



Biotechnology Innovation Organization  
1201 New York Ave., NW  
Suite 1300  
Washington, DC, 20005  
202-962-9200

September 26, 2022

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

Dear Mr. President,

We are writing to express our strong opposition to any form of expansion of the WTO TRIPS waiver to COVID-19 therapeutics or diagnostics. Support for an intellectual property (IP) waiver would send U.S.-developed innovative technologies and biomanufacturing jobs overseas and, consequently, weaken the ability for U.S. biotech firms - including the hundreds of small and medium-sized enterprises (SMEs) involved in the development of COVID-19 therapeutics - to compete globally and grow jobs domestically. This would be an outcome clearly inconsistent with the Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy issued on September 12.<sup>1</sup>

The Executive Order on Advancing Biotechnology and Biomanufacturing Innovation states that the main policy objective is to "enable access to technologies... in a manner that benefits all Americans and the global community and that maintains United States technological leadership and economic competitiveness." In order to protect the technological leadership and economic competitiveness of the United States biotechnology sector, it is imperative that the United States Government oppose the proposed expansion of the WTO TRIPS waiver to therapeutics and diagnostics. With no global supply or demand challenge that would justify the extension of an IP waiver, the proposed expansion of the TRIPS Waiver is nothing more than an effort by adversaries of the United States to use the COVID-19 pandemic as a pretext to fundamentally undermine the global IP rights system, undermine the United States' position as a global leader in biotechnology, and gain access to some of the most innovative biotechnology tools without any good-faith negotiation with IP rights holders.

One of the hallmarks of the U.S. biotech sector is the robust entrepreneurial spirit and scientific leadership driven by SME biotech firms. In the United States, SME biotech companies account for 307 of the 357 unique COVID-19 therapeutics currently in development, roughly 86 percent.<sup>2</sup> A waiver of IP rights applied to COVID-19 therapeutics would give away the tremendous innovative potential in these underlying technologies, benefitting America's foreign competitors at the expense of the investment and ingenuity of hundreds of U.S.-based biotech firms.

The potential impact of an expanded TRIPS waiver on U.S.-based SMEs is compounded by the fact that most COVID-19 therapeutics currently in development are repurposed or redirected drugs. In other words, most of the COVID-19 therapeutics currently under development have or may potentially have other indications - more precisely, 87% of treatments and 25% of antivirals in

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<sup>1</sup> <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/>

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



development are repurposed or redirected drugs. For SME biotech firms in this situation, the expansion of a TRIPS waiver to therapeutics creates significant market risk for the commercialization of their products for indications unrelated to COVID-19. These other indications may be their only path to financial viability and sustained investment to fund future R&D initiatives.

Finally, there is no supply and demand challenge globally that justifies the extension of an IP waiver to therapeutics and diagnostics. Manufacturers are supplying therapeutics at a rate that outpaces demand. BIO members that have developed antivirals 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.<sup>3</sup> Through these collective efforts, our members are illustrating how collaborative, as opposed to coercive, approaches to technology transfer and IP licensing strengthen global collaborations and address global demand for therapeutics (see Annex for a representative list of the BIO members' global R&D and manufacturing collaborations).

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.

The White House National COVID-19 Preparedness Plan commits that the United States would be the "world's arsenal of vaccines."<sup>4</sup> One of the key policy tenets of the recent Executive Order 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.

Yours Sincerely,

A handwritten signature in black ink, appearing to read "M. McMurry-Heath", written in a cursive style.

Dr. Michelle McMurry-Heath  
President & CEO  
Biotechnology Innovation Organization

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<sup>3</sup> 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>

<sup>4</sup> <https://www.whitehouse.gov/covidplan/>



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 monoclonal 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 COVID-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 manufacturers* 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/license-post/pf-07321332>