

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States
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May 4, 2021

The Honorable Katherine C. Tai
U.S. Trade Representative
600 17th Street N.W.
Washington, DC 20508

Dear Ambassador Tai:

The United States should continue to oppose the request by India, South Africa, and other nations to waive certain portions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for all members of the World Trade Organization (WTO).¹ The requested waiver is extraordinarily broad and unnecessary to accomplish the goal of giving as many people as possible access to vaccines and treatments for COVID-19, including in developing countries. Rather, the waiver would undermine the very innovation that has led to the record-breaking rapid development of COVID-19 vaccines already saving lives around the world, and it would not meaningfully improve vaccine availability. The international community should instead focus on overcoming the real obstacles faced by developing countries in accessing vaccines and treatments, which does not require waiving intellectual property (IP) rights.

IP rights are not the bottleneck for worldwide access to COVID-19 vaccines and treatments

The justification for the waiver rests on an incorrect assumption that IP rights are a significant bottleneck to the widespread availability of COVID-19 vaccines and treatments. The waiver's sponsors have presented no convincing evidence to support this assertion. Instead, the sponsors mainly just point out that relevant IP rights exist and speculate that those rights *could* serve as a barrier to access to COVID-19 vaccines and treatments—not that IP rights have actually blocked or significantly hindered their availability.² If anything, the examples of IP “disputes” cited by the waiver sponsors generally demonstrate that IP rights have *not* prevented the involved parties from supplying vaccines and other medicines.³

¹ Communication from India and South Africa: Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/W/669 (Oct. 2, 2020), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True> (“Waiver Request”).

² See Communication from South Africa: Examples of IP Issues and Barriers in COVID-19 Pandemic, IP/C/W/670 (Nov. 23, 2020), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W670.pdf&Open=True> (“Sponsor’s Alleged IP Examples”).

³ See, e.g., *id.* (citing *Moderna loses key patent challenge*, NATURE BIOTECH., Sep. 4, 2020, at 1009, <https://www.nature.com/articles/s41587-020-0674-1#:~:text=A%20dispute%20over%20a%20key,claim%20by%20the%20vaccine%20maker> (describing IP dispute involving Moderna)); Moderna, Inc., Press Release: Moderna

In reality, factors other than IP have had a far greater effect on the availability of vaccines and treatments for COVID-19. For example, the logistical challenges such as the lack of cold storage, transportation and infrastructure problems, and shortages in basic supplies like syringes have posed significant challenges to widespread COVID-19 vaccination, particularly in developing countries.⁴ These issues are nothing new; vaccines have presented such problems for years.⁵ Canceling IP rights would do nothing to alleviate these problems now.

Regulatory obstacles in developing nations also serve as a barrier to accessing COVID-19 medicines. For example, the Philippines reached an agreement with Moderna to supply millions of doses of COVID-19 vaccine, but the Philippine government has not yet approved the Moderna vaccine for use in that country.⁶ Canceling IP rights would do nothing to assist the Philippines or other similarly situated governments in evaluating and approving the vaccine more quickly.

Further, manufacturing COVID-19 vaccines and therapeutics is complex and requires exacting standards to ensure patient safety. The challenges of rapidly expanding manufacturing capacity for vaccines while ensuring sufficient quality control has had a substantial impact on vaccine supply.⁷ Maintaining safety and quality standards is critical to maintaining public confidence in the vaccines. Canceling IP rights would not improve the quality control of any manufacturing facilities. In fact, allowing potentially any manufacturer to ignore IP rights and produce complex COVID-19 drugs on their own could instead *increase* the risk that defective and potentially unsafe medicines are produced, harming the patients who receive them, damaging public confidence, and ultimately undermining global vaccination efforts.

Worldwide access to COVID-19 treatments can be expanded without weakening IP rights

Rather than attack the IP rights of innovative companies that have invested billions of dollars in developing these life-saving medicines, the international community should focus on addressing the real obstacles to widespread access to COVID-19 vaccines and treatments. The United States has been a leader in this effort. A broad coalition of countries, including the United States, are supporting the Access to COVID-19 Tools (ACT) Accelerator initiative and the

Announces Additional Capital Investments to Increase Global Manufacturing Capacity for COVID-19 Vaccine (Feb. 24, 2021), <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-additional-capital-investments-increase-global> (reporting Moderna's production of 60M vaccine doses to date, an expected 700M doses total in 2021, and an expected 1.4B doses in 2022, despite any IP disputes).

⁴ Lori Hinnant & Sam Mednick, *Vaccine storage issues could leave 3B people without access*, ASSOCIATED PRESS, Oct. 19, 2020, <https://apnews.com/article/virus-outbreak-pandemics-immunizations-epidemics-united-nations-fc4c536d62c5ef25152884adb1c14168>.

