

ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON THE JUDICIARY

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February 13, 2024

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

Dear Ambassador Tai:

On May 4, 2021, twelve members of this Committee sent you a letter urging the Biden Administration to oppose the proposed waiver of certain portions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) at the World Trade Organization (WTO) during the COVID-19 pandemic.¹ In that letter, we warned that such a waiver of intellectual property (IP) rights risked undermining the very innovation that led to the record-breaking rapid development of COVID-19 vaccines.² We also noted that the proposed waiver was unnecessary to expand access to COVID-19 vaccines and would not meaningfully improve vaccine availability.³ Regrettably, the Biden Administration instead supported the waiver, and consequently the WTO adopted the measure and authorized the use of certain TRIPS “flexibilities” with respect to COVID-19 vaccines in June 2022.⁴

Subsequently, the WTO has continued to consider whether these TRIPS “flexibilities” should be extended to cover additional products and technologies, such as COVID-19 “diagnostics” and “therapeutics.”⁵ The WTO attempted to address such an extension as recently as October 2023.⁶ The Biden Administration has not yet taken a public position on whether it supports the proposed extension. While presumably recognizing that the decision to support the initial waiver was made without sufficient evidence to justify doing so, this time you requested

¹ Letter from Members of the Committee on the Judiciary, U.S. House of Representatives, to Ambassador Katherine Tai, U.S. Trade Representative (May 4, 2021) (available <https://judiciary.house.gov/sites/evo-subsites/republicans-judiciary.house.gov/files/2021-05/2021-05-04-GOP-Courts-IP-to-USTR-re-WTO-TRIPS-Waiver.pdf>).

² *Id.*

³ *Id.*

⁴ Yuka Hayashi, *WTO Nations Agree to Ease Patent Rights to Boost Covid-19 Vaccine Supplies in Poorer Nations*, WALL ST. J. (June 17, 2022), <https://www.wsj.com/articles/wto-nations-agree-to-ease-patent-rights-to-boost-covid-19-vaccine-supplies-in-poorer-nations-11655441416>.

⁵ *Members to continue dialogue on extending TRIPS Decision to therapeutics and diagnostics*, World Trade Organization (Oct. 31, 2023), https://www.wto.org/english/news_e/news23_e/trip_31oct23_e.htm.

⁶ *Id.*

that the U.S. International Trade Commission (“Commission”) conduct an investigation and prepare a report to address various issues related to the proposed extension of the TRIPS waiver.⁷ Among other items, you asked for the Commission to seek input from the public on the “[s]uccesses and challenges in using existing TRIPS flexibilities,” and “[w]hether and how existing TRIPS rules and flexibilities can be deployed to improve access to medicines.”⁸

On October 17, 2023, the Commission issued the requested report.⁹ The report confirms the concerns expressed in our May 2021 letter—vitiating IP rights using TRIPS flexibilities does not increase vaccine availability. Indeed, as revealed by the Commission’s review of relevant scholarship, “patent protection is generally associated with *faster* launches of medicine.”¹⁰ Contrary to the purported goals of waiver advocates, the Commission found research generally indicating that factors “*other than patent protection* are important determinants for the diffusion of medicine,” particularly in low-income countries.¹¹

The report further explained that the TRIPS flexibilities at issue focus on waiving and clarifying specific requirements for issuing compulsory licenses, specifically for patents directed to COVID-19 vaccines under the original TRIPS waiver.¹² However, as noted in the report, compulsory licenses “have not been used to access patents pertaining to COVID-19 vaccines.”¹³ Simply forcing patent owners to license their patents was doomed to fail because the advanced “know-how” of the innovative companies that developed the vaccines is often critical to effectively apply the patented technology and “reproduce more complex pharmaceutical products such as biologics.”¹⁴

Moreover, the importance of IP protection to drive innovation does not appear to be in dispute. The report acknowledges that responses from stakeholders “generally provide strong support for the importance of patent protection for innovation in the health sector, especially for pharmaceuticals.”¹⁵ As to the potential impact an extension of the “flexibilities” will have on future innovation, many stakeholders sounded the alarm that waiving or weakening IP rights will reduce incentives to invest in future research and development.¹⁶

In light of the failure of the TRIPS flexibilities to increase access to COVID-19 vaccines, as outlined in the Commission’s report, expanding the scope of the flexibilities to include

⁷ Letter from Ambassador Katherine Tai, U.S. Trade Representative, to the Honorable David S. Johanson, Chairman, U.S. International Trade Commission (December 16, 2022) (available https://www.usitc.gov/research_and_analysis/786496-1929259.pdf).

⁸ *Id.*

⁹ COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities, Inv. No. 332-596 USITC Pub. 5469 (Oct. 2023).

¹⁰ *Id.* at 33 (emphasis added).

¹¹ *Id.* at 33 (emphasis added) (in contrast with this general understanding, the Commission was able to identify a mere two studies, narrowly scoped to address consumers in India, where patent protection was found to impose costs on local consumers).

¹² *Id.* at 194.

¹³ *Id.* at 194-95.

¹⁴ *Id.* at 26.

¹⁵ *Id.* at 32.

