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March 22, 2023

Katherine M. Hiner
Acting Secretary to the Commission
U.S. International Trade Commission
500 E Street, S.W.
Washington, DC 20436

Re: *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*
ITC Investigation No. 332-596
Oral hearing statement

Dear Acting Secretary Hiner,

The Biotechnology Innovation Organization (BIO) welcomes the opportunity to provide input related to the USITC's factfinding investigation concerning the global market dynamics and corresponding global intellectual property (IP) landscape of COVID-19 diagnostics and treatments.

BIO's members have made significant contributions to humanity through the research, development, and deployment of lifesaving vaccines and therapeutics for COVID-19. Through the collective research efforts of the global innovative biotechnology community, there have been over 1,000 independent vaccine and therapeutic research and development programs initiated since the beginning of the pandemic.[1] Innovative COVID-19 vaccines and therapeutics have made an incredible contribution to global public health, saving millions of lives around the world.

As innovative therapeutics have become available, breakdowns in the health system infrastructure around the world have become more apparent leading to challenges in the delivery of COVID-19 therapeutics. Proponents of an IP waiver myopically point to IP as the barrier to access while ignoring the number of genuine public health challenges, particularly in the developing world, that frustrate the efficient and equitable distribution of therapeutics. Modernizing health system infrastructure and ensuring robust COVID-19 testing and therapeutic procurement initiatives are examples of measures that can make positive impacts on the public health without undermining IP rights.

A waiver of IP rights would significantly disrupt the existing investment and research landscape in the biotechnology sector– with a particularly acute impact on U.S. based SME biotech firms. Biotechnology innovators in the United States account for over 50% of the COVID-19 therapeutic research and development programs globally. In addition, 87%, or 213 out of the 243 COVID-19 therapeutic development programs in the U.S. originated from SME biotech firms.[2] Furthermore, over 60% of

[1] https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker
[2] https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker

COVID-19 therapeutics in development have other indications, meaning that a waiver jeopardizes the IP rights of existing and future COVID therapeutics as well as the IP covering future and or existing indications unrelated to COVID.

An IP waiver therefore amounts to a broad assault targeting U.S. innovation and the biotechnology pipeline, effectively allowing foreign competitors, like India and China, to leverage this IP to advance their economic agenda and research capabilities in areas that go beyond COVID without any negotiation with the IP rights holders and without any objective demonstration that these IP assets have limited access to therapeutics.

This assault on IP is detrimental to the U.S.-based SME biotech community. SMEs are the lifeblood of the biotech ecosystem and account for approximately 75% of innovation in the global clinical development pipeline. An IP waiver would potentially compromise the core assets of hundreds of U.S. based SME biotech firms, significantly undermining the ability for these companies to leverage their IP to raise the capital needed to invest in research projects and threaten their existence given that most SMEs are pre-commercial and lack an existing revenue stream to offset loss of their IP rights.

Such a result would be devastating for patients waiting for cures and for the U.S. bioeconomy. BIO's members spanning early-stage startup biotech firms, pre-commercial SMEs, and larger multinational biotechnology companies not only make incredible contributions to humankind through their scientific research efforts but also contribute to economic growth in the United States. The U.S. bioscience industry spanning across biotech disciplines directly employs 2.14 million people and contributes to approximately 10.3 million additional jobs resulting in a $2.9 trillion impact to the U.S. economy.[3] The innovative biotechnology community, and the corresponding IP regime which enables scientific innovation and collaboration, should therefore be viewed as a critical component for economic recovery in the eventual post-pandemic context.

The mere contemplation of a waiver of IP rights has already impacted the capital markets for biotechnology investment. The stock prices of SME biotech firms that have invested in COVID-19 related R&D have on average suffered more (-73%) than the average stock in the U.S. (-5.4%) and more than the average SME biotech company not working on COVID-19 related R&D (-55%) since February 2021, which is when the original IP waiver was proposed at the WTO.[4] A decision to adopt a waiver of IP rights for COVID-19 therapeutics and the precedential impact of this policy would add significantly more commercial uncertainty to biotech research efforts and cause investors to shy away from biotech research, which is already fraught with risk and requires on average a $2.6 billion investment for each new FDA approved product.[5] At a time when the global community needs more biotech innovation to cure cancer, prepare for and respond to potential future pandemics, protect the environment, and contribute to economic growth, the U.S., and the global community, should favor policies that encourage greater investment rather than policies, such as the proposed TRIPS Waiver, which would discourage investment.

A waiver would undermine U.S. competitiveness in biotechnology innovation and jeopardize future pandemic preparedness efforts – an outcome clearly inconsistent with the Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy issued by the White House on September 12, 2022, which seeks to protect the technological leadership and

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[3] *The Bioscience Economy: Propelling Life Saving Treatments, Supporting State and Local Communities 2020*, TEConomy/BIO, https://www.bio.org/value-bioscience-innovation-growing-jobs-and-improving-quality-life

[4] Based on period from Feb. 3, 2021 – Dec. 2, 2022 (Source: https://statista.com/statistics/1104278/weekly-performance-of-djia-index/)

[5] https://policymed.com/2014/12/a-touh-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html

economic competitiveness of the United States biotechnology sector. Addressing inequities to COVID-19 therapeutics is an important goal and one our Organization and Membership have been committed to addressing from the beginning of the pandemic – waiving IP, however, presents no solution to these genuine public health concerns and is only successful in compromising cutting-edge scientific endeavors and challenging the growth of the U.S. bioeconomy.