⁵ See Michel Zaffran et al., *The imperative for stronger vaccine supply and logistics systems*, 31S2 VACCINE B73 (2013), https://www.who.int/immunization/sage/meetings/2013/november/3_stronger_vaccine_supply_and_logistics_systems.pdf?ua=1.

⁶ Moderna, Inc., Press Release: Moderna Announces New Supply Agreement with the Philippines for 7 Million Additional Doses of COVID-19 Vaccine (Mar. 22, 2021), <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-new-supply-agreement-philippines-7-million>.

⁷ See, e.g., Christopher Rowland & Laurie McGinley, *Johnson & Johnson confirm vaccine production problems at Emergent plant in Baltimore*, WASH. POST, Apr. 1, 2021, <https://www.washingtonpost.com/business/2021/03/31/vaccine-johnson-johnson-emergent/>.

related COVAX program.⁸ COVAX has already begun supplying over 140 countries with nearly 240 million doses of vaccines from Astrazeneca and Pfizer/BioNTech.⁹ The United States and our allies have already pledged billions of dollars and other resources to support COVAX and the ACT Accelerator.¹⁰ These efforts are providing real solutions for countries that need access to COVID-19 vaccines and treatments *without* dismantling IP protections, even temporarily.

In fact, relevant IP rights have been successfully licensed to expand access to COVID-19 innovations while maintaining IP protections.¹¹ For example, the Serum Institute of India has secured licenses to produce multiple vaccines, including the Astrazeneca and Novavax vaccines.¹² South Africa's Aspen Pharmacare has secured a license to produce the Johnson & Johnson vaccine.¹³ Several vaccine makers have licensed direct competitors to increase vaccine manufacturing capacity.¹⁴ Moderna has announced that it would not seek to enforce any of its COVID-19-related patents against other vaccine makers for the rest of the pandemic, and has pledged to license its COVID-19 vaccine patents.¹⁵ Gilead has licensed nine generic pharmaceutical manufacturers (including in India) to produce its COVID-19 therapeutic drug remdesivir for 127 countries, most of which are developing nations.¹⁶ Moreover, TRIPS already allows countries to impose compulsory licenses to access vital IP rights,¹⁷ and no country has availed itself of that capability to date for COVID-19 vaccines or treatments.

⁸ World Health Organization, COVAX, <https://www.who.int/initiatives/act-accelerator/covax> (last visited Apr. 12, 2021).

⁹ World Health Organization, The COVAX Facility: First Round of Allocation: Astra Zeneca/Oxford Vaccine (Mar. 2, 2021), https://cdn.who.int/media/docs/default-source/3rd-edl-submissions/covax-first-round-allocation-of-az-and-sii-az---overview-tablev2.pdf?sfvrsn=85879c81_1&download=true.

¹⁰ World Health Organization, Press Release: G7 leaders commit US\$ 4.3 billion to finance global equitable access to tests, treatments and vaccines in 2021 (Feb. 19, 2021), <https://www.who.int/news/item/19-02-2021-g7-leaders-commit-us-4.3-billion-to-finance-global-equitable-access-to-tests-treatments-and-vaccines-in-2021>.

¹¹ *Watch Out for a Vaccine Patent Heist*, WALL ST. J., Mar. 28, 2021, <https://www.wsj.com/articles/watch-out-for-a-vaccine-patent-heist-11616959785>.

¹² Grady McGregor, *India's COVID vaccine maker was supposed to supply the world. Now those plans are delayed*, FORTUNE, Feb. 22, 2021, <https://fortune.com/2021/02/22/covid-vaccine-india-serum-institute-supply-world-delay/>. Ironically, the Serum Institute has announced that it will prioritize India's domestic needs for the licensed vaccines over those of other nations, contrary to its earlier promises. *Id.*

¹³ *S.Africa's Aspen Pharmacare to supply J&J's COVID-19 vaccine by end-June*, REUTERS, Mar. 12, 2021, <https://www.reuters.com/article/uk-health-coronavirus-safrica-aspen-phar/s-africas-aspen-pharmacare-to-supply-jjs-covid-19-vaccine-by-end-june-idUSKBN2B413B>.

¹⁴ Christopher Rowland & Laurie McGinley, *Merck will help make Johnson & Johnson coronavirus vaccine as rivals team up to help Biden accelerate shots*, WASH. POST, Mar. 3, 2021, <https://www.washingtonpost.com/health/2021/03/02/merck-johnson-and-johnson-covid-vaccine-partnership/>; Jared S. Hopkins, *To Make More Covid-19 Vaccines, Rival Drugmakers Team Up*, WALL ST. J., Feb. 23, 2021, https://www.wsj.com/articles/to-make-more-covid-19-vaccines-rival-drugmakers-team-up-11614081601?mod=hp_lead_pos3.

