

World Trade Organization: “TRIPS Waiver” for COVID-19 Vaccines

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The Coronavirus Disease 2019 (COVID-19) pandemic spurred pharmaceutical companies to conduct research and development (R&D) to develop vaccines and other medical products in response. Firms generally relied on intellectual property rights (IPR) to commercialize these products and recoup their investment in R&D. Governments and nonprofits also funded and coordinated R&D for COVID-19 countermeasures.

Limited access to and uneven distribution of COVID-19 vaccines in low- and middle-income countries (LMICs) led to calls by some governments and nongovernmental groups for the issuance of compulsory licenses (CLs) by governments to manufacture generic versions, or to waive international IPR obligations related to COVID-19 vaccines and other countermeasures, such as tests and treatments. Other governments and industry groups argued that such moves would both stifle medical innovation and fail to address the root causes of the production and distribution challenges. Members of Congress have differing views on how to promote global access and distribution of COVID-19 vaccines and on IPR-related waiver proposals.

Internationally, these debates have focused on potential waivers of IPR obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Entered into force in 1995, TRIPS incorporated IPR obligations into the multilateral rules-based trading system. TRIPS requires most WTO members to adhere to minimum rules for the protection of patents, copyrights, trademarks, and other rights, and to enforce these commitments domestically. TRIPS also contains certain limitations and flexibilities for these obligations, including provisions to waive requirements for issuing CLs in “the case of a national emergency or other circumstances of extreme urgency....” Long-standing debates over the balance in TRIPS to promote innovation and other societal aims, such as public health, have intensified over access to COVID-19 vaccines and other treatments.

On June 17, 2022, after nearly two years of contentious talks, WTO members reached a decision on a five-year patent-related waiver for COVID-19 vaccines at the WTO’s 12th Ministerial Conference (MC12). The decision permits an “eligible” WTO member to authorize use of patented inventions necessary for COVID-19 vaccine production and supply, without the right holder’s consent. It allows all developing country members to qualify as eligible members, but it encourages developing country members that have existing capacity to manufacture COVID-19 vaccines “to make a binding commitment not to avail themselves” of the decision—a provision largely aimed at China. The decision clarifies or waives for eligible members certain existing TRIPS requirements on issuing CLs. No later than six months from the June 17 decision date, WTO members are to decide whether to extend the waiver to cover the production and supply of COVID-19 diagnostics and therapeutics.

The Biden Administration—which announced its support in 2021 for the concept of a limited IPR waiver for COVID-19 vaccines—supported the final WTO decision. Some Members of Congress and pharmaceutical and other industry groups assert that the decision threatens medical innovation and U.S. competitiveness; distracts from the actual challenges to increasing COVID-19 vaccine access (e.g., supply chain bottlenecks, vaccine hesitancy, health care infrastructure limitations); and undermines current licensing arrangements for global COVID-19 vaccine production and technology transfer. Other Members of Congress and certain public health advocates welcomed the WTO discussions, although some of those proponents criticized the final decision for postponing potential application of the waiver to COVID-19 diagnostics and therapeutics; not addressing access to “technical know-how” (including trade secrets) necessary for vaccine development; and not adding significantly to current TRIPS flexibilities. Differences also exist over possible competitiveness threats that the waiver may pose for the United States, particularly with respect to China. Although China committed not to use the flexibilities under the TRIPS waiver, some policymakers and stakeholders remain concerned about the risk of theft by China of U.S. COVID-19-related technologies.

Members of Congress may examine a number of issues raised by the TRIPS waiver decision, including implications for U.S. IPR and innovation, and COVID-19 vaccine access and distribution. They also may examine the decision’s implication for U.S. trade policy as it relates to historical U.S. positions in advancing IPR in trade agreements. Additionally, they may look into questions concerning congressional-executive engagement on trade agreement negotiations. In the 117th Congress, some bills have been introduced that would allow for more congressional input or approval before the Administration could agree to a waiver.

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Introduction

The Coronavirus Disease 2019 (COVID-19) pandemic spurred pharmaceutical companies to conduct research and development (R&D) to develop vaccines and other products to respond to COVID-19. Firms generally relied on intellectual property rights (IPR) protections to commercialize these patented products and recoup their significant R&D investments. Governments and nonprofits also funded and coordinated R&D for COVID-19 countermeasures. Limited access to and uneven distribution of COVID-19 vaccines in low- and middle-income countries (LMICs) has been a global concern, especially early in the pandemic, and led to ongoing international debate on the role of IPR in a trade policy response to COVID-19.¹

Some civil society groups blame patents and other IPR for these challenges facing LMICs, and they have called for governments to issue compulsory licenses (CLs) to manufacture generic versions of COVID-19 vaccines, or to waive international rules for IPR related to vaccines and other COVID-19 countermeasures, such as tests and treatments. Some in industry argue that such moves would stifle medical innovations while not addressing the root causes of production and distribution issues, or that they are unnecessary in light of existing flexibilities under international IPR rules.

These issues have come to the fore in the World Trade Organization (WTO) in the context of the 1995 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), particularly its provisions on patents. In October 2020, South Africa and India proposed a waiver of certain TRIPS obligations “in relation to prevention, containment or treatment of COVID-19.”² WTO members engaged in contentious discussions on this and other proposals on an IPR and trade policy response to the pandemic. On June 17, 2022, WTO members reached a decision on a five-year waiver of certain requirements concerning CLs for COVID-19 vaccines, as part of a set of multilaterally negotiated outcomes on various trade issues at the WTO’s 12th Ministerial Conference (MC12).³

Members of Congress are divided on how to promote global access and distribution of COVID-19 vaccines and on the WTO “TRIPS waiver” outcome.⁴ The Biden Administration, which supported the concept of an IPR waiver for COVID-19 vaccines and engaged in discussions with other key WTO members, expressed support for the final WTO outcome. The U.S. Trade Representative (USTR) stated:

¹ For general background, see CRS In Focus IF10033, *Intellectual Property Rights (IPR) and International Trade*, by Shayerah I. Akhtar and Liana Wong; and CRS Report RL34292, *Intellectual Property Rights and International Trade*, by Shayerah I. Akhtar, Ian F. Fergusson, and Liana Wong.

