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Update on the Proposed TRIPS Waiver at the WTO: Where is it Headed, and What to Expect?

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On June 8-9, 2021, the World Trade Organization's (WTO) TRIPS Council will hold their first meeting in the wake of the U.S. Trade Representative (USTR) announcing "the Biden-Harris Administration's support for waiving intellectual property protections for COVID-19 vaccines" under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). A TRIPS waiver, if issued, could potentially permit the unimpeded manufacture and distribution of COVID-19 vaccines, diagnostic kits, and therapeutics without regard for the intellectual property rights of the inventors and developers of the technologies that enabled their development, and without following existing effective processes for ensuring widespread access to life-saving immunizations, testing, and treatment.

Since the USTR's announcement, 62 countries sponsoring a TRIPS waiver issued a revised proposal[1] to advance text-based negotiations; China expressed openness to discussing the waiver; Germany and others stated their continued opposition, and the EU has urged a "third way" proposal. The TRIPS waiver has also been disputed in U.S. Congress, with some opponents introducing legislation to limit USTR's authority to agree to a waiver in the WTO. The public debate over the waiver has shifted as well – with an increasing focus on trade secrets, technology transfer, supply chain constraints, and other factors impacting global vaccine production aside from any effects of patent rights.

Continue reading for our update on where the TRIPS waiver proposal is headed; the practical concerns raised by the proposal; and potential legal limitations that may impact passage and implementation of a TRIPS waiver. And see our previous client alert on the TRIPS waiver proposal for additional background and insights.

Where does the TRIPS waiver stand, and where is it headed?

In their original October 2, 2020 submission to WTO, India and South Africa proposed waiving member countries' TRIPS obligations to protect any patents, copyrights, industrial designs, or trade secrets ("undisclosed information") "in relation to prevention, containment or treatment of COVID-19," until "widespread vaccination is in place globally."[2]

For months thereafter, the waiver proposal remained deadlocked in the WTO, largely with developing nations signing on to sponsor or support the waiver, and multiple developed nations opposing the waiver in favor of alternative approaches to increasing global vaccine equity. But on May 5, 2021, USTR Katherine Tai made the unprecedented announcement that the Biden-Harris Administration "supports the waiver of [intellectual property] protections for COVID-19 vaccines," and "will actively participate in text-based negotiations at the [WTO] needed to make that happen."[3]

Since then, international positions surrounding the waiver proposal have been evolving at a rapid pace – with new developments reported almost daily. China announced on May 18 that it would support a TRIPS waiver "that is conducive to fair access to vaccines in developing countries"[4]; Germany expressly stated opposition to a TRIPS waiver; and the EU more broadly announced support for a "third way" alternative that includes "trade facilitation and disciplines on export restrictions," "support for the expansion of production" (including through voluntary licensing agreements), and "clarifying and simplifying the use of compulsory licenses [under TRIPS] during crisis times."[5] WTO Director-General Ngozi Okonjo-Iweala, who has supported a "third way" in recent months,[6] now states that "we must act now to get all our ambassadors to the table to negotiate a [waiver] text."[7]

Notably, the USTR's support for a waiver targeting "COVID-19 ***vaccines***" differs substantially from the May 21, 2021 revised proposal by India, South Africa and their 60 co-sponsors – which relates broadly to "***health products and technologies*** … for the ***prevention, containment or treatment*** of COVID-19." Under the sponsors' revised proposal, WTO members would be relieved (for at least 3 years) of their TRIPS obligations to protect patents, copyrights, industrial designs and trade secrets for any "***diagnostics, therapeutics, vaccines, medical devices, personal protective equipment***" used in relation to preventing, containing or treating COVID-19 – as well as "***their materials or components, and their methods and means of manufacture***." Notably, the revised proposal is not substantially different from the original proposal, and suggests that WTO members may remain divided on this controversial issue.

The next meeting of the TRIPS Council to discuss the waiver proposal is taking place on June 8-9, 2021, and will be closely watched. Because any TRIPS waiver would require consensus of all 164 WTO member countries, any text-based negotiations that take place would likely proceed over the course of several months or more.

