THE UNITED STATES TRADE REPRESENTATIVE
EXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON

April 3, 2024

Chairman Jim Jordan
Committee on the Judiciary
2138 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Chairman,

On February 26, 2024, I provided an initial reply to your letter of February 13, 2024, regarding the World Trade Organization (WTO) *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS Agreement) and the COVID-19 pandemic ahead of the WTO's Thirteenth Ministerial Conference (MC13). I appreciated hearing your views before MC13. The Ministerial Conference concluded in early March, and I am now writing to provide an update on the outcome of MC13 as well as additional information in response to your letter.

In your February 13 letter, you expressed your opposition to the WTO extending the Ministerial Decision on the TRIPS Agreement (Ministerial Decision) reached during the June 2022 Twelfth Ministerial Conference (MC12) to COVID-19 therapeutics and diagnostics. During MC13, WTO Members did not extend the Ministerial Decision to therapeutics and diagnostics.

Your letter also raised the Office of the United States Trade Representative's (USTR) process for considering the TRIPS waiver proposal, and I am pleased to share information on this topic. On October 2, 2020, India and South Africa introduced a proposal at the WTO to waive the implementation, application, and enforcement of certain intellectual property commitments under the TRIPS Agreement "in relation to prevention, containment, or treatment of COVID-19" (TRIPS waiver proposal).[1] The scope of this proposal was later revised to apply specifically to "health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment."[2]

Following the introduction of the TRIPS waiver proposal, my staff and I engaged in consultations with Congress and a wide range of stakeholders, including public health experts

[1] IP/C/W/699.

[2] IP/C/W/669/Rev.1.

and industry representatives. Such wide-ranging consultations are consistent with my office's Transparency Principles, which I released in 2021, that established guidelines for our engagement with Congress, stakeholders, and the public.[3] These principles include: providing inclusive opportunities for the public to participate in the development of trade policy and trade initiatives; encouraging the participation of a broad range of stakeholders; striving to ensure that the membership of federal advisory committees includes a wide variety of expert interests and is reflective of the diverse set of stakeholder perspectives; and adhering to the Guidelines for Consultation and Engagement that USTR adopted in October 2015.

Ahead of the June 17, 2022 Ministerial Conference (MC12), WTO Members discussed the potential waiver of intellectual property protections for COVID-19 vaccines, and these discussions eventually led to text-based negotiations. Throughout these discussions and negotiations, USTR regularly consulted with Congress, as well as a broad range of stakeholders, to gather a wide range of data on this issue, including labor organizations, public health experts both inside and outside of the government, and relevant members of the private sector including pharmaceutical manufacturers.

On June 17, 2022, at MC12 in Geneva, WTO Members reached an outcome on an intellectual property response to the COVID-19 pandemic. This outcome, titled the Ministerial Decision on the TRIPS Agreement, includes accommodations to the intellectual property rules for COVID-19 vaccines that can facilitate a global health recovery in light of the uncertainty around this virus and its potential variants. Developed countries and the People's Republic of China, which has existing capacity to manufacture COVID-19 vaccines, are not eligible to benefit from the Ministerial Decision.

As part of the Ministerial Decision, WTO Members agreed to decide within six months whether to extend the Decision to the production and supply of COVID-19 diagnostics and therapeutics. In the months following MC12, USTR officials held robust and constructive consultations with Congress, government experts, a wide range of stakeholders, multilateral institutions, and WTO Members. Supporters and opponents of extending the Ministerial Decision to COVID-19 diagnostics and therapeutics provided extensive views and arguments. USTR officials also reviewed and analyzed published information, opinions, and analysis. In both cases, the views concern both the system as a whole – whether existing WTO intellectual property protections are an impediment to access to medicines or a critical element of innovation – as well as the specific characteristics of the markets for COVID-19 diagnostics and therapeutics.

Despite USTR's extensive engagement and research, real questions remained on a range of issues. Thus, on December 6, 2022, I announced support for extending the deadline to decide whether there should be an extension of the Ministerial Decision to cover the production and supply of COVID-19 diagnostics and therapeutics.[4] As part of this announcement, my office

[3] Press Release, Office of the U.S. Trade Representative, USTR Releases Agency Transparency Principles (May 7, 2021), *available at* https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/ustr-releases-agency-transparency-principles.

[4] Press Release, Office of the U.S. Trade Representative, U.S. to Support Extension of Deadline on WTO TRIPS Ministerial Decision; Requests USITC Investigation to Provide More Data on COVID-19 Diagnostics and Therapeutics (December 6, 2022), *available at* https://ustr.gov/about-us/policy-offices/press-office/press-

released a summary of the diverse views we heard during the five-month consultation period.[5] I also announced that my office would ask the United States International Trade Commission (USITC) to launch an investigation into COVID-19 diagnostics and therapeutics and provide information on market dynamics to help inform the discussion around supply and demand, price points, the relationship between testing and treating, and production and access.

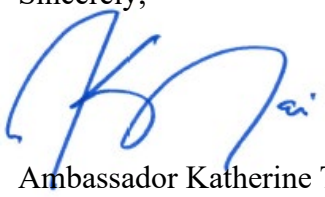
The issues, which concern the intersection between intellectual property and access to medicines, are important and complex, which is why I asked the USITC to use its expertise in studying markets and its robust, transparent processes for soliciting input from a wide variety of stakeholders to conduct an investigation and prepare a report regarding access to COVID-19 diagnostics and therapeutics. I specifically asked the USITC to report on the production, demand, availability, pricing, and market segmentation for COVID-19 diagnostics and therapeutics. The USITC published its report, titled "COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities," on October 17, 2023.[6] This report includes important findings that will inform ongoing work in this field.

The facts in the report and the record the USITC meticulously gathered have played an important role in our deliberations. The report has guided our follow-up consultations with Congress, civil society stakeholders, and industry stakeholders and has led to a more thoughtful and constructive policy discussion. The report has also helped to drive a more fact- and evidence-based discussion among WTO Members on matters so critically important to global public health and economic resilience.

Going forward, I will continue working to support U.S. innovators and producers and to facilitate the global health recovery needed for a strong global economic recovery based on extensive consultations with Congress, stakeholders, and the public.

Thank you again for your letter. I appreciate the opportunity to engage with the Committee on these important issues.

Sincerely,



Ambassador Katherine Tai

cc: Judiciary Committee Ranking Member Jerrold Nadler (D-NY)

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releases/2022/december/us-support-extension-deadline-wto-trips-ministerial-decision-requests-usitc-investigation-provide-0.

[5] Press Release, Office of the U.S. Trade Representative, Summary of Consultations (Dec. 6, 2022), *available at* https://ustr.gov/sites/default/files/2022-12/TRIPS%20Consultations%20Summary.pdf.

[6] Press Release, Office of the U.S. Trade Representative, Statement from Ambassador Katherine Tai on the Release of the USITC Report on COVID-19 Diagnostics and Therapeutics (October 17, 2023), *available at* https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/october/statement-ambassador-katherine-tai-release-usitc-report-covid-19-diagnostics-and-therapeutics.