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INSIGHT

Breakthrough on a Potential COVID-19 Intellectual Property Rights Waiver

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On March 15, 2022, the United States, the European Union (EU), India, and South Africa reached agreement on a proposed "TRIPS" patent waiver for Coronavirus Disease 2019 (COVID-19) vaccines. The Director-General (DG) of the World Trade Organization (WTO) welcomed the compromise among key players in the debate as a "major step forward," but stressed the need to finalize details. The broader WTO membership is expected to discuss the proposed agreement as WTO decisions generally are by consensus. These developments present issues for Congress including regarding the congressional role, COVID-19 medical incentives and global vaccine access, and U.S. trade policy in advancing intellectual property rights (IPR).

WTO Discussions

Propelling the TRIPS waiver discussions were India and South Africa's October 2020 proposal—and revised proposal, supported by many low- and middle-income countries—for broader IPR waivers covering COVID-19-related vaccines, therapeutics, diagnostics, and other health products and technologies. In May 2021, the Biden Administration supported the concept of an IPR waiver for COVID-19 vaccines; Members of Congress have supported and opposed the Administration's position. Some WTO members remained skeptical—the EU described existing TRIPS flexibilities as sufficient and proposed facilitating their greater use.

What is TRIPS?

The 1995 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) contains obligations for WTO members to protect patents and other intellectual property rights (IPR). TRIPS also includes flexibilities, such as provisions for compulsory licenses (CLs) of pharmaceutical patents under certain conditions, and exemptions—which waivers have extended until 2033—for least-developed members from pharmaceutical patent obligations. Uneven global access to COVID-19 vaccines and treatments distribution have renewed debates over TRIPS' balance in supporting innovation and access to medicines.

The breakthrough arose from high-level talks, facilitated by the DG, among the United States, the EU, India, and South Africa, increasing prospects for convergence. Other members generally supported these efforts, but called for greater transparency.

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Proposed Agreement

The reported proposal—which the WTO has not published but other sources have shared—would permit an "eligible" WTO member to temporarily authorize use of patented inventions necessary for COVID-19 vaccine production and supply, without the right holder's consent. An eligible member would be 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). It could use any instrument available in law (e.g., executive orders, emergency decrees, judicial rulings, or administrative orders) to make the authorization; it need not have a compulsory licensing (CL) regime.

The proposed agreement would clarify or waive existing CL requirements, providing that an eligible member, for example:

- may issue a single authorization to use multiple patented subject matter necessary for COVID-19 vaccine production and supply. TRIPS requires CL authorization of a patented subject matter to be considered on its individual merits.
- would not need to require the proposed patent user to first make efforts to obtain the right holder's consent. TRIPS generally requires such efforts for CL use, but waives them in cases of "national emergency" or "extreme urgency," including "public health crises."
- may waive the general CL requirement that such authorized use be predominantly to supply the domestic market, and allow its use for exports to eligible members and global COVID-19 vaccine access initiatives. TRIPS allows the export of CL-covered pharmaceuticals to countries with limited domestic manufacturing capacity.
- could 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. Under TRIPS, such determination is to take into account the authorization's "economic value."

An eligible member would have to report measures it takes under the agreement, and take steps to prevent the re-export of COVID-19 vaccines imported into its territory. WTO members would not be able to challenge measures taken in conformity with the agreement.

The proposed agreement's duration would be three or five years from its decision date, with a possible extension. Within six months of the decision date, members would have to decide whether to extend coverage to COVID-19 diagnostics and therapeutics.

Stakeholder Reactions

The proposed agreement has drawn concerns from waiver supporters and opponents. Pharmaceutical and industry associations assert that it would threaten medical innovation and U.S. competitiveness; distract from the actual challenges to increasing COVID-19 vaccine access (e.g., supply chain bottlenecks); and undermine current licensing arrangements for global COVID-19 vaccine production and technology transfer. Some public health advocates welcome the breakthrough but criticize it for not covering other technologies or "technical know-how," and not adding enough to current TRIPS flexibilities. Recent developments, including news that a South Africa company, with World Health Organization support, reverse-engineered the Moderna COVID-19 vaccine, add new dimensions to the debate.

Issues for Congress

Members may continue to oversee and seek to shape the Administration's participation and position in the TRIPS waiver talks. Key issues include:

- Should more congressional input or approval be required before the Administration could agree to modifying TRIPS obligations (as proposed in some pending bills)?
- How would the proposed agreement affect innovation incentives for COVID-19 vaccines and other treatments? What would it mean for U.S. competitiveness vìs-a-vìs China, which poses major IPR theft challenges?
- How would the proposed agreement affect global COVID-19 vaccine production and access? Would any boost occur quickly enough to respond to the pandemic's current stage, or be more relevant to respond to potential future variants? What does the proposed agreement mean for future pandemic responses?
- Is the U.S. position on this waiver particular to COVID-19 or a general policy shift as it relates to historical U.S. positions in advancing IPR in trade agreements? How may these issues shape potential debate on Trade Promotion Authority renewal and U.S. IPR trade negotiating objectives?
- What would a timely COVID-19 IPR outcome—or its absence—mean for debates about the WTO's relevance in the changing global economy?

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