What are the ongoing efforts to expand vaccine production without a TRIPS waiver?

Proponents have advanced the proposed TRIPS waiver in the name of meeting global vaccine demand. But even in the absence of a waiver, pharmaceutical manufacturers have continued efforts to expand global production and distribution of COVID-19 vaccines and therapies, with a focus on expanding access to developing countries. For example, Pfizer announced its plan to deliver two billion doses to developing nations over the next 18 months, with one billion doses coming this year.[8] One forecast estimates that, by the end of 2021, total global COVID-19 vaccine production may exceed 11 billion doses – an amount potentially sufficient to achieve global herd immunity.[9]

Several pharmaceutical industry groups have also proposed a five-step plan to "urgently advance COVID-19 equity," including: (1) increasing dose sharing among countries through COVAX and other mechanisms; (2) optimizing production of vaccines and raw materials; (3) eliminating trade barriers for critical raw materials; (4) supporting country readiness to deploy vaccination programs; and (5) driving further innovation.[10]

Manufacturers have also continued to partner with other companies in efforts to scale up global production. For example, Moderna recently engaged Samsung Biologics to provide fill-and-finish manufacturing for Moderna's vaccine.[11] Merck and Gilead also each entered into or expanded voluntarily licensing programs with manufacturers in India to produce the companies' respective COVID-19 antiviral agents molnupiravir and remdesivir.[12]

Some WTO members have also considered using the existing TRIPS flexibilities to expand their vaccine access. For example, Bolivia has continued to pursue its effort to import the Johnson & Johnson COVID-19 vaccine from Canadian company Biolyse Pharma, under a compulsory license pursuant to TRIPS Article 31*bis* (if one could be obtained).[13]

How might a TRIPS waiver impact ongoing efforts to scale COVID-19 vaccine production?

A TRIPS waiver would potentially hurt, not help, the current efforts to expand global production of COVID-19 vaccines and therapies. For example, expanding vaccine production to unlicensed manufacturers could further exacerbate the challenging supply chain issues and high demand for limited raw materials that have hindered even the authorized vaccine manufacturers from scaling up production in recent months.[14]

A TRIPS waiver could also disincentivize the current vaccine manufacturers from entering into further voluntary licensing agreements with manufacturing partners in other countries. In the wake of the USTR's announcement, supporters of a TRIPS waiver have shifted the public discussion from patents to confidential trade secrets and technology transfer – acknowledging that waiving patent rights would not be sufficient to expand global production of safe and effective COVID-19 vaccines.[15] But, in the absence of voluntary licensing agreements, there is no clear mechanism for countries to compel the original vaccine manufacturers to divulge trade secrets or provide technology transfer support to unlicensed parties. And if pharmaceutical companies perceive that their technology transfer to a voluntary licensee could lead to the licensee's country disseminating their competitively sensitive know-how, they might forgo such voluntary licensing entirely.

Likewise, global pharmaceutical development could be seriously harmed if WTO members use a TRIPS waiver to divulge the vaccine manufacturers' confidential trade secrets submitted during regulatory review – information that TRIPS generally protects from disclosure and unfair commercial use by unauthorized parties.[16] If pharmaceutical companies perceive that submitting to regulatory review in certain countries means losing protections for proprietary manufacturing processes and other competitively sensitive trade secret information, those companies might consider avoiding such countries altogether when considering where to develop, make, sell, or license their products.

Finally, the TRIPS waiver could negatively impact the continued development of COVID-19 vaccine. There are more than 60 additional vaccines under development worldwide; and for many of these efforts, the investment of time and money is premised on the potential for licensing the vaccine or partnering with a larger manufacturer to produce it. Prospectively waiving intellectual property protections for these vaccines in development will likely undermine continued investment and research – a proposition made all the more alarming due to the possibility of new and different strains of COVID-19.

What legal factors might prevent passage or limit implementation of a TRIPS waiver?