² World Trade Organization (WTO) TRIPS Council, “Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19,” communication from India and South Africa, IP/C/W/669, October 2, 2020. The Council for TRIPS (“TRIPS Council”) is the WTO body legally responsible for administering and monitoring the operations of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). See WTO, “TRIPS Council Regular Meetings,” at https://www.wto.org/english/tratop_e/trips_e/intel6_e.htm.

³ WTO, “Ministerial Decision on the TRIPS Agreement” (adopted on June 17, 2022), WT/MIN(22)/30, WT/L/1141, June 22, 2022. The WTO Ministerial Conference brings together all members of the WTO and can take decisions on all matters under any of the WTO multilateral trade agreements. See WTO, “Ministerial Conferences,” at https://www.wto.org/english/thewto_e/minist_e/minist_e.htm.

⁴ E.g., Office of Congresswoman Jan Schakowsky, “Members of Congress that Led Push for TRIPS Waiver Applaud Biden Administration Announcement,” press release, May 5, 2021; and Office of Senator Thom Tillis, “Tillis and Cotton Statement on President Biden’s Disastrous Decision to Support the TRIPS Waiver,” press release, May 5, 2021.

The text-based negotiations with other WTO Members that we have called for have produced accommodations to the intellectual property rules for COVID-19 vaccines that can facilitate a global health recovery. Through difficult and protracted discussions, [WTO] Members were able to bridge differences and achieve a concrete and meaningful outcome to get more safe and effective vaccines to those who need it.... During a global pandemic, under difficult circumstances, the WTO moved quickly to address a major global challenge and respond to the strong desire of our African partners to produce a meaningful outcome.⁵

This report provides: (1) a background of the WTO TRIPS Agreement, with a focus on key provisions relevant to the WTO "TRIPS waiver" debate for COVID-19 vaccines; (2) an overview of the WTO discussions on proposed TRIPS waivers; (3) a discussion of the provisions of the June 17, 2022, Ministerial Decision on the TRIPS Agreement; and (4) an analysis of key issues for Congress presented by the "TRIPS waiver" developments.

Background on WTO TRIPS Agreement

TRIPS, which entered into force in 1995, is a WTO agreement that incorporates IPR obligations into the multilateral rules-based trading system.⁶ TRIPS requires most WTO members to adhere to minimum rules for the protection of patents, copyrights, trademarks, and other rights, and to enforce these commitments domestically. It also has certain limitations to, and flexibilities for, these obligations, particularly for least developed economies. TRIPS obligations are subject to enforcement under the WTO dispute settlement mechanism.

TRIPS is the subject of long-standing debates over the balance it strikes between promoting innovation and other societal aims. Uneven global access to COVID-19 vaccines and treatments renewed debates over TRIPS's role in supporting innovation and access to medicines.⁷ Select relevant TRIPS flexibilities are summarized below.

Transition

Least-developed country (LDC) members have certain extended transition periods to implement their TRIPS obligations.⁸

- *Extended general transition period.* Since its inception, TRIPS provided LDCs an extended general transition period to apply TRIPS obligations, "[i]n view of the special needs and requirements of [LDCs], their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base" (Article 66). WTO members have extended the transition period, most recently to July 31, 2034 (or when an LDC ceases to be an LDC).⁹
- *Pharmaceutical extended transition period.* In the 2001 Doha Declaration on the TRIPS Agreement and Public Health, WTO members agreed that LDC members

⁵ USTR, "Statement from Ambassador Katherine Tai on an Intellectual Property Response to the COVID-19 Pandemic," press release, June 17, 2022.

⁶ See the WTO TRIPS Agreement (as amended on January 23, 2017), available at https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm.

⁷ CRS In Focus IF11796, *Global COVID-19 Vaccine Distribution*, by Sara M. Tharakan and Tiaji Salaam-Blyther.

⁸ Currently, there are 35 WTO members that are least-developed countries (LDCs), based on United Nations criteria. See WTO, "Least-Developed Countries," at https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm.

⁹ WTO, "Extension of the Transition Period Under Article 66.1 for Least Developed Country Members," TRIPS Council decision, IP/C/88, June 29, 2021.

should be given an extended transition period for implementing their obligations concerning patents and undisclosed information in the pharmaceutical sector.¹⁰ After adopting an initial extension of this transition period in 2001, WTO members further extended it until January 1, 2033 (or when an LDC ceases to be an LDC).¹¹

The extension of time limits on these transition periods relied on WTO waiver authority.¹²

Patentability Exceptions

Under TRIPS, members must make available patents “for any inventions, whether products or processes, in all fields of technology” that are: (1) new; (2) involve an inventive step (“non-obvious”); and (3) are capable of industrial application (“useful”). TRIPS also allows members to exclude certain inventions from patentability, including if necessary to protect human health or life, or if they are diagnostic, therapeutic, or surgical treatment methods (Article 27).

TRIPS further allows members to make limited exceptions to patent rights, provided that certain conditions are met, such as that the exceptions do not “unreasonably” conflict with the patent’s “normal” use (Article 30). Many countries use this provision to advance science and technology, allowing researchers to use a patented invention for research purposes. Some countries also provide for a “regulatory exception”—allowing manufacturers of generic drugs to use the patented invention in the process of obtaining regulatory approval to market a generic drug, without the patent owner’s permission and before the patent protection expires; the generic producers can then market their versions as soon as the patent expires.¹³

Compulsory Licenses

TRIPS allows a member to issue a compulsory license (CL) to authorize a third party to use a patented product or process without the patent owner’s consent under certain conditions (Article 31). These conditions include requiring the proposed user to first seek a license on reasonable commercial terms; giving adequate remuneration to the patent owner; and using the CL mainly to supply the domestic market. The requirement to first seek a license on reasonable commercial terms may be waived in “the case of a national emergency or other circumstances of extreme urgency....”

Paragraph 6 of the 2001 Doha Declaration on the TRIPS Agreement and Public Health “recognize[d] that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of” CLs under TRIPS, and it instructed the TRIPS Council “to find an expeditious solution to this problem.” In 2003, relying on the WTO’s waiver authority, WTO members adopted a decision to waive the TRIPS obligation

¹⁰ See WTO, “Declaration on the TRIPS Agreement and Public Health” (adopted on November 14, 2001), November 20, 2001, WT/MIN901/DEC/2.

