendment entered into force in 2017, following its ratification by two-thirds of WTO members (the United States accepted in 2005). The WTO has periodically extended the deadline to ratify the waiver, most recently to December 31, 2021. For members who have not accepted the amendment, the waiver continues to apply. The first and only use of this additional CL flexibility was in 2007-2009 (until potential recent developments), for a Canadian company to make and export an AIDS therapy drug to Rwanda. In 2021, Bolivia notified the WTO of its need to use the flexibility to import COVID-19 vaccines. Debate over the effectiveness of this mechanism persists.

Essential Security Interests. A WTO 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

In October 2020, India and South Africa proposed a waiver of certain TRIPS obligations (copyrights, patents, industrial designs, and undisclosed information) "in relation to prevention, containment or treatment of COVID-19." The specific time period for the waiver would be determined during negotiations among WTO members; India and South Africa proposed to extend the period "until widespread vaccination exists." The proposal drew support from many LMICs seeking greater access to COVID-19 vaccines and other health products, but it prompted skepticism, largely from a number of high-income countries, due to concerns about its scope, duration, and possible adverse effects on innovation incentives and drug quality and safety.

In May 2021, India, South Africa, and 60 other mainly lower-income countries submitted a revised proposal in hopes of garnering more support. As revised, the proposal would waive the same IPR obligations as originally proposed, but by contrast, it would limit the waiver to cover initially a period of three years, and apply "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."

Momentum for support for the concept of a TRIPS waiver and/or ongoing WTO discussions on it has broadened to include some higher-income countries and economic groupings (the BRICS nations of Brazil, Russia, India, China, and South Africa, and the 19-member Asia-Pacific Economic Cooperation). The scope of a potential waiver, however, remains a key issue. The Biden Administration, for instance, voiced support for a narrower concept of a TRIPS waiver than contemplated in the revised proposal by India, South Africa, and other countries. Members of Congress remain divided in their support for or opposition to the concept of a waiver. Some other high-income countries have remained skeptical. The European Union (EU) has submitted in the WTO an alternative proposal for equitable access to COVID-19 vaccines and treatments, with elements on reducing export restrictions and keeping supply chains open, expanding production, and facilitating CL use under TRIPS, as needed.

WTO members' positions remain divergent on "the appropriate and most effective way" to address shortage and access issues for COVID-19 vaccines and other products. It remains to be seen whether WTO members will reach an agreement on these issues before or at the 12th WTO Ministerial Conference (MC12), planned for November 30-December 3, 2021.

The WTO generally reaches decisions by consensus, a procedure used, for example, to adopt the TRIPS CL amendment. Voting, however, is possible in certain cases where members cannot reach consensus. If the WTO were to adopt a potential TRIPS waiver, it would not change members' domestic IP protections automatically. Each WTO member would need to undertake 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 process for issuing a CL is 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 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 the development of some COVID-19 vaccines, the IP should be shared publicly.

Other countries, industry, and stakeholders argue that IPRs facilitate innovation and access to COVID-19 treatments. They point to the unprecedented speed of the development of COVID-19 vaccines and claim that the waiver would constrain the 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 if patent protection is removed for more developed economies. They further claim little evidence exists to show that IPR is delaying vaccine production and distribution, and point 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 a waiver would help accelerate the production and deployment of vaccines and therapeutics in low-income countries. The pharmaceutical industry points to ongoing voluntary licensing agreements and technology transfer of COVID-19 treatments as a means to support global vaccine distribution. Companies doubt third-party manufacturers' ability 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. Some foreign firms say they are willing and able to make the vaccine save for the lack of access to the IPR. Evaluating these claims is difficult, 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 IPR or to cover other COVID-19-related products beyond vaccines. Critics may press the Administration to consider alternative responses, including those related to voluntary licensing, transfer of know-how, use of existing TRIPS flexibilities, or scaling up production. Various bills have been introduced to allow for more congressional input or approval before the Administration can agree to a waiver. Issues that Members of Congress may examine include

- What should be the role of Congress in any potential U.S. agreement to modify TRIPS?
- Would a waiver, if adopted, promote greater global production and access to COVID-19 treatments? If so, would it do so in a sufficient period of time to respond to the urgency of the crisis, including with respect to the new challenges associated with the delta variant? Would further steps be necessary to ensure product safety?
- How might a waiver affect U.S. industry, economic interests, and competitiveness in future innovation, including with respect to China?
- Does support for a waiver represent a unique position in U.S. trade policy specific to the pandemic, or a general shift in such policy as it relates to historical U.S. positions in advancing IPR in trade agreements?

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*.

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