

**INTELLECTUAL PROPERTY: U.S. INTERESTS, EMERGENCIES,
AND THE WTO'S TRIPS WAIVER FOR COVID-19 VACCINES**

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Mr. Chairman and Mr. Ranking Member,

Thank you very much for inviting me to testify at this morning's hearing on intellectual property, innovation, and the U.S. competition with China, focused on the World Trade Organization and its decision on waiver of patent obligations for COVID-19 vaccines and potentially for "diagnostics and therapeutics" related to COVID-19.

By way of introduction, I am Vice President of the Progressive Policy Institute (PPI) here in Washington, D.C., a 501(c)(3) nonprofit research institution established in 1989 and publishing in a wide range of public policy topics. Before joining PPI, I served at the Office of the U.S. Trade Representative from 2015 to 2021 as Assistant U.S. Trade Representative for Policy and Economics, with responsibility for overseeing USTR's economic research and use of trade data, chairing the interagency Trade Policy Staff Committee, and administering the Generalized System of Preferences. This period coincided with the beginning of the COVID-19 pandemic in December 2019 and extended through the initial WTO discussions on a temporary waiver of some elements of the 1994 TRIPS agreement relating to COVID vaccines.

The hearing poses some important questions. Specifically, how does the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) relate to U.S. interests in innovation and technological progress? Was the Biden administration correct to support a waiver of some of the TRIPS patent provisions for COVID-19 vaccines? Will this be to the advantage of China vis-à-vis the United States? I can summarize my view of this in four points:

R&D, TRIPS, AND THE U.S. INTEREST

First, the promotion of scientific research and the invention of new technologies is both an important worldwide good, and a specific area of U.S. comparative advantage. The U.S. is the world's largest investor in scientific research and development at over \$700 billion per year, accounting for roughly 30% of all world R&D spending, and is home to top-tier research universities; innovative businesses in every field from agriculture to life sciences, information technology, aerospace, and automotive industry; and world-renowned government laboratories. In numbers, the 3.4% of GDP the U.S. now committed to scientific research and development ranks fourth in the world after only Israel, Korea, and Taiwan.¹ This is one of the U.S.' significant strengths and safeguarding this investment from piracy and infringement is an important national interest.

For the past three decades, the WTO's TRIPS agreement has been an important element of policy designed to secure this interest. It imposes reasonable obligations on the WTO's 164 members to maintain and enforce a basic set of patent, copyright, trademark, and other laws, with flexibility for emergency situations. While causality is always hard to determine, a few data points suggest that since the TRIPs agreement, both U.S. and world R&D commitments have grown:

- From the conclusion of TRIPS in 1994 through 2019, the data site "Our World in Data" reports that high-income country R&D spending has risen from 2.2% of GDP to 2.6%, and middle-income country R&D from 0.5% to 1.6% of GDP.²
- The U.S.' R&D rate has grown especially rapidly, rising according to the National Science Foundation from 2.4% of GDP in the early 1990s to 3.4% in 2020 and 2021. These last two figures are the highest levels in NSF's records.³

As such TRIPS appears to serve a worldwide interest in encouraging research, invention, and artistic creation and also a specifically U.S. interest in a detailed set of rights and obligations, enforceable under Dispute Settlement Understanding rules pending completion of WTO discussions on institutional reform. TRIPS, then, is an important tool for the American government, as policymakers seek ways to promote innovation and research and to defend U.S.-based researchers against infringement and piracy.

With respect to China specifically, China has a well-documented program of developing its national technological base by all available means, ranging from public investment in research, to open-source and collaborative work with foreign scientists and governments, to coercive extraction of technology from investors and exporters, to clandestine cyber-theft programs. With this as part of the landscape, the U.S. government and American

¹ "Gross Domestic Spending on R&D," OECD, accessed June 2023, <https://data.oecd.org/rd/gross-domestic-spending-on-r-d.htm>.

² Hannah Ritchie, Edouard Mathieu, and Max Roser, "Research and Development," Our World in Data, 2023, <https://ourworldindata.org/research-and-development>.

³ 1. "National Patterns of R&D Resources: Table 1 U.S. Gross Domestic Product, R&D," National Center for Science and Engineering Statistics, 2021, <https://nces.nsf.gov/data-collections/national-patterns/2021>.

businesses need to be vigilant, aware of threats, and share best practices to protect themselves. The U.S. government in addition should be using international law and organizations to defend American innovators' and researchers' rights, including the WTO and the TRIPS rules.