¹¹ WTO, “Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products,” IP/C/73, November 6, 2015.

¹² Article IX of the Marrakesh Agreement Establishing the World Trade Organization (“the WTO Agreement”) that allows the WTO Ministerial Conference to waive an obligation imposed on a member “[i]n exceptional circumstances.”

¹³ In the U.S. context, see, for example, 35 U.S.C. §271(e)(1). For more information, see CRS In Focus IF11214, *Drug Pricing and the Law: Pharmaceutical Patent Disputes*, by Kevin J. Hickey.

to generally limit CL use to supply pharmaceutical products to a member's domestic market.¹⁴ The waiver allowed members to export pharmaceutical products made under CLs to LDCs and other eligible countries that cannot make these products themselves, subject to certain requirements—e.g., the importing member must specify the names and expected quantities of the products needed, and the exporting member must distinguish the products under CL through specific labelling or marketing. In 2005, WTO members formally amended TRIPS to make the so-called "Paragraph 6 System" waiver permanent.¹⁵ The amendment entered into force in 2017, after its ratification by two-thirds of WTO members (the United States accepted it in 2005).¹⁶ Use of the Paragraph 6 System has been limited, and subject to ongoing debate (see **text box**).

Use of the TRIPS Additional Compulsory Licensing Flexibility

To take advantage of the additional compulsory licensing (CL) flexibility under the "Paragraph 6 System" of the WTO TRIPS Agreement, some WTO members have adopted domestic implementing laws or regulations to incorporate the system into their legislative frameworks, to act as an exporter, an importer, or both.

To date, the one use of the Paragraph 6 System was in 2007-2009 for exports of an AIDS therapy drug from Canada to Rwanda. In July 2007, Rwanda notified the WTO of its intent to import 260,000 packs of a patented triple combination AIDS therapy drug over two years, as it was unable to manufacture the drug itself. In October 2007, Canada notified the WTO that it had authorized a domestic company, Apotex Inc., to make a generic version of the patented drug under a CL. Rwanda issued a public tender for the drug, which the Canadian company ultimately won after halving its price—reportedly making it more competitive than some generic manufacturers in India. Drug shipments took place in September 2008 and September 2009. Per Canada's Access to Medicines Regime (CAMR) and TRIPS, the drugs shipments had distinctive marks and coloring compared to the version manufactured for the domestic market.

In May 2021, Bolivia notified the WTO via the Paragraph 6 System of the country's need to use the flexibility to import 15 million doses of COVID-19 vaccines. Bolivia and Canada-based Biolyse Pharma signed an agreement to seek a CL for the latter to produce and export the COVID-19 vaccines using Johnson and Johnson patented technology. The Canadian government does not appear to have approved the application to date, and Bolivian leaders reportedly criticized this delay.

WTO members and other stakeholders have expressed a range of views regarding the Paragraph 6 System. While some attribute limited use of the system to what they say is complexity and administrative difficulty, others contend that the limited use of the system is not an appropriate gauge of its success and that it may have potential for future use.

Source: WTO, "Members' Laws Implementing the 'Paragraph 6' System," available at https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm; 2013 World Health Organization (WHO), World Intellectual Property Organization (WIPO), and WTO Trilateral Study – *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property, and Trade*, p. 3; Biolyse Pharma, "Bolivia and Biolyse Sign Landmark Agreement for Export of COVID-19 Vaccines," May 12, 2021, accessed via Cision; and Ahmar Khan, "Canada Lacks 'Political Will' to Waive COVID-19 Vaccine Patents, Bolivian Minister Says," *Global News*, October 6, 2021.

Trade Secrets

TRIPS requires members to protect "undisclosed information"—commonly referred to as trade secrets or know-how. Under TRIPS, the protection must apply to information that is secret, has

¹⁴ WTO, "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," General Council decision (August 30, 2003), WT/L/540 and Corr. 1, September 1, 2003.

¹⁵ WTO, "Amendment of the TRIPS Agreement," General Council decision (December 6, 2005), WT/L/641, December 8, 2005.

¹⁶ WTO, "WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines," press release, January 23, 2017; and WTO, "Amendment of the TRIPS Agreement – Eighth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement," General Council decision (November 22, 2021), WT/L/1122, November 23, 2021. The WTO has periodically extended the deadline to ratify the waiver, most recently until December 31, 2023. For members who have not accepted the amendment, the waiver continues to apply.

commercial value because it is secret, and has been subject to reasonable steps to keep it secret (Article 39.2). TRIPS requires that a person lawfully in control of this information have the possibility of preventing it from being disclosed to, acquired by, or used by others without their consent in a "manner contrary to honest commercial practices" (for example, a breach of a non-disclosure contract).

TRIPS also imposes obligations on members in situations where they require the submission of test and other data as a condition of approving the marketing of pharmaceutical products that use new chemical entities (Article 39.3). Members must protect the data against unfair commercial use. They also must protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure the data are protected against unfair commercial use.

Technology Transfer

TRIPS aims to achieve transfer and dissemination of technology as part of its objectives (Article 7). It specifically requires developed country members to provide incentives for their companies to promote the transfer of technology to LDCs (Article 66.2). Following a 2001 Doha Ministerial decision, in February 2003, the TRIPS Council set up a reporting mechanism to ensure monitoring and full implementation of the LDC-related technology transfer mechanism. The effectiveness of the mechanism has been subject to ongoing debate among WTO members.

Essential Security Interests

TRIPS contains certain security exceptions. Among them, WTO members can take measures in derogation of TRIPS if it is "necessary for the protection of its essential security interests ... taken in time of war or other emergency in international relations" (Article 73).

