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Legal Sidebar

COVID-19: International Trade and Access to Pharmaceutical Products

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As the coronavirus disease (COVID-19) pandemic continues, governments and the private sector have begun assessing the possibility of developing medical countermeasures (e.g., vaccines, antiviral treatments) to improve patient recovery rates and contain the virus's spread. Some Members of Congress have expressed concern about access to, and the affordability of, any potential countermeasures. As outlined in this CRS Sidebar, Congress can take, and has taken, several steps to address these issues, some of which may raise questions under U.S. law. This Sidebar addresses how certain congressional or executive actions intended to increase access to medical countermeasures might be viewed under the rules of the international trade regime, including: (1) exclusion from patent protection; (2) compulsory licensing of patented products; and (3) increasing domestic capacity.

Exclusion from Patent Protection

Congress has constitutional authority to design and control the scope of a patent system. Thus, as described in this CRS Sidebar, Congress may consider whether to exclude from patent protection certain medical countermeasures to address the COVID-19 pandemic.

The World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) requires all WTO Members to make patents "available for any inventions, whether products or processes, in all fields of technology." Thus, excluding medical countermeasures from patentability may raise questions regarding the legality of such an action. However, the TRIPS Agreement includes several potentially relevant exceptions. First, it expressly permits WTO Members to exclude certain inventions from their patent systems if "necessary to protect," among other things, human life or health. Second, it allows WTO Members to exclude "diagnostic, therapeutic and surgical methods for the treatment of humans" from patentability. These exceptions reflect a consensus among WTO Members "that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health." In particular, WTO Members recognize "that the Agreement can and should be interpreted and implemented in a manner . . . to promote access to medicines for all." Accordingly, Congress may be able to exclude patent protection for at least some medical countermeasures to address COVID-19 (e.g., diagnostic and therapeutic methods) without violating WTO obligations. However, the

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precise contours of the exception are unclear, as the WTO's Dispute Settlement Body has not considered this issue.

Third, Article 30 of the TRIPS Agreement allows WTO Members to create "limited exceptions to the exclusive rights conferred by a patent." However, these exceptions: (1) must "not unreasonably conflict with a normal exploitation of the patent"; (2) must not "unreasonably prejudice the legitimate interests of the patent owner"; and (3) must consider "the legitimate interests of third parties." The scope of this provision is not well defined. However, some WTO Members have used it to allow pharmaceutical manufacturers to seek marketing approval of generic drugs before a patent expires. This use, known as a "regulatory exception" (found in U.S. law at 35 U.S.C. § 271(e)(1)), has been considered and approved in the only WTO dispute involving Article 30 of the TRIPS Agreement. Further, some WTO Members have relied on Article 30 for research and development purposes, allowing scientists to use a patented product for purposes of better understanding the invention. Based on this prior practice, Congress may potentially be able to enact legislation, consistent with WTO obligations, that provides for certain limited research exceptions to patentability, which may allow researchers to use patented pharmaceuticals relevant to the development of new medical countermeasures to address COVID-19.

Compulsory Licensing of Patented Products

If an entity already holds a patent on a medical countermeasure that could be used to treat COVID-19, Congress could consider whether to require the patent holder to allow others to use the patent in order to meet supply needs, a practice known as compulsory licensing. This mechanism has been used in the past to address other diseases, including HIV/AIDS in Thailand and leukemia in Colombia. Recently, Chile has taken steps to permit compulsory licensing for COVID-19 vaccines and medicines. Given the sensitivities involved—including protecting intellectual property rights, providing incentives for innovation, accounting for the increased complexity of products (e.g., multiple patents covering a single product), and meeting public health needs—compulsory licensing has been described as a fairly "heavy-handed" option, and has been used with growing infrequency, especially by wealthier countries. Even if compulsory licensing might hasten the ability to produce a pharmaceutical, any product marketed in the United States would still need to obtain approval from the U.S. Food and Drug Administration.