EMERGENCY SITUATIONS AND THEIR IMPLICATIONS

Second, in emergency circumstances, governments must often act quickly on the basis of incomplete information and in ways they would not choose to act in normal times. Their actions in these cases should be seen as *sui generis* actions that may not be useful once the emergency is ended, and need not be seen as precedents that need to be kept once circumstances return to normal.

The COVID-19 pandemic was such an emergency, as a wholly new and quite dangerous virus, easily transmissible, with no known treatment, and in many cases deadly. In the 3.5 years since its appearance, we have seen nearly 100 million known cases worldwide and 7 million deaths, including over 1 million deaths here in the United States. This was a medical emergency unique in my lifetime, and as such it required and received an extraordinary response in the United States and worldwide:

- Massive government and private-sector commitment to vaccine development, and distribution once vaccines became available in December 2020;
- Conversion of important manufacturing supply chains to produce personal protective equipment and specialized medical devices;
- Economic emergency measures, including closing much of the retail economy, developing work-from-home procedures for white-collar workers, and emergency fiscal stimulus including direct support to closed businesses.

In retrospect, this effort appears to me to have been very successful. Within less than a year, we had several new and very successful vaccines, with nearly 14 billion vaccinations and booster shots now delivered. Like many Americans, I am a personal beneficiary of this work; with vaccines and boosters, my own recent case of COVID, contracted about a week ago, has been much more like a mild cold than a severe (let alone life-threatening) illness. More generally, an early study published in the *Lancet* suggests that these vaccinations helped cut world COVID mortality by a range of 41% to 64%,⁴ or in total numbers from a potential 20 million to 7 million. A more recent review by the Commonwealth Fund focusing on the United States estimates that vaccinations prevented more than 18.5 million hospitalizations and 3.2 million deaths.⁵ This is a remarkable success story and one in which many people in the U.S. government, science and business, and non-profits and families should take pride.

⁴ Oliver J Watson et al., "Global Impact of the First Year of COVID-19 Vaccination: A Mathematical Modelling Study," *The Lancet Infectious Diseases* 22, no. 9 (2022): 1293–1302, [https://doi.org/10.1016/s1473-3099\(22\)00320-6](https://doi.org/10.1016/s1473-3099(22)00320-6).

⁵ Meagen C. Fitzpatrick et al., "Two Years of U.S. COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths," The Commonwealth Fund, December 13, 2022, <https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations>.

2022 TRIPS WAIVER FOR COVID-19 VACCINES

One element of the Biden administration's (and more generally, the WTO membership's) response to this emergency was a decision to authorize a temporary, five-year waiver of several elements of the TRIPS agreement's patent rules for COVID vaccines.

Debate over the TRIPS agreement's relationship to public health crises is a familiar topic for the WTO. One point of reference is the 2001 "Declaration on TRIPS and Public Health," for example, expressed a consensus view of WTO members that:

*"[T]he [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all... [and that] [e]ach member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."*⁶

It is not surprising that the outbreak of the COVID-19 pandemic elicited some debate over whether ordinary rules would need to be suspended as governments grappled with a fast-moving and deadly disease. Some WTO members, notably India and South Africa, proposed a very broad set of TRIPS waivers, either of the agreement's patent sections broadly or for particular products including vaccines but also extending to personal protective equipment, medical technologies such as ventilators, and larger categories of goods not specifying particular products such as "diagnostics and therapeutics."⁷

This debate continued in the run-up to the WTO's 12th Ministerial Conference, originally scheduled for December 2021 but delayed until June 2022 after the emergence of the *omicron* variant of the COVID-19 virus. At the June 2022 Ministerial, the WTO members agreed on a limited, five-year waiver specifically for Covid-vaccines (while deferring decisions on any broader range of products and technologies) as follows:

*"[A]n eligible Member1 may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter "the Agreement") by authorizing the use of 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 COVID-19 pandemic" ... "An eligible Member may waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market and may allow any proportion of the products manufactured under the authorization in accordance with this Decision to be exported to eligible Members" ... though the member must also "undertake all reasonable efforts to prevent the re-exportation of the products manufactured under the authorization in accordance with this Decision that have been imported into their territories."*⁸

⁶ "Declaration on the TRIPS Agreement and Public Health," World Trade Organization, November 14, 2001, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

⁷ "Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19," World Trade Organization, October 2, 2020, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf>.