The most immediate hurdle to passage of a TRIPS waiver lies in the requirement that all 164 WTO member countries agree to a specific waiver text. As noted above, Germany (among others) presently objects to any waiver proposal; the U.S. has only stated support for a waiver of significantly narrower scope than the sponsors' current proposal; and a "third way" proposal that sidesteps a TRIPS waiver remains on the table. And in the U.S., legislation has been proposed in Congress to limit the USTR's authority to agree to a TRIPS waiver, *e.g.*, by requiring Congressional approval of any waiver,[17] or prohibiting the use of federal funds to support a waiver.[18] One of the proposals in the Senate was narrowly voted down, but garnered some bipartisan support. We expect that Congressional interest will remain high on this topic, and there may be a pathway to bipartisan action that would constrain the Administration's waiver of IP protections under TRIPS.

Even if a TRIPS waiver of some scope were passed in the WTO after text-based negotiations, hurdles would remain to its effective implementation. A TRIPS waiver would not change the applicable IP protections in the WTO member states; and each member state would need to decide on their own (through their individual lawmaking procedures) whether and how to change their domestic laws within the scope permitted by the TRIPS waiver. It is unlikely that the resulting global patchwork of inconsistent IP protections would facilitate further expansion of vaccine production – particularly if voluntary technology transfer from existing manufacturers remains critical to making safe and effective vaccines at scale.

To that end, some waiver proponents have called on the U.S. to compel technology transfer from the U.S.-based vaccine manufacturers.[19] But current U.S. statutes largely prohibit the FDA and other regulatory agencies from publicly divulging trade secret information submitted for purposes of regulatory approval.[20] And even if authorized by future legislation, the Taking Clause of the Fifth Amendment would likely prohibit the U.S. government from disclosing trade

secret information submitted under the current statutory and regulatory protections, without just compensation (*e.g.*, damages awarded against the U.S. under the Tucker Act by the Court of Federal Claims).[21]

Additionally, even in the wake of a TRIPS waiver, companies subject to unauthorized use of their COVID-19 vaccine or therapy IP outside the U.S. may have remedies available under international law. Even though the type of obligations included in TRIPS are also included in certain U.S. trade agreements, such as the United States-Canada-Mexico Agreement (the "USMCA"), it is highly unlikely that the current U.S. administration will seek to invoke state-to-state dispute settlement on this matter given their support of the waiver proposal.[22]

IP rights holders can also consider the availability of investor-state dispute settlement or other arbitration procedures. For example, affected holders of IP rights might be able to bring claims for compensation against WTO member states under any applicable bilateral investment treaties (BITs) – to the extent that such treaties do not contain express exceptions to IP-related rights under the TRIPS Agreement. Foreign investors may be able to claim that such states had committed to providing greater protections under any applicable BIT, such that these protections cannot be displaced by any waiver under the TRIPS Agreement. That said, such states – particularly those with limited resources – may try to rebut any claims of wrongfulness by asserting an ongoing state of necessity for public health emergencies during the COVID-19 global pandemic. The strength of a potential claim under a BIT would be fact-specific for each IP rights holder, and should be assessed individually.

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In light of continuing developments at the WTO, companies that hold intellectual property in medical products related to COVID-19 should seek the advice of counsel to develop legal and policy strategies regarding the TRIPS waiver request, including (1) if they receive requests for licensing authorization, (2) if they learn of unauthorized use of their intellectual property, or (3) if they engage with national governments or international organizations to advocate for desired policy outcomes.

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[1] Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, TRIPS Communication IP/C/W/669/Rev.1 (May 21, 2021)

[2] Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, TRIPS Communication IP/C/W/669 (Oct. 2, 2020)

[3] *See* Statement from Ambassador Katherine Tai on the COVID-19 TRIPS Waiver (May 5, 2021), *available at* https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver

[4] *See* Inside Health Policy, Tai Talks TRIPS Waiver with Allies as China Gets Behind it, GOP Balks (May 20, 2021), *available at* https://insidehealthpolicy.com/daily-news/tai-talks-trips-waiver-allies-china-gets-behind-it-gop-balks