Compulsory licensing, which arguably infringes on the existing property rights of patent holders, may raise legal issues under U.S. law (e.g., violations of the U.S. Constitution's Takings Clause), as discussed here. It may also raise questions under the WTO regime in certain circumstances. Under the TRIPS Agreement, for instance, WTO Members are obligated to respect and enforce intellectual property rights. In other words, Members may not generally require patent holders to allow third parties to use the protected product or process. However, Article 31 of the TRIPS Agreement allows Members to act contrary to this general rule and enact measures that allow for compulsory licensing on a case-by-case basis, provided these measures satisfy several conditions. These conditions include: (1) making an effort to obtain authorization for use from the patent holder on "reasonable commercial terms" before opting for a compulsory licensing measure, except in cases of "national emergency or other circumstances of extreme urgency"; (2) ensuring the measure is time-limited; and (3) paying the patent holder "adequate remuneration." Additionally, although compulsory licensing must generally be implemented to address the needs of the WTO Member's own market, it may also be used to export the relevant product to developing or least-developed countries that lack the capacity to produce the relevant product.

As with the public health-related exception to the WTO's patentability obligation, the compulsory licensing exception reflects a concern about access to medicines, particularly in developing and least-developed countries. In 2001, WTO Members affirmed that they have "the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." Although compulsory licenses may be used even absent emergencies, the precondition for their use—that the

government negotiate with the patent holder before implementing compulsory licenses—is waived during "a national emergency or circumstances of extreme urgency." WTO Members have also agreed that "public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics" can qualify as "a national emergency or circumstances of extreme urgency."

If Congress chose to use a compulsory licensing system as part of a strategy to promote access to medical countermeasures during the COVID-19 pandemic, it may be able to rely on the TRIPS Agreement's authorization provision, provided any system complies with all of the Agreement's conditions. To date, there has been no legal challenge before the WTO to a compulsory licensing system introduced during a pandemic.

Increasing Domestic Capacity

Presuming that any intellectual property rights issues could be navigated, a related question is how to increase domestic capacity or production rapidly. This section provides a brief overview of current or proposed federal actions in this area.

On March 18, 2020, President Trump issued an Executive Order (EO) invoking the Defense Production Act to allow the U.S. Secretary of Health and Human Services to decide how to address potential shortages of "health and medical resources needed to respond to the spread of COVID-19." This Act permits the Executive Branch to incentivize domestic production or to direct the fulfillment of certain product orders before others, as with the President's order that General Motors produce ventilators. Thus far, the Act has not been used to place orders or to direct production of pharmaceuticals. It is uncertain whether the "resources" referenced in the President's EO includes pharmaceuticals, as no definition of "resources" is given and the EO emphasized production of protective personal equipment (e.g., masks, garments) and medical equipment (e.g., ventilators). As described in this CRS Sidebar, financial incentives might amount to unlawful subsidies in violation of WTO rules, but the United States could potentially seek to rely on exceptions for essential security or protection of public health to justify such incentives.

The Administration may also be considering an executive order requiring or encouraging federal agencies to purchase American-made pharmaceuticals and pharmaceutical ingredients, amongst other items. In itself, such a requirement does not increase domestic production, but is part of a broader strategy to incentivize and increase domestic production capacity due, in part, to concern about meeting the demand for pharmaceuticals in the event of severe disruptions to international supply chains. Some scholars, industry groups, and Members of Congress have expressed reservations about such an executive order. In particular, they note that current U.S. capacity may be insufficient to meet immediate public health care needs (manufacturing of 72 percent of pharmaceutical ingredients for U.S. markets occurs outside of the United States), and closing off access to foreign suppliers may raise supply chain vulnerabilities in the event of disruptions within the United States.

Depending on its contents, such an executive order could also raise a number of issues under WTO rules. For example, the Agreement on Government Procurement, a plurilateral WTO agreement that the United States has joined, prohibits Members from discriminating against foreign suppliers in the procurement process in favor of domestic producers. An executive order requiring federal agencies to "Buy American" may potentially violate this obligation. However, the Executive may waive these procurement requirements to comply with trade obligations. To the extent that a waiver is not granted, the United States might seek to justify discriminatory purchasing requirements under Article III of this Agreement, which permits WTO Members to implement potentially inconsistent measures for "procurement indispensable for national security or for national defence purposes" and, subject to certain limitations, to protect public health.

Aside from executive action, Congress could also consider legislative means of incentivizing domestic production. As with those incentives that the Executive Branch may offer, congressional incentives may potentially amount to unlawful subsidies under the WTO regime, but the United States could seek to justify its measures under the essential security or protection of public health exceptions.

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