WTO jurisprudence on Article 73 appears to be limited. One instance is in the WTO dispute settlement panel in *Saudi Arabia – Intellectual Property Rights*, which applied interpretations formulated by some prior WTO panels. The panel in *Saudi Arabia – Intellectual Property Rights* considered that essential security interests is "evidently a narrower concept than 'security interests'" and would relate to "the quintessential functions of the state, namely, the protection of its territory and its population from external threats, and the maintenance of law and public order internally."¹⁷ The panel also said that the discretion of a WTO member to designate particular concerns as "essential security interests" would be governed by the obligation to interpret and apply Article 73 in good faith.¹⁸

Regarding an "emergency in international relations," the panel in *Saudi Arabia – Intellectual Property Rights* concluded that the term refers generally "to a situation of armed conflict, or latent armed conflict, or of heightened tension or crisis, or of general instability engulfing or surrounding a state." It also concluded that while "political" or "economic" conflicts will sometimes be considered politically "urgent" or "serious," they are not "emergenc[ies] in international relations."¹⁹

¹⁷ Panel Report, *Saudi Arabia – Intellectual Property Rights*, paras. 7.249-7.250, cited in the WTO Analytical Index, TRIPS Agreement – Article 73 (Jurisprudence).

¹⁸ Ibid.

¹⁹ Ibid.

WTO Discussions on a Proposed Waiver

Discussions in the WTO on a potential IP response to COVID-19 formally began in October 2020, when India and South Africa initially proposed a waiver of certain TRIPS obligations (copyrights, patents, industrial designs, and undisclosed information) “in relation to prevention, containment or treatment of COVID-19.”²⁰ India and South Africa proposed to extend the waiver 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 have waived the same IPR obligations as originally proposed, but would have limited the waiver to cover initially a period of three years. It would have applied the waiver: “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.”²¹ Debate over the scope of the proposed waiver persisted among WTO members.

On May 5, 2021, the Biden Administration voiced support for the concept of an IPR waiver limited to COVID-19 vaccines, and pledged to “actively participate in text-based negotiations at the [WTO] to make that happen.”²² The announcement followed months of advocacy from stakeholders on both sides of the debate, as well as expressions of support and opposition from Members of Congress.²³ Many observers saw the Administration’s decision as a reversal of the Trump Administration’s stance on the issue, as well as a departure from long-standing U.S. trade policy to seek stronger IPR protection and enforcement in trade agreements.²⁴

Support for the concept of a TRIPS waiver and/or ongoing WTO discussions on it broadened to include some higher-income countries and economic groupings (e.g., the BRICS nations of Brazil, Russia, India, China, and South Africa, and the 19-member Asia-Pacific Economic Cooperation). Some other WTO members continued to oppose or remain skeptical of waiver proposals; these members included the European Union (EU), Switzerland, and the United Kingdom (UK). The EU, for instance, submitted an alternative proposal for equitable access to

²⁰ WTO TRIPS Council, “Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19,” communication from India and South Africa, IP/C/W/669, October 2, 2020.

²¹ WTO TRIPS Council, “Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19,” communication from the African Group, Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, Venezuela, and Zimbabwe, revised decision text, IP/C/W/669/Rev. 1, May 25, 2021.

²² USTR, “Statement from Ambassador Katherine Tai on the COVID-19 TRIPS Waiver,” press release, May 5, 2021.

²³ For an illustration of supporting views, see Office of Senator Bernie Sanders, “NEWS: Senators Urge Biden to Approve Vaccine Patent Waiver to Boost Production and End Pandemic,” press release, April 17, 2021, available at <https://www.sanders.senate.gov/wp-content/uploads/SenateTRIPSletter4.15.21.pdf>; and for an illustration of opposing views, see letter from Republican members of the U.S. House Ways & Means Committee to President Biden, April 13, 2021, available at <https://gop-waysandmeans.house.gov/wp-content/uploads/2021/04/LaHood-WM-IP-Letter-to-Biden-4.13.217.pdf>.

²⁴ Andrew Green, “US Backs Waiver for Intellectual Property Rights for COVID-19 Vaccines,” *Devex*, May 6, 2021.

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.²⁵

Throughout 2021, WTO members' positions remained divergent on "the appropriate and most effective way" to address shortage and access issues for COVID-19 vaccines and other products.²⁶ Some stakeholders expressed hope that WTO members would be able to reach an agreement on these issues before or at the MC12, originally planned for late 2021. The WTO postponed MC12 due to concerns about an outbreak of the Omicron variant of COVID-19, which led to the imposition of travel restrictions and quarantine requirements in Switzerland and elsewhere.

On March 15, 2022, the United States, the EU, India, and South Africa—which the WTO termed the "Quad"—reached a "compromise outcome" agreement on a proposed patent-related TRIPS waiver for COVID-19 vaccines.²⁷ The proposal arose out of an informal process facilitated by the WTO Director-General (DG) in hopes of finding convergence.²⁸ The DG welcomed the compromise among key players in the debate as a "major step forward," but stressed the need to finalize details.²⁹ A USTR official also commented, "The difficult and protracted process has resulted in a compromise outcome that offers the most promising path toward achieving a concrete and meaningful outcome."³⁰ Other WTO members generally supported the informal efforts, but some called for them to have more transparency. The WTO did not publish the reported proposal, but other sources shared leaks with details of it.

On May 3, the DG forwarded the text of the Quad's document to the full WTO membership.³¹ The official outcome document was similar to the earlier reported version, the primary difference being some additional text bracketed (i.e., indicating such text has not been agreed and is still under discussion). Many WTO members welcomed the proposal as a positive development. A number of WTO members called for further engagement to address specific issues that remained bracketed in the outcome document, including which WTO members would be eligible to use the waiver.³² At the May 10 WTO General Council meeting, WTO members agreed that the outcome document opened up the prospect for text-based negotiations on an IPR response to COVID-19.³³

Negotiations on a WTO decision reportedly were contentious and continued until the final hours of the MC12, which was held on June 12-17, 2022. WTO members reached a ministerial decision

²⁵ European Commission, "EU Proposes a Strong Multilateral Trade Response to the COVID-19 Pandemic," press release, June 4, 2021.

²⁶ WTO, "TRIPS Council Agrees to Continue Discussions on IP Response to COVID-19," press release, July 20, 2021.

²⁷ WTO, DG, "Director-General Okonjo-Iweala Hails Breakthrough on TRIPS COVID-19 Solution," press release, March 16, 2022.

²⁸ WTO, "Members Updated on High-Level Talks Aimed at Finding Convergence on IP COVID-19 Response," press release, March 10, 2022.

²⁹ WTO, DG, "Director-General Okonjo-Iweala Hails Breakthrough on TRIPS COVID-19 Solution," press release, March 16, 2022.