¹⁵ Moderna, Inc., Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic (Oct. 8, 2020), <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19>.

¹⁶ Gilead Sciences, Inc., Voluntary Licensing Agreements for Remdesivir, <https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir> (last visited Apr. 12, 2021).

¹⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 313-314 (1994) ("TRIPS Agreement").

The requested waiver of IP rights is excessively broad

Even if a temporary waiver of some IP rights related to COVID-19 could be justified, the waiver request at issue is excessively broad and far exceeds any reasonable measure to address the COVID-19 pandemic. The proposed waiver is not limited to patents on vaccines or treatments for COVID-19—the waiver would also gut protections for copyrights, industrial designs (e.g., textile patterns or other ornamental designs), and trade secrets.¹⁸ The waiver’s supporters have only offered vague, unsubstantiated explanations for how waiving IP protections for copyrights or industrial designs would lead to improved vaccine or therapeutics availability.¹⁹ It is also unclear how a waiver of TRIPS obligations would provide more access to trade secrets and proprietary technologies, which are confidential by definition and typically closely guarded.

The breadth of the IP that would be circumvented by the waiver is particularly problematic considering that the waiver would cover IP for anything “in relation to prevention, containment or treatment of COVID-19.”²⁰ This sweeping waiver would potentially cover an enormous range of IP rights far beyond just COVID-19 drugs, including critical technology with wide-ranging applications unrelated to COVID-19. For example, advanced diagnostic systems used to rapidly and accurately diagnose a host of health conditions—from leukemia to meningitis to dozens of other bacterial or viral infections—would be vulnerable to the waiver if they can also be used to detect the COVID-19 virus.²¹ Because COVID-19 can lead to respiratory issues requiring imaging of patients’ lungs, the waiver could also encompass advanced CT scanner technology useful for treating countless conditions unrelated to COVID-19.

In addition, many drugs that are primarily used for conditions unrelated to COVID-19 may be subject to the waiver as well because they could potentially be used to treat a symptom common to many diseases, including COVID-19. For example, tocilizumab and other similar anti-inflammatory drugs are primarily indicated for treating auto-immune conditions like rheumatoid arthritis, but they could potentially be used to reduce respiratory inflammation in some COVID-19 patients.²² The breadth of potentially vulnerable IP rights would not be limited even to those with medical applications—industrial protective equipment, HVAC systems, disinfectant chemicals, computer systems/software, and even artificial intelligence could have some “relation to [the] prevention, containment or treatment of COVID-19.”²³

¹⁸ See Waiver Request at 3.

¹⁹ Communication from the Plurinational State of Bolivia et al.: Response to Questions on Intellectual-Property Challenges Experienced by Members in Relation to COVID-19 in Document IP/C/W/671, IP/C/W/673, at 9-10 (Jan. 15, 2021), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W673.pdf&Open=True>. The only specific example cited actually involved alleged patent infringement, not copyrights or industrial designs. *Id.*

²⁰ See Waiver Request at 3.

²¹ See, e.g., Cepheid, GeneXpert® Systems, https://www.cepheid.com/en_US/systems/GeneXpert-Family-of-Systems/GeneXpert-System (last visited Apr. 12, 2021); Biofire Diagnostics, BioFire® FilmArray® Panels, <https://www.biofire.com/products/the-filmarray-panels> (last visited Apr. 12, 2021).

²² National Institutes of Health, The COVID-19 Treatment Guidelines Panel’s Statement on the Use of Tocilizumab for the Treatment of COVID-19 (Mar. 5, 2021), <https://www.covid19treatmentguidelines.nih.gov/statement-on-tocilizumab>.

²³ See Waiver Request at 3.

The requested waiver of IP rights would harm American innovation, technological leadership, and economic competitiveness

Even if IP protections on the broad array of technology covered by the waiver are bypassed only temporarily, the damage could not be undone for key trade secrets and proprietary know-how if countries force the disclosure of such sensitive information. Tremendous harm may be done to a wide range of innovative American companies that depend on IP to protect their R&D investments and enable them to stay in business. The waiver could enable foreign competitors to effectively steal the crown jewels of many American businesses without any compensation whatsoever, unlike existing procedures in TRIPS designed to strike a balance between the need to respond to emergency situations and preserve the benefits of IP rights.²⁴

Thus, the proposed waiver represents a danger to American technological leadership and economic competitiveness *without* any significant benefit to global public health. This danger is particularly acute considering that many of the crucial technological advances made by American businesses and institutions in the fight against COVID-19 were made on the backs of billions of dollars of investment by American companies as well as billions more in American taxpayer money. This includes over \$12 billion invested by the Trump Administration in Operation Warp Speed, which stands as one of the most successful vaccine development programs in history.²⁵ Operation Warp Speed has yielded the successful development of four COVID-19 vaccines considered the gold standard worldwide, and did so at an unprecedented pace—all were developed within a year when the previous record for a vaccine was four years.²⁶