⁸ "Ministerial Decision on the TRIPS Agreement," World Trade Organization, June 22, 2017, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True>

In effect, the “waiver” creates a time-limited option to set aside patent rights for COVID-19 vaccines to manufacture vaccines within a Member’s country in the event there is no supply of vaccines, and also allows a member to export the resulting vaccine to other WTO members findings themselves short of vaccine. It does not authorize this for other products. In tandem with this, the Chinese government made a “binding commitment” not to make use of this waiver.⁹

A year later, I would make three points about this decision:

1. First, it is limited in scope and in time, meant to deal with the specific cases of a country’s lacking urgently needed vaccine. As such it does not seem to me an unreasonable decision to take in an emergency, especially as the debate began at a time when there were widespread fears that vaccines might not be manufactured in sufficient quantity for the entire world.
2. Second, no WTO member government has yet used this waiver. This suggests that the major challenges for vaccine distribution in practice have been related first to developing the ability to mass-produce vaccines, and later to distribute them safely and effectively, rather than to a problem arising from intellectual property rules.
3. Third, it includes a formal statement by China foregoing the use of the waiver.

With respect to the potential use of this waiver by China, we have many reasons to be concerned about Chinese efforts to access and use proprietary American technology. The WTO TRIPS agreement is one tool to deter this, though not the only one. But the fact that China has foregone the use of the waiver means that to the extent there is reason for concern about patent rights to COVID vaccines vis-à-vis China, the relevant issue is one of enforcing current legal rules, rather than of opening a gap in those rules for China.

NEXT STEPS: “DIAGNOSTICS AND THERAPEUTICS”

Finally, the Ministerial decision on Covid vaccines is not the end of the argument. The WTO members, and the U.S. as one of them, are now considering a broader proposal to waive TRIPS rules for “production and supply of COVID-19 therapeutics and diagnostics.” This suggests a much broader array of products and technologies, though therapeutics and diagnostics are not terms of art and the range of devices and medicines they might cover is unclear. The U.S. International Trade Commission is reviewing submissions on this matter, with a report that should add context and information due in mid-October.

⁹ “Record in Accordance with Footnote 1 of the Ministerial Decision on the TRIPS Agreement of 17 June 2022,” World Trade Organization, June 22, 2022, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W690.pdf&Open=True>.

I would note as a general matter, however, that the emergency situation of the pandemic's first two years has abated. With nearly two-thirds of the world's public vaccinated,¹⁰ the need for emergency measures seems to me harder to justify that it might have been two years ago.

CONCLUSION

In conclusion, I would emphasize again that emergency situations often require governments to take extraordinary actions in defense of public health and security, and that these actions are not necessarily ones that need to be sustained afterward or viewed as precedents for future decisions.

With this in mind, I believe the Biden administration's decisions on this topic are quite reasonable. In 2021 the incoming administration inherited a worldwide crisis posing a grave threat to life and health in the U.S. and elsewhere. In considering the requests of a number of WTO members appealed for a temporary waiver of patent rules. Its officials, in particular U.S. Trade Representative Katherine Tai and Ambassador to the WTO Maria Pagan, managed the subsequent negotiations in my view professionally and reasonably. Their work with other WTO members ended in an agreement which:

- (a) Allows countries to take emergency steps in the event other measures are not able to provide them with the vaccines they need;
- (b) Limits this to 5 years and to vaccines specifically; and
- (c) Stipulates that China (among other things as a country producing its own version of a vaccine) will not take advantage of patent waivers under the decision.

Under the circumstances, this seems to me a reasonable outcome, and not one that should be viewed as putting at risk U.S. intellectual property broadly or undermining the commitment American businesses, research labs, and inventors make to scientific research and development.

Thank you for this opportunity to share my views, and I welcome any questions you may have.

¹⁰ Edouard Mathieu et al., "Coronavirus (COVID-19) Vaccinations," Our World in Data, last modified June 4, 2023, <https://ourworldindata.org/covid-vaccinations>.