[5] *See* Health Policy Watch, G20 Leaders Promise to Share More Vaccines While EU Digs in Against TRIPS Waiver (May 21, 2021), *available at* https://healthpolicy-watch.news/g20-leaders-promise-to-share-more-vaccines-while-eu-digs-in-against-trips-waiver/; European Commission, Opening Statement by Executive Vice-President Valdis Dombrovskis at the European Parliament plenary debate on the Global COVID-19 challenge (May 19, 2021), *available at* https://ec.europa.eu/commission/commissioners/2019-2024/dombrovskis/announcements/opening-statement-executive-vice-president-valdis-dombrovskis-european-parliament-plenary-debate_en; Bloomberg, EU's Trade Response to Pandemic Stops Short of Vaccine IP Waiver, *available at* https://www.bloomberg.com/news/articles/2021-06-03/eu-s-trade-response-to-pandemic-stops-short-of-vaccine-ip-waiver

[6] *See* Statement of Director-General Elect Dr. Ngozi Okonjo-Iweala to the Special Session of the WTO General Council (Feb. 13, 2021), *available at* https://www.wto.org/english/news_e/news21_e/dgno_15feb21_e.pdf

[7] *See supra* note 5

[8] Wall Street Journal, Pfizer, BioNTech to Deliver 2 Billion Covid-19 Vaccine Doses to Developing Countries (May 21, 2021), *available at* https://www.wsj.com/livecoverage/covid-2021-05-21/card/GsPYoFscRppTzYYt0l4f

[9] Airfinity, How Much Vaccine Will be Produced This Year? (May 19, 2021), *available at* https://www.airfinity.com/insights/how-much-vaccine-will-be-produced-this-year

[10] IFPMA, Five steps to urgently advance COVID-19 vaccine equity (May 19, 2021), *available at* https://www.ifpma.org/resource-centre/five-steps-to-urgently-advance-covid-19-vaccine-equity/

[11] Samsung Biologics, Moderna and Samsung Biologics Announce Agreement for Fill-Finish Manufacturing of Moderna's COVID-19 Vaccine (May 22, 2021), *available at* https://www.prnewswire.com/news-releases/moderna-and-samsung-biologics-announce-agreement-for-fill-finish-manufacturing-of-modernas-covid-19-vaccine-301297280.html

[12] Fierce Pharma, Gilead, Merck step in to help India's drug manufacturers fight surging COVID-19 outbreak (Apr. 27, 2021), *available at* https://www.fiercepharma.com/pharma/gilead-merck-plan-production-boosts-for-covid-19-drugs-india-amid-surging-outbreak

[13] WTO News, Bolivia outlines vaccine import needs in use of WTO flexibilities to tackle pandemic (May 12, 2021), *available at* https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm

[14] *See, e.g.*, EndPoints News, As fears mount over J&J and AstraZeneca, Novavax enters a shaky spotlight (Apr. 21, 2021), *available at* https://endpts.com/as-fears-mount-over-jj-and-astrazeneca-novavax-enters-a-shaky-spotlight/; New York Times, U.S. to Send Virus-Ravaged India Materials for Vaccines (Apr. 25, 2021), *available at* https://www.nytimes.com/2021/04/25/us/politics/india-us-coronavirus.html

[15] Financial Times, Biden Urged to Oblige US Vaccine Makers to Share Technology (May 15, 2021), *available at* https://www.ft.com/content/9408223f-0a6c-43b7-9f67-c7e4697005c2

[16] *See* TRIPS Agreement, Article 39.3

[17] *See, e.g.*, H.R. 3236, 117th Cong.

[18] *See, e.g.*, H.R. 3035, 117th Cong.; S. 1683, 117th Cong.

[19] *See supra* note 15

[20] *See, e.g.*, 21 U.S.C. § 331(j); 18 U.S.C. § 1905; 5 U.S.C. § 552(b)(4); *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979)

[21] *See, e.g.*, *Ruckelhaus v. Monsanto Co.*, 467 U.S. 986 (1984); 28 U.S.C. § 1491

[22] *See* USMCA Ch. 20. Morever, in the event of a TRIPS waiver, the USMCA provides that "the Parties shall immediately consult in order to adapt this [agreement] as appropriate." USMCA Art. 20.6(c)