Importantly, this R&D has also produced ground-breaking mRNA vaccine technology that could revolutionize future vaccine development.²⁷ Sponsors of the waiver are seeking not only the COVID-19 vaccines produced using that technology but also that technology itself, which they could then use for other purposes. It is no coincidence that most of the IP rights the waiver sponsors are planning to bypass are owned by American companies.²⁸ At a time when the Biden Administration is proposing trillions of debt-funded spending, the United States must not give away advanced technology developed with billions of Americans' tax dollars to other

²⁴ See TRIPS Agreement art. 31 (requiring “adequate remuneration” be paid to the rights holder in the event of a compulsory license, including for a national emergency).

²⁵ Alicia Smith, *Perspective: Operation Warp Speed's Success*, THE GAZETTE, Jan. 31, 2021, https://gazette.com/opinion/perspective-operation-warp-speeds-success/article_69bc85ac-60e1-11eb-b498-efd6de51565d.html; Emily Barone, *The Trump Administration's 'Operation Warp Speed' Has Spent \$12.4 Billion on Vaccines. How Much Is That, Really?*, TIME, Dec. 14, 2020, <https://time.com/5921360/operation-warp-speed-vaccine-spending> (reporting that the U.S. government spent \$12.4 billion on COVID-19 vaccine development through Operation Warp Speed).

²⁶ Jocelyn Solis-Moreira, *How did we develop a COVID-19 vaccine so quickly?*, Med. News Today, Dec. 15, 2020, <https://www.medicalnewstoday.com/articles/how-did-we-develop-a-covid-19-vaccine-so-quickly>.

²⁷ Patrick Boyle, *mRNA technology promises to revolutionize future vaccines and treatments for cancer, infectious diseases*, ASS'N OF AM. MED. COLLEGES (Mar. 29, 2021), <https://www.aamc.org/news-insights/mrna-technology-promises-revolutionize-future-vaccines-and-treatments-cancer-infectious-diseases>.

²⁸ Sponsor's Alleged IP Examples at 2-7 (identifying Regeneron, Merck, Atea Pharmaceuticals, Incyte, Pfizer, Moderna, and Gilead).

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countries, including adversaries like China and Russia.²⁹ Gifting away our technological leadership and competitive advantage at a time when the U.S. economy remains vulnerable would be irresponsible and send the wrong message to millions of American taxpayers. The damage would extend beyond even the considerable value of COVID-19 vaccines and medicines, also endangering the far greater value of the jobs and economic growth promised by these IP rights and the advanced technologies they represent.

* * *

Respect for IP rights has been a cornerstone of U.S. trade policy for decades and should not be set aside lightly. Although some flexibility may be warranted in emergency situations, the waiver of TRIPS IP protections requested by India, South Africa, and other countries would do little to improve public health during this critical period in the COVID-19 pandemic. The scope of the requested waiver is overbroad and unjustified in light of the economic harm it would cause and the negligible benefits it would provide. Existing aspects of TRIPS and global public health initiatives, along with the existing actions of key IP rights holders and innovators, make the waiver unnecessary. While considerable work can still be done to improve access to COVID-19 medicines and other innovations, that work can be done without the drastic step of suspending IP rights, and significant progress has already been made to address the real obstacles hampering the global COVID-19 response.

For all these reasons, we urge you and the Biden Administration to maintain U.S. opposition to the waiver, and we are willing to work with the Administration on solutions to the actual problems causing shortages and supply issues with COVID-19 vaccines and treatments.

Sincerely,



Jim Jordan
Ranking Member



Darrell Issa
Ranking Member
Subcommittee on Courts, Intellectual Property,
and the Internet

²⁹ Josh Rogin, *The wrong way to fight vaccine nationalism*, WASH. POST, Apr. 8, 2021, https://www.washingtonpost.com/opinions/global-opinions/the-wrong-way-to-fight-vaccine-nationalism/2021/04/08/9a65e15e-98a8-11eb-962b-78c1d8228819_story.html.

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Steve Chabot
Subcommittee on Courts,
Intellectual Property, and the Internet



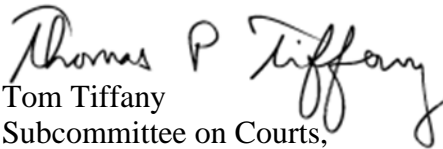
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cc: The Honorable Jerrold Nadler, Chairman
The Honorable Hank Johnson, Chairman, Subcommittee on Courts, Intellectual Property,
and the Internet