¹⁶ *Id.* at 32.

diagnostics and therapeutics is similarly unlikely to increase access to those products. Thus, the Biden Administration should oppose any request to expand the TRIPS waiver, particularly given the risks to the innovation ecosystem. Moreover, the Administration should also prevent similar ineffective measures from being adopted at the World Health Organization (WHO) or any other international bodies.¹⁷ We urge the Administration to lead the international community in focusing instead on the real logistical obstacles faced by developing countries in accessing treatments, which are similar to the obstacles described in our May 2021 letter with respect to vaccines and which do not require waiving IP rights to overcome. Such a course would make real contributions to global public health while preserving the incentives for innovators to develop the next generation of medicines and technologies that will protect us in future pandemics.

As the committee of jurisdiction with respect to IP, the House Judiciary Committee is conducting oversight on the Biden Administration's policies, processes, and decisions relating to the TRIPS Agreement, particularly regarding the proposed expansion of TRIPS "flexibilities," as well as involvement in other international agreements, bodies (e.g., WHO), or initiatives that affect IP rights. In conjunction with that oversight, we request that you provide the following documents and information that are in your custody, possession, or control, or that of the Office of the United States Trade Representative (USTR):

1. All communications, documents, or other materials sent or received, internally or externally, by the USTR, including to or from *inter alia* Senior Advisor to the U.S. Trade Representative Elizabeth Baltzan, referring or relating to (A) the adoption of the waiver of certain portions of the TRIPS Agreement at the WTO in 2022; (B) the proposed expansion of that waiver to include COVID-19 therapeutics and diagnostics; or (C) any other current proposal or negotiation regarding any waiver of IP rights at any international body or with respect to any international agreement.
2. All documents, data, policies, communications, or other information that (A) formed the basis for the Biden Administration's decision to support the adoption of a waiver of certain portions of the TRIPS Agreement at the WTO in 2022; or (B) is being considered by the Biden Administration to form a basis for a decision on whether to support the proposed expansion of that waiver to include COVID-19 therapeutics and diagnostics; or (C) is being considered by the Biden Administration to form a basis for a decision on whether to support a provision in any international agreement that would allow a foreign government or international body to waive, cancel, suspend, assign, transfer, seize, or compel a license to IP, in whole or in part, which is owned by U.S. individuals or entities.
3. Records of any meetings, phone calls, conferences, consultations, negotiations, or discussions, including any materials distributed at or in conjunction with such events, within or involving the USTR, including *inter alia* Senior Advisor to the U.S. Trade Representative Elizabeth Baltzan, at which any of the following were discussed: (A) the

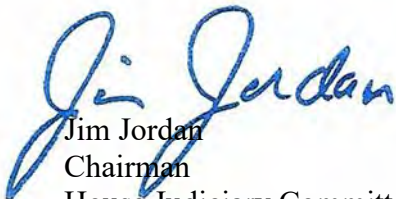
¹⁷ Carmen Paun, Evan Peng, Daniel Payne, Erin Schumaker, *Pharma sees a threat in pandemic treaty*, POLITICO (October 17, 2023, 2:00 PM), <https://www.politico.com/newsletters/future-pulse/2023/10/17/pharma-sees-a-threat-in-pandemic-treaty-00121883>.

adoption of the waiver of certain portions of the TRIPS Agreement at the WTO in 2022; (B) the proposed expansion of that waiver to include COVID-19 therapeutics and diagnostics; or (C) any other proposal or negotiation regarding any waiver of IP rights at any international body or with respect to any international agreement in the last three years.

4. All policies, procedures, directives, memoranda, and internal guidance documents relating to the process by which the USTR assesses, analyzes, formulates, or approves a decision, or a recommendation for a decision, on the position of the United States with respect to an action by, or in conjunction with, an international body relating to IP rights.
5. The name and title of the individuals at the USTR most knowledgeable about each of the following: (A) the adoption of the waiver of certain portions of the TRIPS Agreement at the WTO in 2022; (B) the proposed expansion of that waiver to include COVID-19 therapeutics and diagnostics; (C) any other current proposal or negotiation regarding any waiver of IP rights at any international body or with respect to any international agreement; and (D) the documents and information requested above.

Please provide the requested documents and information as soon as possible, but no later than 5:00 p.m. on February 27, 2024. If you have any questions, please contact Committee staff at (202) 225-6906. Thank you for your prompt attention to this matter.

Sincerely,



Jim Jordan
Chairman
House Judiciary Committee



Darrell Issa
Chairman
Subcommittee on Courts, Intellectual
Property, and the Internet



Thomas Massie
Member
Subcommittee on Courts, Intellectual
Property, and the Internet



Scott Fitzgerald
Member
Subcommittee on Courts, Intellectual
Property, and the Internet



Cliff Bentz
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Ben Cline
Member
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Property, and the Internet



Lance Gooden

Member

Subcommittee on Courts, Intellectual
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Nathaniel Moran

Member

Subcommittee on Courts, Intellectual
Property, and the Internet



Russell Fry

Member

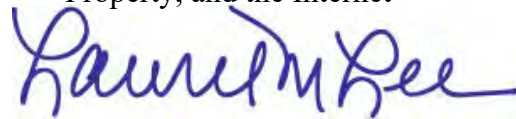
Subcommittee on Courts, Intellectual
Property, and the Internet



Kevin Kiley

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Laurel M. Lee

Member

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Property, and the Internet