UNITED STATES COUNCIL FOR INTERNATIONAL BUSINESS

September 12, 2022

The Honorable Antony Blinken
Secretary of State
U.S. Department of State
2201 C St. NW
Washington, DC 20520

The Honorable Gina Raimondo
Secretary of Commerce
U.S. Department of Commerce
1401 Constitution Ave. NW
Washington, DC 20520

The Honorable Katherine Tai
United States Trade Representative
The Winder Building
600 17th Street, NW
Washington, DC 20508

The Honorable Jacob Sullivan
Assistant to the President for National
Security Affairs, National Security Council
The White House
1600 Pennsylvania Ave. NW
Washington, DC 20500

The Honorable Brian Deese
Director, National Economic Council
The White House
1600 Pennsylvania Ave. NW
Washington, DC 20500

The Honorable Ashish Jha
Coordinator of the COVID-19 Response and
Counselor to the President
The White House
1600 Pennsylvania Ave. NW
Washington, DC 20500

The Honorable Kathi Vidal
Director, U.S. Patent and Trademark Office
600 Dulany St.
Alexandria, VA 22314

Dear Secretary Blinken, Secretary Raimondo, Ambassador Tai, Mr. Sullivan, Mr. Deese, Dr. Jha and Ms. Vidal:

The U.S. Council for International Business (USCIB) lauds the Biden-Harris Administration for its effective management of COVID-19 pandemic, a successful partnership between government and a world class biopharmaceutical industry. Unfortunately, the remarkable innovation that brought us COVID-19 vaccines, diagnostics, and therapeutics is under threat by pressure at the World Trade Organization (WTO) to waive intellectual property (IP) protections that fueled these pandemic breakthroughs. USCIB urges the Administration to oppose these efforts.

It took decades studying coronaviruses and developing messenger RNA ("mRNA") technologies to lay the foundation for the highly effective COVID-19 vaccines and other medicines of today. These revolutionary innovations, developed at unprecedented speed and scale, were fueled by global rules that protect IP which provide companies with confidence to undertake high-risk ventures over extended timelines. Some 90 percent of pharmaceutical clinical trials end in failure. Over 20 years, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has provided the legal architecture for safeguarding innovation and inspiring researchers to take extraordinary risk to develop cutting edge pharmaceuticals that combat infectious diseases and save lives around the globe.

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TRIPS rules, however, are under challenge at the WTO by nations seeking to leverage the COVID-19 pandemic to gain unfettered access to competitively sensitive, proprietary biopharmaceutical manufacturing technology. USCIB was extremely disappointed with the TRIPS waiver for COVID-19 vaccines announced at the 12th Ministerial Conference of the WTO in June and is staunchly opposed to extending the waiver to COVID-19 therapeutics and diagnostics. TRIPS waivers do not solve supply problems, but instead undermine innovation, global health security, international rule of law, and faith in the global trading system.

There is no need to waive IP rights to increase access. The TRIPS agreement already provides ample policy flexibilities to address disparities in access to medicines and treatments, allowing low-income countries to obtain licenses to produce truly lifesaving technologies. Global biopharmaceutical companies – Merck, Gilead, Pfizer, for example – have already entered into myriad voluntary licensing agreements and patent pools to boost manufacturing and distribution of COVID therapeutics. (See Attachment A)

There is no need to waive or otherwise compromise IP rights to increase production. The projected supply for COVID antiviral treatments is likely to meet or exceed demand in 2022, according to predictive health analytics company Airfinity.[1] Approximately two-thirds of Paxlovid™ production and half of the production of the anti-viral molnupiravir is estimated to be available for middle- and lower-income countries as numerous licensed generic manufacturers prepare to launch.[2] Already there are indications that licensed generic manufacturers are responding to lower-than-expected demand and potential oversupply.[3]

The real problem in the administration of vaccines and therapeutics is insufficient healthcare infrastructure and distribution systems necessary to reach remote populations. This explains why, despite sufficient availability of vaccines, vaccination rates in parts of the developing world remain stubbornly low. Pharmaceutical companies around the globe have produced enough vaccine to treat the world, yet many of these vaccines remain unused, destroyed, or turned away by underserved countries because they do not have ability to distribute them. This is not new; nor should it be a surprise. The lack of infrastructure and distribution systems with the concomitant essential education have posed formidable challenges in the distribution and administration of pharmaceuticals and other medical care.

