March 17, 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
Prehearing Brief

Dear Acting Secretary Hiner,

The Council of State Bioscience Associations (CSBA) is a coalition of independent, state and territory based non-profit trade associations, each of which advocates for public policies that support responsible development and delivery of innovative life-enhancing and life-saving biotechnology solutions. We write to express our serious concerns with the proposed expansion of the WTO TRIPS waiver to include COVID-19 therapeutics and diagnostics.

Support for an intellectual property (IP) waiver would have serious consequences for the companies CSBA represents, namely small and medium sized enterprises (SMEs) – most of which have yet to bring a product to the market and thus rely heavily on sound and predictable international IP legal regimes to protect their assets and enable greater collaboration and scientific advancement.

CSBA welcomes the USITC's efforts to investigate market dynamics and examine the importance of intellectual property protections related to COVID-19 therapeutics and diagnostics. In response to the public notice regarding this fact-finding investigation, CSBA would like to formally incorporate the entirety of our October 25, 2022 letter to President Biden into the record, to aid the USITC in its investigation.

Ultimately, IP is essential to support our biotech companies which employ millions across the United States. Our industry comprised of companies from every part of the United States has contributed to researching and developing COVID-19 related therapeutics. Waiving IP would compromise the ability for the U.S. private companies to properly respond to future pandemics and jeopardize research efforts in other related fields. We stand committed to work together to find real solutions to genuine public health concerns brought about by the COVID-19 pandemic.

Please contact me at (moshman@bio.org) with any questions.

Sincerely,

Michele M. Oshman
Executive Director, CSBA and Vice President for External Affairs, BIO

October 25, 2022

President Joseph R. Biden
The White House
1600 Pennsylvania Ave., NW
Washington, DC 20500

Dear Mr. President,

The Council of State Bioscience Associations (CSBA) is a coalition of independent, state and territory based non-profit trade associations, each of which advocates for public policies that support responsible development and delivery of innovative life-enhancing and life-saving biotechnology solutions. We write today to express our serious concerns with the proposed expansion of the WTO TRIPS waiver to include not only vaccines, but also COVID-19 therapeutics and diagnostics.

The US Government's support for an intellectual property (IP) waiver would have serious consequences for the companies CSBA represents, namely small and medium sized enterprises (SMEs) -- most of which have yet to bring a product to the market.

Inconsistency with the Executive Order

A waiver would allow U.S.-developed innovative technologies to be manufactured overseas and exported without regard to intellectual property protections, meaning that U.S. biomanufacturing jobs would be lost. There is no question that waiver expansion is inconsistent with your *Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy,* issued on September 12.[1]

The Executive Order states that the U.S. must *"safeguard the United States bioeconomy, as foreign adversaries and strategic competitors alike use legal and illegal means to acquire United States technologies and data… and proprietary or precompetitive information, which threatens United States economic competitiveness and national security."* While we applaud your leadership in issuing this Executive Order, a TRIPS waiver expansion would fundamentally undermine a key objective of the EO itself, which is to ensure United States' global leadership in the field of biotechnology.

[1] https://www.whitehouse.gov/briefing-room/presidential-actions/2022/09/12/executive-order-on-advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american-bioeconomy/

Protecting America's SMEs

Over 50% of COVID-19 therapeutics in development worldwide originated in the United States, thanks to the robust entrepreneurial and innovative biotech ecosystem in our country. Of the over 350 therapeutics being developed in the United States, 86% -- totaling 307 therapeutics -- originated from SME biotech firms spanning over 28 States.[2] A waiver of IP rights applied to COVID-19 therapeutics would give away the tremendous innovative potential, benefitting America's foreign competitors at the expense of hundreds of U.S.-based biotech firms.

Furthermore, over 60% of all COVID-19 therapeutics in development have other indications beyond COVID-19. Accordingly, waiving IP rights for these therapies could unintentionally impact medicines across a range of therapeutic areas and would result in a disproportionate impact on U.S.-based enterprises, particularly the U.S. based entrepreneurial and SME biotech community[3]. For SME biotech firms, the expansion of a TRIPS waiver to therapeutics creates significant market risk for the commercialization of their products for indications unrelated to COVID-19

Global Voluntary Licensing Agreements Abound

There is no global supply challenge that justifies the extension of an IP waiver to therapeutics and diagnostics. Manufacturers are supplying therapeutics at a rate that outpaces demand. Biotech antiviral manufacturers have entered into dozens of voluntary licensing agreements with companies in South America, Africa, and Asia to manufacture generic antivirals and distribute these products to countries throughout the developing world.[4] Through these collective efforts, our members are illustrating the impact of collaborative, as opposed to coercive, approaches to technology transfer and IP licensing. These collaborations strengthen global interconnectedness and efficiently address global demand for therapeutics (see Annex for a representative list of current global R&D and manufacturing collaborations).