³⁰ USTR, "Statement from USTR Spokesperson Adam Hodge on the WTO TRIPS Waiver Discussions," press release, March 15, 2022.

³¹ WTO, TRIPS Council, "Communication from the Chairperson," IP/C/W/688, May 3, 2022.

³² WTO, TRIPS Council, "TRIPS Council Hears Initial Reactions to Quad's Outcome Document on IP COVID-19 Response," press release, May 6, 2022.

³³ WTO, General Council, "Members Welcome Quad Document as Basis for Text-Based Negotiations on Pandemic IP Response," May 10, 2022.

via consensus on a WTO TRIPS waiver for COVID-19 vaccines on June 17, as part of a broader "Geneva Package" of multilaterally negotiated outcomes on various trade issues.³⁴

TRIPS Waiver Decision for COVID-19 Vaccines

The WTO's Ministerial Decision on the TRIPS Agreement, adopted on June 17, 2022, provides a five-year waiver of certain requirements concerning CLs for COVID-19 vaccines.³⁵ The decision permits an eligible member to use the subject matter of a patent, including ingredients and processes necessary to manufacture the COVID-19 vaccine, without the right holder's consent through any instrument available in the law of the member that permits such an authorization (e.g., executive orders, emergency decrees, and judicial or administrative orders). The member need not have a CL regime in place.

Noting "the exceptional circumstances of the COVID-19 pandemic," the decision uses the authority provided for in the WTO Marrakesh Agreement for the WTO Ministerial Conference to waive an obligation imposed on a member "[i]n exceptional circumstances."³⁶

Scope and Potential Expansion

The decision presently is limited to "the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address" the pandemic. It contains an understanding that the "subject matter of a patent" includes "ingredients and processes necessary for the manufacture of the COVID-19 vaccine."

The decision states that no later than six months from the decision date, members are to decide whether to extend the decision to also cover the production and supply of COVID-19 diagnostics and therapeutics. The WTO TRIPS Council has begun discussion on the possible extension.³⁷

Member Eligibility

The decision provides that all "developing country" WTO members qualify as eligible members to take advantage of the waiver, but it encourages developing country members with existing capacity to manufacture COVID-19 vaccines "to make a binding commitment not to avail themselves" of the decision (see **text box** on related debate).³⁸ The decision notes that such binding commitments include statements made by eligible members to the WTO General Council, including at its May 10, 2022, meeting and that such statements will be recorded by the TRIPS Council and compiled and published publicly on the WTO website.

³⁴ WTO, "Ministerial Decision on the TRIPS Agreement" (adopted on June 17, 2022), WT/MIN(22)/30, WT/L/1141, June 22, 2022.

³⁵ Ibid.

³⁶ WTO, Marrakesh Agreement Establishing the World Trade Organization, Article IX.

³⁷ WTO, "TRIPS Council Welcomes MC12 TRIPS Waiver Decision, Discusses Possible Extension," press release, July 6, 2022.

³⁸ The WTO does not have definitions of "developed" and "developing" countries. WTO members announce for themselves whether they are "developed" or "developing" countries. See WTO, "Who are the Developing Countries in the WTO?," available at https://www.wto.org/english/tratop_e/devel_e/d1who_e.htm.

Debate on Country Eligibility

Country eligibility, particularly for China, was a major point of contention during negotiations among WTO members on a potential waiver of the WTO TRIPS Agreement for COVID-19 vaccines. The earlier draft of the outcome document contemplated two options. One option was similar to what was ultimately agreed in the June 17, 2022, decision at the WTO 12th Ministerial Conference—allowing all developing countries to be eligible, while encouraging developing country members with the capacity to export vaccines to opt out of the decision (although not making references to binding commitments, a change that came with the final decision). The other option would have made eligible any developing country member that exported less than 10% of world exports of COVID-19 vaccine doses in 2021 (e.g., India and South Africa, but not China, per an international vaccine trade tracker).

The U.S. delegation reportedly sought a stringent definition of eligibility to ensure that China would not be able to use the proposed waiver. China's representatives strongly opposed language that it claimed would target it specifically, and expressed a preference for flexibility. At the May 10, 2022, WTO General Council meeting, the Chinese delegation announced that China would not use the flexibilities under the Quad waiver text, provided that language was used to open the benefits of the waiver to all developing members while encouraging those with capacity to export vaccines to opt out. China and several other members rejected the option that would have restricted waiver eligibility to those developing countries that exported more than 10% of the world's vaccine doses in 2021.

Sources: WTO, "WTO-IMF COVID-19 Vaccine Trade Tracker," last updated April 28, 2022; and WTO General Council, "Members Welcome Quad Document as Basis for Text-Based Negotiations on Pandemic IP Response," press release, May 10, 2022.

CL Clarifications and Waiver

The decision includes a waiver and a number of CL-related clarifications that are intended to make it easier for eligible members to access COVID-19 vaccines produced under CL, compared to existing TRIPS flexibilities for CLs (see **Table 1**).

Table 1. WTO TRIPS Waiver Decision on COVID-19 Vaccines: Selected Provisions

CL Issue	Related General TRIPS Flexibility	WTO June 17, 2022, Ministerial Decision on the TRIPS Agreement
Efforts to obtain authorization	TRIPS generally requires efforts to obtain an authorization from the right holder for CL use, but it waives them in cases of "national emergency" or "extreme urgency."	An eligible member does not need to require the proposed user of the patented subject matter to first seek an authorization from the right holder.
Scope of authorization	TRIPS generally limits CL use predominantly to supply the domestic market, but allows the export of CL-covered pharmaceuticals to countries with limited domestic manufacturing capacity.	An eligible member may waive the TRIPS requirement that authorized CLs be used predominantly to supply its domestic market, and also may allow any proportion of the products manufactured under the authorization per the decision to be exported to eligible members—including through international or regional initiatives that aim to ensure the equitable access of eligible members to the COVID-19 vaccine covered by the authorization.