There also remains an unhealthy dose of vaccine hesitancy in certain populations impacting uptake. Energy must be directed at addressing these bottlenecks at the point of delivery. Toward that end, the biopharmaceutical industry has partnered to form the global "Strategy for Harnessing Access Reaching Everyone" (SHARE) program to advance the supply of COVID-19 vaccines and therapeutics as well as enhance healthcare delivery systems in underserved areas around the world.

In the months since the WTO adopted the COVID vaccine IP waiver, despite its ostensible urgency and necessity, not a single country has taken steps to employ this new flexibility. Instead of solving for low vaccine uptake, certain countries are now demanding waivers of COVID therapeutic and diagnostic IP absent which, it is said, they cannot mount a response to the pandemic. But distribution of COVID antivirals is, if anything, logistically more difficult than deployment of COVID vaccines. For oral COVID antivirals, deployment depends on an effective test-to-treat strategy, requiring easy and prompt access to diagnostic testing sites in conjunction with drug dispensing within a short time of symptom onset. Further, for antibody products and remdesivir, distribution for use in intravenous infusion facilities is required. It is not obvious

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[1] https://www.airfinity.com/insights/sales-of-covid-19-antiviral-pill-paxlovid-to-leap-frog-mercks-competitor.

[2] Paxlovid is a registered trademark of Pfizer.

[3] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/companies-stare-at-huge-losses-as-unsold-covid-drugs-pile-up/articleshow/91260493.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

how countries that struggle logistically to roll out vaccines would find it easier to comprehensively roll out COVID therapy programs.

A TRIPS waiver for COVID-19 diagnostics and therapeutics creates more problems than solutions. There is disagreement even within the United States over what strictly constitutes a COVID therapeutic: how will this be resolved at the international level where there is heightened pressure to define broadly? The definition could extend to a wide range of drugs with dual use, such as steroids and anti-inflammatories used to treat arthritis, cancer, and other illnesses. Moreover, where would the TRIPS waivers end and at what cost to American competitiveness and the millions of U.S. workers who innovate?

No nation has more to lose from a weakening of intellectual property rules than the United States, the world's leader in biopharmaceutical and technological research, producing some of the most important lifesaving vaccines, therapeutics, diagnostics, and devices used around the globe. U.S. health security is at risk today while the pandemic mutates, monkey pox spreads, and polio resurfaces. Innovation enables us to respond to the dynamic nature of these diseases. Strong and predictable intellectual property protections are the cornerstone of innovation, incentivizing not just investment into research and development, but also the licensing, partnering, and orderly dissemination of technology that helps to prepare the United States and the world for the health challenges we face today and will face in the future.

For all these reasons, USCIB urges the United States to oppose efforts at the WTO to extend the TRIPS waiver to COVID-19 diagnostics and therapeutics. It is a solution in search of a problem, needlessly putting in peril U.S. jobs, innovation, global health security, and faith in the global trading system.

Since 1945, USCIB has been a leading voice of U.S. business in the United Nations system and in other multilateral institutions. Our membership includes global corporations, professional firms, and industry associations, that provide business input for USCIB to convey to policymakers at home and abroad. USCIB and our member companies have long believed that open, fair, rules-based international trade and investment in all directions can be dynamic forces for economic growth, jobs, and better lives. We are proud to serve as the sole U.S. affiliate of Business at OECD (BIAC), the International Chamber of Commerce (ICC), and the International Organization of Employers (IOE). We have supported UNFCCC and the Paris Agreement, alongside the UN 2030 Agenda for Sustainable Development and its SDGs.

USCIB members and staff welcome the opportunity to engage with you on this very important matter.

Best regards,

Brian Robert Lowry
Senior VP, Innovation, Regulation, and Trade
U.S. Council for International Business

CC: Marina Lamm, IP Attaché, U.S. Permanent Mission to the United Nations
Helene Liwinski, IP Attaché, U.S. Mission to the World Trade Organization

Attachment A
A Sample of COVID-19 Business Partnerships[4]

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

[4] List provided by the Biotechnology Innovation Organization (BIO) - https://www.bio.org/.

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