THE UNITED STATES TRADE REPRESENTATIVE
EXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON

December 16, 2022

The Honorable David S. Johanson
Chairman
U.S. International Trade Commission
500 E Street, S.W.
Washington, DC 20436

Dear Chairman Johanson:

COVID-19 is a global health crisis that has killed more than 6 million people, left millions more with long-term physical challenges, and is not yet over. It has also taken a severe economic toll worldwide and, according to the World Bank, aggravated inequality among countries. The pandemic has reinforced the longstanding concern about the sufficiency of access to medicines and, in particular, global inequity in access to medicines. This is not a new concern, but rather one that has persisted since the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) entered into force in 1995.

The HIV/AIDS crisis was perhaps the first global health crisis after the TRIPS Agreement to illustrate the tension between intellectual property rights protection and access to medicines. The TRIPS Agreement struck a balance in which innovators could enjoy, for example, a 20-year patent term, but all governments would enjoy flexibilities with respect to these rules. In the context of patents, these flexibilities include Article 30 ("Exceptions to Rights Conferred"), Article 31 (commonly understood as the article authorizing compulsory licensing), and Article 31*bis*.

In June 2022, Members of the World Trade Organization (WTO) agreed to provide further flexibilities with respect to COVID-19 vaccines, as well as to consider extending those flexibilities to diagnostics and therapeutics. USTR has consulted with Congress and a wide range of stakeholders on the question of extending those flexibilities. The positions are divergent, even on basic questions around whether there is adequate global supply of diagnostics and therapeutics. These interested parties also diverge on whether extending these flexibilities to diagnostics and therapeutics would in fact improve access, particularly in non-high-income countries, or undermine innovation.

To help inform this discussion, given the Commission's expertise in studying markets and its robust, transparent processes for soliciting input from a wide range of stakeholders, I am asking today that the Commission conduct an investigation and prepare a report under section 332(g) of the Tariff Act of 1930 that, to the extent practicable with available data and information while also identifying where there are significant information gaps:

- Identifies the range of definitions for "diagnostics" and "therapeutics" in the medical field.
- Identifies and defines the universe of existing COVID-19 diagnostics and therapeutics covered by patents as well as COVID-19 diagnostics and therapeutics in development.
- Provides a broad overview of relevant COVID-19 diagnostics and therapeutics, including a description of the products and any intellectual property protections, and containing, to the extent practicable and where data are available:

    - An overview of production and distribution, including key components, the production processes, key producing countries, major firms, operational costs, a description of the supply chain, and the level of geographic diversification within the supply chain;
    - An overview of demand, including key demand factors, an assessment of where unmet demand exists, supply accumulation and distribution, and the impact of the relationship between testing and demand for treatment, if any exists;
    - Information on market segmentation of global demand and consumption, which may be delineated by low-income countries (LICs), lower middle-income countries (LMICs), upper middle-income countries (UMICs), and high-income countries (HICs);
    - Information on availability and pricing (or manufacturing costs in the cases where goods are donated) for COVID-19 diagnostics and therapeutics, if available; and
    - Global trade data for COVID-19 diagnostics and therapeutics or diagnostics and therapeutics in general if specific data are not available.

- Catalogs, to the extent practicable based on available information and a critical review of the literature:

    - The reasons for market segmentation and barriers to a more diverse geographical distribution of the global manufacturing industries for COVID-19 diagnostics and therapeutics;
    - The relationship between patent protection and innovation in the health sector and between patent protection and access to medicine in LICs, LMICs, UMICs, and HICs;
    - Actions taken by WTO Members to use or attempt to use compulsory licenses for the production, importation, or exportation of pharmaceutical products and the outcomes of those actions, including the effect on product access, innovation, and global health;
    - A description of any alternatives to compulsory licensing available to WTO Members, such as voluntary licenses, including through the Medicines Patent Pool (MPP); multilateral programs, including the GlobalFund and United Nations Children's Fund (UNICEF); government-to-government programs; and private-sector donations; and
    - The effect, or lack thereof, of the MPP on access to COVID-19 diagnostics and therapeutics.

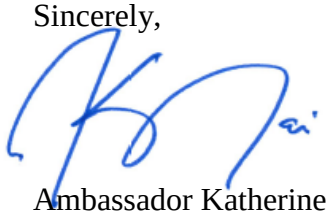
I further request that the Commission, following its usual practice, solicit comments from the public and hold a hearing. In particular, participation from foreign governments, non-

governmental health advocates, organizations such as MPP and Foundation for Innovative New Diagnostics (FIND), and diagnostic and therapeutic manufacturers on these issues is encouraged. I would find public input on the following to be particularly salient:

- How the TRIPS Agreement promotes innovation in and/or limits access to COVID-19 diagnostics and therapeutics;
- Successes and challenges in using existing TRIPS flexibilities;
- The extent to which products not yet on the market, or new uses for existing products, could be affected by an extension of the Ministerial Decision to diagnostics and therapeutics;
- Whether and how existing TRIPS rules and flexibilities can be deployed to improve access to medicines;
- To what extent further clarifications of existing TRIPS flexibilities would be useful in improving access to medicines;
- The relationship between intellectual property protection and corporate research and development expenditures, taking into account other expenditures, such as share buybacks, dividends, and marketing;
- The relevance, if any, of the fact that diagnostic and therapeutic products used with respect to COVID-19 may also have application to other diseases; and
- The location of jobs associated with the manufacturing of diagnostics and therapeutics, including in the United States.

I am not asking the Commission to draw any policy conclusions, but rather I am seeking a robust record with respect to these issues. I ask that you provide this report no later than October 17, 2023.

Sincerely,



Ambassador Katherine Tai