CL Issue	Related General TRIPS Flexibility	WTO June 17, 2022, Ministerial Decision on the TRIPS Agreement
Re-exportation	TRIPS requires members to take "reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories" under the Paragraph 6 System. For eligible developing country or LDC importing members experiencing difficulty implementing this provision, developed country members must provide, upon request and by mutual agreement, technical and financial cooperation to facilitate its implementation.	Eligible members must "undertake all reasonable efforts to prevent the re-exportation" of COVID-19 vaccines that have been imported into their territories under the decision. Re-exportation by an eligible member to other eligible members is permissible "[i]n exceptional circumstances," subject to communication requirements. Eligible members also must "ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products manufactured under the authorization ... and diverted to their markets inconsistently with" the decision's provisions, using means that already must be available under TRIPS.
Remuneration	TRIPS requires the right holder to "be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."	Eligible members may take into account the "humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines ... at affordable prices" and "existing good practices in instances of national emergencies, pandemics, or similar circumstances," in determining compensation to the right holder. This includes remuneration aspects outlined in a 2020 study on promoting access to medical technologies and innovation by the World Health Organization (WHO), World Intellectual Property Organization (WIPO), and WTO, and a set of WHO remuneration guidelines.

Source: CRS, based on the WTO decision and the WTO TRIPS Agreement.

Transparency

The decision requires, for purposes of transparency, an eligible member to communicate to the TRIPS Council any measure related to the implementation of this decision, including the granting of an authorization. It specifies that the information must include the name and address of the authorized entity, the products for which the authorization has been granted, and the duration of the authorization. It requires information about the quantities for which the authorization has been granted and the countries to which the products are to be supplied to be "notified as soon as possible after the information is available."

Duration of the Decision

An eligible member may apply the decision's provisions until five years after the date of the June 17, 2022, decision. The decision provides that the General Council "may extend" this period, "taking into consideration the exceptional circumstances" of the pandemic. It requires the General Council to review the operation of the decision annually.

Relation to Other WTO Rules

The decision also has provisions regarding how it relates to other WTO rules:

- *Vaccine approval speed and test data protection.* The decision includes an understanding that TRIPS Article 39.3 does not prevent an eligible member from enabling the rapid approval for use of a COVID-19 vaccine produced under this decision. Article 39.3 requires members—when requiring submission of undisclosed test data as a condition of approving a pharmaceutical product using new chemical entities—to protect that undisclosed data against unfair commercial use. It requires members to protect such data from disclosure, except where necessary to protect the public, or unless steps are taken to ensure protection of the data from unfair commercial use.
- *WTO dispute challenges.* The decision prohibits WTO members from challenging any measures taken in conformity with this decision under Article XXIII, subparagraphs 1(b) and 1(c), of the GATT 1994.³⁹ These subparagraphs relate to disputes concerning “nullification or impairment” of any benefit a member expects to accrue to it under an agreement, or impeding the attainment of the WTO’s objectives as a result of the application by another contracting party of any measure, whether or not it conflicts with the WTO Agreement, or any other situation. The decision does *not* prohibit nullification or impairment challenges with respect to subparagraph 1(a) of Article XXIII, which concerns the failure of another contracting party to carry out its obligations under the WTO Agreement. In other words, if a WTO member invokes the TRIPS waiver in a way that does not conform to the terms of the decision, then the usual TRIPS obligations apply to the situation. That WTO member could then potentially face challenges from other WTO members that it has violated the TRIPS Agreement by failing to adhere to its TRIPS obligations (e.g., failure to protect patent owners’ exclusive rights as required by Article 28).
- *Existing TRIPS flexibilities.* The decision states that it is “without prejudice” to the existing flexibilities that members have under TRIPS, including those affirmed in the Doha Declaration, and that it is also “without prejudice” to members’ rights and obligations under TRIPS, except as otherwise provided for in the waiver’s CL provision. It also states, “[f]or greater certainty,” the decision is without prejudice to the interpretation of the above-mentioned flexibilities, rights and obligations *outside* the scope of the decision.

Issues for Congress

The TRIPS waiver decision on COVID-19 vaccines presents a number of possible issues for Congress.

Impact on IPR, Innovation, and Vaccine Production and Access

Some Members of Congress and many in the pharmaceutical and other industries opposed the concept of a TRIPS waiver and were highly critical of the outcome at the WTO’s 12th Ministerial

³⁹ This is consistent with all other TRIPS complaints, as Members have committed to not bring any Article XXIII(b) and (c) complaints. See WTO, “TRIPS Non-Violation and Situation Complaints Moratorium,” General Council Decision (adopted on December 10, 2019), WT/L/1080, December 11, 2019.

conference.⁴⁰ They assert that IPR supported the unprecedented development and scale-up of COVID-19 vaccines.⁴¹ They also assert that the IP framework has provided the basis for "more than 380 voluntary partnerships for COVID-19 vaccines to be set up in record time, 88% of which involve technology transfer."⁴² They argue that patents and other forms of IPR incentivize innovation, and that the TRIPS waiver could weaken these incentives by preventing innovator companies from recouping their investments and pursuing future innovations, hampering partnerships, voluntary licensing, and knowledge-sharing that has taken place during the pandemic under the IP-based framework.⁴³ Many in industry further argue that the WTO decision undermines efforts to boost COVID-19 vaccine production and access. The U.S. Chamber of Commerce, for instance, contended that IP waiver proposals "distract from the real issues preventing more shots in arms, such as logistical hurdles, supply chain bottlenecks, and vaccine hesitancy."⁴⁴ The Pharmaceutical Researchers and Manufacturers of America (PhRMA) expressed a similar sentiment, and pointed to other issues that they described as problematic as well, such as border tariffs on medicines.⁴⁵

Some other Members of Congress and many public health and other civil society stakeholders had expressed support for the concept of a TRIPS waiver.⁴⁶ They contended that existing general TRIPS flexibilities were insufficient to address the massive scale of the pandemic, arguing that the process for issuing a CL is too lengthy, costly, and cumbersome to be a viable strategy to address shortfalls in domestic manufacturing of COVID-19 vaccines.⁴⁷ They further argued that suspending IPR obligations could allow countries to authorize producers to manufacture COVID-19 products without facing the threat of a WTO dispute or other negative trade consequences. They also asserted that the IP should be shared publicly, given that the government and nongovernmental organization (NGO) funding underlies much of the innovations in COVID-19 vaccines.⁴⁸ While some of these supporters of the concept of a TRIPS waiver generally welcomed the WTO ministerial decision on a TRIPS waiver, some of them disapproved of its negotiated

⁴⁰ See, for example, Senate Finance Committee, "Crapo Statement on TRIPS Waiver," press release, May 5, 2021; Office of Senator Thom Tillis, "Tillis and Cotton Statement on President Biden's Disastrous Decision to Support the TRIPS Waiver," press release, May 5, 2021; and House Ways & Means Committee (Republican website), "Brady, Crapo: President Biden Set America's Interests Back at WTO—No Dispute Reform, Surrendered Crucial Medical Patents, Failed to Protect U.S. E-Commerce, Fishing Interests," press release, June 17, 2022.

