PERSONALIZED MEDICINE COALITION

May 5, 2023

Lisa Barton
Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

Re: Written Submission on Investigation No. 332-596, COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities

Dear Secretary Barton:

The Personalized Medicine Coalition (PMC), a non-governmental health advocacy organization supported by more than 230 member institutions from multiple health and medicine-related business sectors, appreciates the opportunity to comment on the International Trade Commission (ITC)'s investigation into the impact that expanding the scope of the World Trade Organization (WTO)'s Trade-Related Aspects of Intellectual Property (TRIPS) waiver for COVID-19 vaccines could have on the future development of new medical tools.

PMC supports ongoing efforts to ensure that individuals can prevent, detect, and, when necessary, treat COVID-19 infections. We are concerned, however, about ongoing discussions regarding expansion of the TRIPS waiver for COVID-19 vaccines to also include COVID-19 diagnostics and therapeutics. Such an expansion could hamper our members' ability to develop the innovative new tools required to further treat individuals who develop serious COVID-19 infections. It could also inhibit efforts to address diseases with unmet needs for which treatment development has been redirected in response to COVID-19. Finally, it could undermine our capacity to understand the implications of COVID-19 and enable a better response to any future pandemics.

PMC defines personalized medicine as an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC's members are leading the way in personalized medicine and recommend that patients who may benefit from this

approach undergo appropriate testing and tailored treatment as soon as possible during their clinical experiences.

Statement of Neutrality

Many of PMC's members will present their own views on the ITC's investigation and the possible expansion of the TRIPS waiver to include COVID-19 therapeutics and diagnostics. PMC is providing feedback so that the general concept of personalized medicine can advance. This letter is not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to this issue.

Pandemic response and intellectual property (IP)

The COVID-19 pandemic was an unprecedented historical experience for human societies across the globe. Leaders in the personalized medicine community worked rapidly to scale the United States' diagnostic capacity, identify treatments for patients suffering from COVID-19 infection, and develop vaccines, all while continuing to learn about individual responses to the SARS-CoV-2 virus and its many variants. The incentives provided by a strong but flexible network of global intellectual property (IP) protections played a key role in enabling swift responses to the COVID-19 pandemic. The IP system supported the remarkable development and scale-up of COVID-19 vaccines and provided the basis for more than 380 voluntary partnerships for COVID-19 vaccines to be set up in record time, with 88 percent of those partnerships involving technology transfers[i].

The IP system continues to play a critical role in efforts to produce safe and effective vaccines, treatments, and diagnostics, and to make them available globally through collaborative technology transfer and IP licensing approaches. Since the start of the COVID-19 pandemic, 140 voluntary licensing and manufacturing agreements for COVID-19 have been signed,[ii] including many that enable manufacturers to supply generic versions of Paxlovid, one of the most impactful COVID-19 treatments, to low- and middle-income countries covering up to approximately 53 percent of the world's population.[iii] This demonstrates that equitable access can be achieved within the current IP protection framework.

Development of COVID-19 therapeutics and diagnostics

There are 11 approved and authorized medicines in the United States to protect patients from severe illness resulting from COVID-19 infection. There are just under 2,000 clinical trials under way globally to fight COVID-19, approximately 1,500 of which are investigating non-vaccine treatments.[iv] Therapeutics under investigation cover a variety of medicine types, such as antivirals designed to block further replication of the virus in infected patients, small molecules, and biologics such as monoclonal antibodies using ingredients and methods with additional applications.[v] Many of these medicines are also used or are under development to treat cancer, other infectious diseases, and neurological conditions. Most COVID-19 therapeutics currently in development are repurposed or redirected drugs. Of the COVID-19 therapeutics currently under development, 87 percent of treatments and 25 percent of antivirals are repurposed or redirected drugs.[vi] For some companies, these indications unrelated to COVID-19 may be the only path to financial viability and sustained investment to fund future research and development activities. Expansion of the TRIPS waiver to include therapeutics with COVID-19 indications would therefore add significant market risks for companies invested in commercializing

products that may be useful for treating COVID-19 and other diseases with unmet needs. As such, the expansion could unintentionally disincentivize needed therapeutic innovations across a wide range of disease states.