Alternatives for Consideration

As an alternative to the Geneva-driven WTO TRIPS waiver discussion, we encourage the Administration to consider and propose other potential options that more concretely address genuine public health concerns that would improve the management of COVID-19 and, consequently, the health of vulnerable populations around the world. Strengthening health systems infrastructure, addressing vaccine hesitancy, and supporting more robust COVID-19 testing and therapeutic procurement initiatives are examples of some initiatives that can have a meaningful impact.

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[2] BIO COVID-19 Therapeutic Development Tracker - https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker

[3] ibid

[4] Pfizer 35 Generic Manufacturing Agreements through Medicines Patent Pool: https://medicinespatentpool.org/news-publications-post/35-generic-manufacturers-sign-agreements-with-mpp-to-produce-low-cost-generic-versions-of-pfizers-oral-covid-19-treatment-nirmatrelvir-in-combination-with-ritonavir-for-supply-in-95-low-and; Merck 27 Generic Manufacturing Agreements through Medicines Patent Pool: https://medicinespatentpool.org/news-publications-post/27-generic-manufacturers-sign-agreements-with-mpp-to-produce-molnupiravir; Gilead 9 Generic Manufacturing Agreements: https://www.gilead.com/purpose/medication-access/global-access/access-partnerships

The White House National COVID-19 Preparedness Plan commits that the United States would be the "world's arsenal of vaccines."[5] The President's Action Plan on Resilience in the Americas provides an effective model for US leadership in responding to the global pandemic.[6]

CSBA shares a key tenet of the recent White House Executive Order, which is to maintain United States technological leadership and economic competitiveness in biotech and biomanufacturing innovation. To truly be the world's arsenal of COVID-19 vaccines and therapeutics and to realize the full potential of the Executive Order, there is no other decision to make than to firmly oppose the expansion in any form of the WTO TRIPS waiver to COVID-19 therapeutics and diagnostics.

Please contact CSBA Executive Director, Michele Oshman at moshman@bio.org with any questions.

Sincerely,

BioAlabama
Arizona BioIndustry Association, Inc.
Biocom California
California Life Sciences
Southern California Biomedical Council
Colorado BioScience Association
BioCT
Delaware BioScience Association
BioFlorida
CGHI: Georgia Bio
Idaho Technology Council
Illinois Biotechnology Innovation Organization
Indiana Health Industry Forum
Iowa Biotechnology Association
BioKansas
Kentucky Life Sciences Council
Louisiana BIO
Bioscience Association of Maine
Maryland Technology Council
Massachusetts Biotechnology Council
Michigan Biosciences Industry Association
Medical Alley Association
Missouri Biotechnology Association
Montana BioScience Alliance

[5] https://www.whitehouse.gov/covidplan/

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/08/fact-sheet-biden-harris-administration-announces-action-on-covid-19-pandemic-response-and-improving-health-systems-and-health-security-in-the-americas/

Bio Nebraska
Nevada Biotechnology & Health Science
BioNJ
New Mexico Biotechnology & Biomedical Association
NewYorkBIO
North Carolina Biosciences Organization
Bioscience Association of North Dakota
BioOhio
Oklahoma Bioscience Association
Oregon Bioscience Association
Life Sciences Pennsylvania
INDUNIV
Rhode Island Bio
South Carolina BIO
South Dakota Biotech Association
Life Science Tennessee
Texas Healthcare and Bioscience Institute
BioUtah
Vermont Biosciences Alliance
Virginia Biotechnology Association
Life Science Washington
Bioscience Association of West Virginia
BioForward Wisconsin

cc: The Honorable Xavier Becerra
Secretary of Health and Human Services

The Honorable Antony Blinken
Secretary of State

The Honorable Brian Deese
Director, National Economic Council

The Honorable Gina Raimondo
Secretary of Commerce

The Honorable Jacob Sullivan
Assistant to the President for National Security Affairs
National Security Council

The Honorable Katherine C. Tai
United States Trade Representative

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

Annex

Representative List of Global COVID-19
Therapeutic R&D and Manufacturing Collaborations