⁴¹ See, for example, Biotechnology Innovation Organization (BIO), "WTO TRIPS Waiver a 'Distraction'—And 'Vehicle to Raid U.S. Innovation,'" June 20, 2022.

⁴² International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), "Pharmaceutical Industry Expresses Deep Disappointment with Decision on Waiving Intellectual Property Rights Adopted at the World Trade Organization Ministerial Conference," press release, June 17, 2022.

⁴³ Ibid.

⁴⁴ U.S. Chamber, "U.S. Chamber Letter on the 'No Free TRIPS Act' and the 'Protecting American Innovation Act,'" April 11, 2022.

⁴⁵ Pharmaceutical Researchers and Manufacturers of America (PhRMA), "PhRMA Statement on the TRIPS Waiver Agreement," press release, June 17, 2022.

⁴⁶ See, e.g., Office of Senator Bernie Sanders, "NEWS: Senators Urge Biden to Approve Vaccine Patent Waiver to Boost Production and End Pandemic," press release, April 17, 2021; and Office of Congresswoman Jan Schakowsky, "Members of Congress that Led Push for TRIPS Waiver Applaud Biden Administration Announcement," press release, May 5, 2021.

⁴⁷ See, e.g., Médecins Sans Frontières, "India and South Africa Proposal for WTO Waiver from Intellectual Property Protections for COVID-19 Related Medical Technologies," November 18, 2020.

⁴⁸ For background, see CRS In Focus IF11951, *Domestic Funding for COVID-19 Vaccines: An Overview*, by Kavya Sekar. See also Judy Stone, "The People's Vaccine—Moderna's Coronavirus Vaccine Was Largely Funded by Taxpayer Dollars," December 3, 2020; and Richard G. Frank, Leslie Dach, and Nicole Lurie, "It was the Government That Produced COVID-19 Vaccine Success," *Health Affairs*, May 14, 2021.

scope.⁴⁹ Key concerns cited included that the TRIPS waiver did not cover COVID-19 diagnostics and therapeutics but rather postponed a decision on whether to extend coverage to these countermeasures by six months, did not address access to the “know-how” that is critical to develop and distribute COVID-19 vaccines, and did not add significantly to existing TRIPS flexibilities.⁵⁰ Some of these groups also argue that the WTO decision was made so late into the pandemic that it is no longer timely.⁵¹

Another point of debate is whether the TRIPS waiver poses any threats to U.S. competitiveness. Some Members of Congress and business groups argue that it could compromise U.S. competitiveness internationally and pose major national security threats in terms of risks of IPR theft by China and Russia.⁵² For example, some Members of Congress express doubt about China’s commitment not to use the TRIPS waiver.⁵³ Such critics contend that China’s record shows that it could engage in economic espionage or commercial IPR theft to steal valuable COVID-19-related patent information, and that Chinese firms have been trying to steal U.S. COVID-19-related research.⁵⁴ They argue that little is stopping other developing countries from sharing COVID-19-related technology with China, as a condition of financial support or market access. TRIPS waiver supporters argue that these concerns are overblown. They contend that the WTO decision does not increase risks of China gaining access to foreign COVID-19 vaccine technology, as China is already engaged in technology transfer agreements with foreign manufacturers and in advanced R&D efforts domestically.⁵⁵ They also argue that any additional source of vaccines globally, even if from China, is a net benefit to global health.

Members of Congress may conduct oversight of and legislate on whether and how the executive branch supports the use of the TRIPS waiver by eligible WTO members. The debate may take on new dimensions with possible continued mutations of the Omicron variant, as well as possible new variants of SARS-CoV-2, and other developments in the ongoing pandemic.

⁴⁹ See, e.g., Andrew Green, “WTO Finally Agrees on a TRIPS Deal. But Not Everyone is Happy,” *Devex*, June 17, 2022. Looking more broadly at MC12, some Members of Congress generally welcomed the WTO agreements reached in June 2022, while noting that the agreements may have limitations or that work on the issues remain. See House Ways & Means Committee, “Neal Statement on World Trade Organization 12th Ministerial Conference,” press release, June 17, 2022; and Senate Finance Committee, “Wyden Statement on WTO Ministerial Conference Agreements,” press release, June 17, 2022.

⁵⁰ Andrew Green, “WTO Finally Agrees on a TRIPS Deal. But Not Everyone is Happy,” *Devex*, June 17, 2022.

⁵¹ See, e.g., India Ministry of Commerce & Industry, “Statement by Shri Piyush Goyal During the WTO 12th Ministerial Conference at the Meeting with Co-Sponsors of the TRIPS Waiver,” press release, June 14, 2022.

⁵² China and Russia are countries of major ongoing U.S. concern more broadly in terms of IPR theft. See USTR, 2022 *Special 301 Report*, April 2022.

⁵³ Senate Finance Committee, “Crapo, Brady: President Biden Set America’s Interests Back at WTO—No Dispute Reform, Surrendered Crucial Medical Patents, Failed to Protect U.S. e-Commerce, Fishing Interests,” press release, June 17, 2022.

⁵⁴ See, e.g., Federal Bureau of Investigation (FBI), “People’s Republic of China (PRC) Targeting of COVID-19 Research Organizations,” press release, May 13, 2020; and Department of Justice (DOJ), “Two Chinese Hackers Working with the Ministry of State Security Charged with Global Computer Intrusion Campaign Targeting Intellectual Property and Confidential Business Information, Including COVID-19 Research,” press release, July 21, 2020.

