United States Senate
WASHINGTON, DC 20510

October 19, 2022

Ambassador Katherine Tai
United States Trade Representative
600 17th Street NW
Washington, D.C. 20508

Dear Ambassador Tai:

We write seeking additional information regarding the contemplated expansion of the waiver of certain obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for COVID-19 vaccines to also cover diagnostics and therapeutics.

As you know, with the support of the United States, on June 17, 2022, WTO member countries agreed by consensus to waive for a period of five years TRIPS obligations covering patents for COVID vaccines. This waiver, announced at the twelfth session of the Ministerial Conference (MC12) in Geneva, allows eligible WTO members to access the "subject matter of a patent" for a vaccine, including the "ingredients and processes necessary for the manufacture" of the vaccine. In practical terms, the waiver commits the United States to not enforcing certain intellectual property (IP) rights on behalf of American companies at the WTO.

Importantly, in addition to the waiver on patent subject matter, Paragraph 8 of the MC12 document commits the United States to a decision by mid-December on whether or not to expand the current waiver to include COVID-related diagnostics and therapeutics, which are undefined in scope. Specifically, Paragraph 8 states:

> *No later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics*.

The United States is a global leader in research and development (R&D) and innovation in part because of our strong protections for IP. Additionally, the United States will continue its leadership with our partners across the globe to ensure developing countries have access to the tools and treatments needed to combat COVID, and we believe this can be accomplished without undermining U.S. leadership in medical innovation.

Since the adoption of the MC12 waiver, the United States Trade Representative's Office (USTR) has shared little data or other evidence with regard to the impact that the MC12 waiver had on COVID vaccine accessibility worldwide. Logistical complexities, such as last mile distribution, the need for a "cold chain" for certain vaccines, and the availability of trained healthcare workers to administer doses remain significant barriers that have yet to be addressed. We are concerned that the expansion of the waiver to cover COVID treatments and tests could face similar issues, and we urge you to consider the range of variables impacting global access to these products before developing a position that could undermine healthcare innovation and accessibility of treatments.

American companies are committed to numerous cooperative agreements to increase global access to therapeutics and diagnostics in addition to vaccines. In fact, many countries that initially proposed this waiver are producing their own products and have not indicated that domestic demand exceeds their own supplies.

We would like to better understand the range of variables impacting global access to these products. According to statute[1], USTR must consult with the appropriate congressional Committees, including members of the Senate Finance Committee, prior to formalizing a decision at the WTO in regards to the possible expansion of the TRIPS waiver under Paragraph 8 of the MC12 decision. In order to facilitate these consultations, we respectfully request that you respond in writing to the following questions no later than October 31, 2022.

1. Since the adoption of the TRIPS waiver for COVID vaccines, what analysis has your office conducted about the impact of the waiver on global vaccine supply? If any, please describe the findings of such analysis and how this analysis may help inform a U.S. position on whether to expand the waiver to COVID-related therapeutics and diagnostics.

2. Please list all countries which have, either publicly or privately, expressed interest in obtaining access to American IP, broadly defined, for COVID-related diagnostics and therapeutics. Do any of these countries produce COVID-related diagnostics or therapeutics domestically?

3. Has your office considered alternatives to a TRIPS waiver in order to increase access to COVID therapeutics and diagnostics, such as the promotion of voluntary licensing at the WTO or the existing cooperative agreements in place for production of these products? If so, please describe.

4. Please detail how your representatives to the TRIPS Council have considered defining "diagnostic" and "therapeutic" for the purposes of a possible waiver expansion.

5. What economic data points do you intend to analyze prior to making a decision on expansion of the MC12 waiver? Please be specific.

    a. Do you intend to consider projected impact on American jobs?

    b. Do you intend to consider projected impact on future R&D investment for vaccines, therapeutics, and diagnostics, including those unrelated to COVID?

6. According to recent media reporting, USTR officials are "gathering information about the use, production, demand, and supply of COVID-19 diagnostics and therapeutics" and are "continuing […] consultations with domestic stakeholders".[2]

    a. Please describe your information collection efforts to date.

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[1] *See* 19 U.S.C. 3532(b), which states that USTR "shall consult with the appropriate congressional committees ***before*** any vote is taken by the Ministerial Conference or the General Council relating to […] the granting of a waiver of any obligation under such an agreement" (emphasis added). For the purposes of consultation, we consider the entering into an agreement or decision by consensus as a de-facto affirmative vote on behalf of the United States.
[2] "WTO members take up TRIPS talks, consider schedule," *Inside U.S. Trade*, September 19, 2022, https://insidetrade.com/daily-news/wto-members-take-trips-talks-consider-schedule (accessed September 23, 2022).

b. Please list the domestic stakeholders you have consulted with, the duration and nature of any consultations, and when such consultations took place.

It is our expectation that Congress will be kept apprised of the ongoing negotiations at the TRIPS Council and be given the opportunity to weigh in on behalf of our constituents prior to the announcement of a U.S. position on a waiver expansion.

Thank you for your attention to this matter, and we look forward to your prompt response.

Sincerely,

Thomas R. Carper
United States Senator

Pat Toomey
United States Senator

John Barrasso, M.D.
United States Senator

Richard Burr
United States Senator

Bill Cassidy, M.D.
United States Senator

Christopher A. Coons
United States Senator

Robert Menendez
United States Senator

Kyrsten Sinema
United States Senator

Jon Tester
United States Senator

Thom Tillis
United States Senator