Business to Business

- **Regeneron**
  - Partnered with *Roche (Switzerland)* for global manufacturing of Regeneron's antibody. (press release)
- **SAB Therapeutics**
  - SAB Biotherapeutics (US), a clinical-stage biopharmaceutical company, partnered with *CSL Behring (Australia)* to advance and deliver a novel immunotherapy targeting COVID-19. The potential therapy would be produced without the need for blood plasma donations from recovered COVID-19 patients. (press release)
- **BeiGene**
  - Collaboration with *Atreca* (*US*) and *IGM Biosciences* (*US*) on novel antibody treatment for COVID-19. (press release)
  - BeiGene is collaborating with *Singlomics* (China) and *Peking University* for the use of monocolonal antibodies (mAbs) against COVID-19. (press release)
- **AvantGen**
  - AvantGen (US) granted *IGM Biosciences (US)* the rights to convert the antibody clones into IgA or IgM format for further development for the treatment of COVID-19. (press release)
- **Athersys**
  - Athersys (US) and *Healios (Japan)* are partnering to develop a MultiStem treatment for ARDS patients, which includes patients diagnosed with ARDS due to COVID-19. (press release)
- **Biocon**
  - Biocon (India) entered into a licensing agreement with *Equillium (US)* to develop and commercialize Biocon's novel biologic, itolizumab. (press release)

- **Rigel Pharmaceuticals**
    - Rigel Pharmaceuticals (US) collaborate with researchers at Imperial College London (UK) to evaluate the use of fostamatinib in patients with COVID-19 pneumonia. (press release)
- **CSL Behring**
    - CSL Behring has launched a clinical trial into the use of CSL312 (garadacimab, Factor XIIa antagonist monoclonal antibody) to treat patients suffering from severe respiratory distress, a leading cause of death in patients with COVID-19 related pneumonia. (press release)
- **Eli Lilly**
    - *Six Indian drugmakers* received royalty-free licenses to produce baricitinib and expand its availability for the treatment of COCID-19. (press release)
    - Eli Lilly and *AbCellera* (Canada) co-developed antibody therapies for the treatment of COVID-19. (press release)
    - Partnership with *Junshi Biosciences* (China) to co-develop antibody therapies for the prevention and treatment of COVID-19. (press release)
    - Collaboration with *Samsung Biologics* to mass produce Lilly's COVID-19 antibody therapies. Lilly hopes to make up to 1 million doses this year and many more in 2021 (press release and here)
    - Manufacturing collaboration with *Amgen* for COVID-19 antibody therapies (press release)
- **Gilead**
    - Gilead signed non-exclusive voluntary licensing agreements with *nine manufacturer*s based in India, Pakistan and Egypt to expand access to generic remdesivir in 127 low and middle-income countries. (press release)
    - Gilead also forged collaborations with more than 40 trusted manufacturing partners in North America, Europe, and Asia to expand its Veklury (remdesivir) manufacturing network and meet global demand. (press release)
    - When COVID-19 cases began surging in India in April 2021, Gilead initiated efforts to expand availability of remdesivir by providing technical assistance to its seven India-based voluntary licensing partners, supporting the addition of new local manufacturing facilities, and donating API to scale up production of remdesivir. Gilead is also committed to providing support to voluntary licensees based outside of India to increase their production capacity. (press release)

- **AbbVie, Amgen and Takeda**
    - AbbVie (US), Amgen (US) and Takeda (Japan) are members of the COVID R&D Alliance, which is a group of more than 20 companies working to speed the development of potential therapies, novel antibodies and anti-viral therapies for COVID-19 and its related symptoms. (press release)
- **Merck, Ridgeback Biotherapeutics and Emory University**
    - Merck announced voluntary licensing agreements with *5 Indian generic manufacturers* to accelerate and expand global access to Molnupiravir. (press release)
- **Vir Biotechnology**
    - Collaboration with *GlaxoSmithKline (UK)* on monoclonal antibody (mAbs) treatment for COVID-19 (press release)

Business and Government/Regional Partnerships

- **Pfizer**
    - The *Africa CDC* signed a Memorandum of Understanding with *Pfizer* for African countries to receive supplies of the Paxlovid pill to treat COVID-19. Pfizer will provide the treatment at cost. (Article)

Other Global Partnerships

- **Merck, Ridgeback Biotherapeutics and Emory University**
    - Merck and the *Medicines Patent Pool (MPP*) entered into a license agreement for Molnupiravir, an investigational oral therapeutic for the treatment of COVID-19. Under the terms of the agreement, MPP, through the license granted by Merck, will be permitted to further license non-exclusive sublicenses to manufacturers ("MPP License") and diversify the manufacturing base for the supply of quality-assured or WHO-prequalified molnupiravir to countries covered by the MPP License, subject to local regulatory authorization. (press release). So far*, 23 generic pharmaceutical companies* have been licensed to produce molnupiravir for 105 developing countries https://medicinespatentpool.org/licence-post/molnupiravir-mol
- **Pfizer**
    - Pfizer and the Medicines Patent Pool signed a licensing agreement for low- and middle-income countries to manufacture Paxlovid. (press release). To date, *38 generic pharmaceutical companies* have entered into sublicensing agreements covering 95 developing countries. https://medicinespatentpool.org/licence-post/pf-07321332