⁵⁵ On China’s collaborations with foreign manufacturers, see, for instance, BioNTech, “BioNTech and Fosun Pharma Form COVID-19 Vaccine Strategic Alliance in China,” press release, March 16, 2020; and Alexandra Stevenson, “These Vaccines Have Been Embraced by the World. Why Not in China?,” *The New York Times*, February 18, 2022. On China’s domestic vaccine development efforts, see Yvaine Ye, “China’s First mRNA Vaccine is Close—Will That Solve Its COVID Woes,” *Nature*, June 27, 2022; and Eleanor Olcott, “New Covid Variants Threaten China’s mRNA Vaccine Hopes,” *Financial Times*, July 6, 2022.

Trade Policy Implications

Congress may examine the implications of the Biden Administration's support for a TRIPS waiver for COVID-19 vaccines for various aspects of U.S. trade policy. An open question is whether U.S. policy moving forward will entail limiting U.S. support for additional TRIPS flexibilities to the unprecedented crisis presented by the COVID-19 pandemic, or lead to a pursuit of a more general policy shift away from the historical U.S. positions in advancing IPR in trade agreements and negotiations. This issue may factor into potential debate on renewal of Trade Promotion Authority (TPA), which expired in 2021.⁵⁶ In particular, Members may examine whether to adjust the principal U.S. trade negotiating objectives for IPR in any future TPA grant.

Congress also may examine the TRIPS waiver's potential implications for the WTO. The TRIPS waiver negotiations and the ongoing debate surrounding the final decision come at a time when many questions continue to swirl about the WTO's ongoing relevance to the changing global economy, including its negotiating function.⁵⁷ Until the "Geneva Package" at MC12 agreed in June 2022, some commentators observed that the WTO had not concluded a major trade agreement since its establishment in 1995, apart from the Trade Facilitation Agreement in 2013.⁵⁸ After MC12, the WTO Director-General and the Administration characterized the TRIPS waiver decision as a significant development and as an example of the WTO's utility.⁵⁹ Stakeholders on different sides of the debate have variously countered that WTO members mainly secured the decision as a "political stunt" and "technocratic fudge aimed at saving reputations, not lives."⁶⁰

Congressional Role and Transparency

A question that intensified as the WTO talks progressed was whether there should be more of a congressional role before the Administration could agree to modifying TRIPS obligations and future WTO agreements or negotiations. In the 117th Congress, several Members of Congress introduced legislation that would require more congressional input or approval before the President could agree to modifying TRIPS obligations.⁶¹

Several Members of Congress in both political parties expressed dismay with the USTR's approach to the negotiations in terms of consultation with Congress and transparency. A letter to Ambassador Tai by six Members of Congress of the Senate Finance Committee, including the Chairman and Ranking Member, pointed to the USTR's approach to the TRIPS waiver talks as falling short of the USTR's 2021 Transparency Principles, which incorporated Guidelines for

⁵⁶ CRS In Focus IF10038, *Trade Promotion Authority (TPA)*, by Ian F. Fergusson and Brock R. Williams.

⁵⁷ For background, see CRS In Focus IF11513, *WTO: 12th Ministerial, COVID-19, and Ongoing Issues*, by Cathleen D. Cimino-Isaacs and Rachel F. Fefer; and CRS Report R45417, *World Trade Organization: Overview and Future Direction*, by Cathleen D. Cimino-Isaacs and Rachel F. Fefer.

⁵⁸ See, for example, James McBride and Anshu Siripurapu, "What's Next for the WTO?," Council on Foreign Relations, June 10, 2022.

⁵⁹ WTO, "MC12 Closing Session," remarks by WTO Director-General Ngozi Okonjo-Iweala, June 17, 2022, available at https://www.wto.org/english/news_e/spno_e/spno27_e.htm; and USTR, "Statement from Ambassador Katherine Tai on an Intellectual Property Response to the COVID-19 Pandemic," press release, June 17, 2022.

⁶⁰ See, e.g., PhRMA, "PhRMA Statement of the TRIPS Waiver Agreement," press release, June 17, 2022; and Oxfam, "Responding to News that Governments at the World Trade Organization (WTO) Have Agreed a Deal on Patents for COVID-19 Vaccines in Developing Countries," press release, June 17, 2022, accessed via ReliefWeb.

⁶¹ See, for example, H.R. 3811, H.R. 3236, H.R. 3694, H.R. 3788, H.R. 7430, H.R. 7582, H.Res. 1169, H.Res. 1285, S. 1683, and S. 4063.

Consultation and Engagement to which USTR agreed in 2015.⁶² The letter stated that USTR announced the “compromise outcome” before informing Congress about the specifics of the compromise or sharing the text of the proposal—which it asserted was a departure from USTR’s commitment in the Guidelines to share both text of U.S. proposals and consolidated text with Members of Congress and their cleared staff during negotiations. The letter also asserted that “USTR should promptly provide any new U.S. proposals or consolidated text to Congress.”⁶³ In describing the TRIPS waiver outcome at the WTO MC12, the USTR said, “Consultations with our stakeholders in the private sector and civil society, with Members of Congress and their staffs, and colleagues across the Administration, were critical in informing USTR’s understanding of the nuances in the global market, production challenges, and the public health needs of the world’s people.”⁶⁴

Members may continue to oversee and seek to shape the Administration’s participation in any continued WTO discussions on the TRIPS waiver decision, including on its implementation and use by eligible members and the potential for it apply to COVID-19 diagnostics and therapeutics. They also may consider congressional-executive dynamics in relation to potential future waivers of obligations under TRIPS or other WTO agreements in various policy contexts.

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⁶² Senate Finance Committee, “Bipartisan Senate Finance Committee Members Call for Improved Transparency from U.S. Transparency; Cite Failure to Consult with Congress on Recent Negotiations,” press release, May 10, 2022; letter available at <https://www.finance.senate.gov/imo/media/doc/05102022%20USTR%20Consultation%20and%20Transparency%20Letter.pdf>. See also USTR, “USTR Releases Agency Transparency Principles,” May 2021.

⁶³ Ibid.

⁶⁴ USTR, “Statement from Ambassador Katherine Tai on an Intellectual Property Response to the COVID-19 Pandemic,” press release, June 17, 2022.

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