In addition to vaccine and therapeutic development, diagnostic testing has been an essential part of the global response to COVID-19. Diagnostic tests are front-line tools used to screen for and diagnose infection, guide treatment decisions, conduct contact tracing, inform public health decisions, and understand disease epidemiology. Over the course of the COVID-19 pandemic, the diagnostics industry mobilized an unprecedented effort to develop and manufacture hundreds of millions of COVID-19 molecular, antigen, serology/antibody, and T-cell tests to support patient care.[vii] Diagnostic tests have helped enable a precision approach to public health through the use of more accurate measures of disease spread, susceptibility, and characterization of the SARS-CoV-2 virus to improve COVID-19 vaccine effectiveness.

Typically, it takes three to five years from development of a new diagnostic test to availability in commercial markets. During that time, there are several issues diagnostics developers must consider for new diagnostic technologies, including protecting proprietary know-how and manufacturing capabilities as well as minimizing IP infringement when launching products in multiple markets. Through unprecedented collaboration and public-private partnerships developed due to the nature of the public health emergency, the diagnostics industry greatly accelerated the timeline for bringing COVID-19 diagnostics forward and expanding its capacity to manufacture tests.

TRIPS requires that most WTO members adhere to minimum rules for the protection of patents, copyrights, trademarks, and other rights. Patents and other forms of IP incentivize innovation. Advancing the research and development of new vaccines, therapeutics and diagnostics is necessary to not only improve our efforts against the COVID-19 pandemic but to also better prepare us for the next crisis. Improved understanding of biological vulnerabilities offers leads for targeted therapies, approaches to identify risks of adverse treatment effects for patients with certain genetic variants, and provides more complete information on viruses that can improve vaccine effectiveness. Expanding the TRIPS waiver to therapeutics and diagnostics may hinder such endeavors by weakening incentives to pursue future innovations, hampering partnerships and the knowledge-sharing that has occurred during the pandemic.

Conclusion

Thank you for carefully considering these comments as you prepare your report on possible expansion of the TRIPS waiver to COVID-19 therapeutics and diagnostics for the Office of the U.S Trade Representative. If PMC can be of further assistance or if you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely yours,

Cynthia A. Bens
Senior Vice President, Public Policy

[i] *International Federation of Pharmaceutical Manufacturers & Associations*. Pharmaceutical Industry Expresses Deep Disappointment with Decision on Waiving Intellectual Property Rights Adopted at the World Trade Organization Ministerial Conference" https://ifpma.org/news/pharmaceutical-industry-expresses-deep-disappointment-with-decision-on-waiving-intellectual-property-rights-adopted-at-the-world-trade-organization-ministerial-conference/

[ii] *International Federation of Pharmaceutical Manufacturers & Associations*. "Is an extension of the TRIPS waiver needed for COVID-19 tools?" https://ifpma.org/insights/is-an-extension-of-the-trips-waiver-needed-for-covid-19-tools/

[iii] *Geneva Network*. "Five reasons the TRIPS waiver should not be expanded to COVID therapeutics" https://geneva-network.com/research/5-five-reasons-the-trips-waiver-should-not-be-expanded-to-covid-therapeutics/

[iv] *World Health Organization*. International Clinical Trials Registry Platform. https://www.who.int/clinical-trials-registry-platform

[v] *Pharmaceutical Researchers and Manufacturers of America.* PhRMA provides comments and testimony to USITC investigation on COVID-19 medicines and the TRIPS Agreement. https://catalyst.phrma.org/phrma-provides-comments-and-testimony-to-usitc-investigation-on-covid-19-medicines-and-the-trips-agreement?utm_campaign=2023-q1-ini-inn&utm_medium=pai_srh_cpc-ggl-adf&utm_source=ggl&utm_content=clk-pol-tpv_scl-geo_std-usa-dca-pai_srh_cpc-ggl-adf-TRIPSWaiverDCHearingSearchDCWC2-inn_ipr-edu-inf-lrm-soc_txt-std-vrb-adf&utm_term=&gclid=CjwKCAjwjMiiBhA4EiwAZe6jQ6HTdfJLro3Ub-lREfOAs4ru0JzYqmqfqh5huQx18EYjVeRcoAxUcxoCmMUQAvD_BwE

[vi] *Biotechnology Industry Organization.* BIO comments to USTR on the Agency's 2023 Special 301 Review, January 30, 2023. https://www.bio.org/letters-testimony-comments/bio-comments-ustr-agencys-2023-special-301-review-january-30-2023

[vii] *Advanced Medical Technology Association*. AdvaMedDx COVID Testing Supply Retrospective Report. https://www.advamed.org/member-center/resource-library/advameddx-covid-testing-supply-retrospective-report/