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202-962-9200

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 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 also would like to comment on the USITC's broader examination of the role of IP as a tool to defeat COVID-19, drive biotech innovation and propel U.S. and global economic recovery in the post-pandemic context.

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.

The global IP framework has enabled this lifesaving innovation and provides a reliable legal foundation for companies to voluntarily license their IP to enhance research collaborations and provide timely, equitable global access to safe and effective therapeutics. In addition to the many international research collaborations for the development of COVID-19 therapeutic drug candidates, BIO members have also entered into over 140 licensing collaborations with partners around the world to support the distribution and manufacturing of approved COVID-19 therapeutics. As a result, there are over 200 production sites across the world and over 650 R&D sites. Furthermore, greater than 96% of these collaborations involve technology transfer and, to illustrate the geographic diversity of these arrangements, over 67% of licensees are in LMICs.[2]

[1] https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker
[2] https://ifpma.org/resources/impact-of-a-waiver-of-intellectual-property-rights-for-covid-19-therapeutics/

These voluntary research and manufacturing agreements for COVID-19 therapeutics have contributed to a scenario where supply of therapeutics exceeds demand. According to Airfinity, governments and NGOs purchased 80 million courses of COVID-19 therapeutics in 2022 but administered only 18 million courses.[3]

As innovative therapeutics have become available, breakdowns in the health system infrastructure around the world have become more apparent leading to significant 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.

The acute focus on IP rights by proponents of an IP waiver and their failure to focus on addressing genuine public health challenges to address the safe administration of COVID-19 therapeutics suggest that there are ulterior motives for their advocacy in support of a waiver of IP rights. With no global supply or demand challenge that would justify the extension of an IP waiver, the proposed expansion of the IP waiver to therapeutics is nothing more than an effort by competitors 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.

The breadth of the proposed IP waiver for COVID-19 therapeutics is of significant concern to BIO membership. An IP waiver for COVID-19 therapeutics threatens and could implicate the universe of current therapeutics as well as drug candidates in the global clinical development pipeline that today or someday in the future may have an indication for COVID-19. In addition, over 60% of COVID-19 therapeutics in development have other indications – for example, as anti-inflammatory or oncology drugs. Accordingly, a waiver of IP rights for COVID-19 related technologies jeopardizes the IP rights of existing therapeutics, future drug candidates, and COVID-19 related drugs or drug candidates with other indications. Furthermore, IP covering methods of manufacture, research tools, and intermediates related to the development of COVID-19 therapeutics may also be in scope. As a result, the proposed IP waiver would inevitably cover and could negatively impact a wide segment of the global innovative clinical biotechnology pipeline.

The exposure of an IP waiver is particularly acute to United States based biotech firms, and especially small and medium sized (SMEs) biotech companies. 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 United States originated from U.S.-based SME biotech firms.[4] An IP waiver for COVID-19 therapeutics would therefore directly target U.S. innovation and IP rights, effectively allowing foreign competitors to leverage this IP to advance their economic agenda and research capabilities without any negotiation with the IP rights holders and without any objective demonstration that these IP assets have restricted access to therapeutics.

SMEs are the lifeblood of the biotech ecosystem and account for approximately 75% of innovation in the global clinical development pipeline. SME biotech firms generally do not have approved products and a

[3] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/2022-09-30-PhRMA-TRIPS-Waiver-Expansion-FINAL_November-2022.pdf

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

revenue stream – their most valuable asset is their IP portfolio. A waiver of IP rights for COVID-19 therapeutics 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.

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.[5] 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.[6] A decision to adopt a waiver of IP rights for COVID-19 therapeutics and the precedential impact 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.[7] 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.

In conclusion, a waiver of IP rights would significantly disrupt the existing investment and research landscape in the biotechnology sector globally – with a particularly acute impact on U.S. based SME biotech firms. A waiver of IP rights would unnecessarily compromise U.S. leadership in the life sciences, jeopardize future pandemic preparedness efforts and undermine U.S. competitiveness in biotechnology innovation – 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.[8] This Executive Order seeks to protect the technological leadership and economic competitiveness of the United States biotechnology sector. Opposing the proposed expansion of the WTO TRIPS Waiver to therapeutics and diagnostics is essential for achieving these goals and ensuring U.S. leadership in the life sciences.

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[5] *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

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

[7] 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

[8] 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/

I. ABOUT BIO – INNOVATING TRANSFORMATIONAL BIOTECHNOLOGY SOLUTIONS

BIO is a non-profit organization with a membership of more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in almost all fifty States. BIO's members research and develop health care, agricultural, industrial, and environmental biotechnology products.

The U.S. life sciences industry, fueled by the strength of the global IP system embedded in the TRIPS Agreement, has delivered incredible contributions to society, transforming lives of patients, farmers, and consumers around the world through the development of breakthrough drug products, medical diagnostic tests, genetically engineered crops, and environmentally beneficial products such as renewable fuels and bio-based plastics. The innovations of our member companies cure diseases, protect our climate and nourish humanity. Our sector also has a major economic footprint in the United States, directly employing 2.14 million people and contributing to approximately 10.3 million additional jobs resulting in a $2.9 trillion impact to the U.S. economy.[9]

BIO acknowledges our role as innovators to ensure that our technologies reach people around the world. We are committed to championing broad access to transformative and disruptive therapies to ensure all patients can benefit from the achievements of modern biotechnology and so that biotechnology can improve nutrition and clean the environment, elevating community health globally. Accordingly, we are committed to work constructively towards a global policy environment that provides access to affordable care, incentivizes novel transformative breakthroughs, and creates financial incentives to enable the biotechnology innovations of the future.

II. INTELLECTUAL PROPERTY ENABLES BIOTECHNOLOGY INNOVATION

The vast majority of BIO's members are small and medium sized enterprises (SMEs) that currently do not have products on the market. As such, BIO's members rely heavily on the strength and scope of their IP to generate investments needed to develop and commercialize their technologies.

The strength of the global IP system, therefore, is critical to realize and deliver promising biotechnology solutions to humanity by providing a framework to unite and empower biotech innovators and their ecosystems to improve lives. Strong and predictable IP systems cultivate partnerships around the world, enhance knowledge sharing, support the entrepreneurial journey, and ultimately ensure that innovation is resourced and funded so that technologies with the potential to deliver better care for patients and products for consumers are developed.

Biotechnology business models for agriculture, pharmaceutical and industrial solutions are built on collaborations between universities, small biotechnology companies, venture capital and larger private company partners. Governments support this model, and benefit from the development of biotechnology innovations into products when they establish enabling environments for innovation.

Biopharmaceutical companies rely heavily on IP rights for legal certainty needed to attract investments. The development of a single biotechnology product often takes scientists more than a decade to commercialize

[9] *The U.S. Bioscience Industry: Fostering Innovation and Driving America's Economy Forward 2022,* TEConomy/BIO, https://www.bio.org/value-bioscience-innovation-growing-jobs-and-improving-quality-life

and more than a billion of dollars of capital investment, a significant amount of which comes from private sources.[10] Biotechnology product development is also fraught with high risk – the vast majority of researched biotech therapies fail to ever reach the marketplace.

Venture capital firms invest in capital-intensive, long-term, and high-risk research and development endeavors only if they believe that there will be an attractive return on their investment. Patents and regulatory data protection help provide this assurance. According to a patent survey conducted by researchers at the University of California Berkeley, 73% of the biotechnology entrepreneurs reported that potential funders, such as venture capitalists, angel investors, and commercial banks, indicated patents were an important factor in their investment decisions.[11]

Without strong and predictable patent protection, investors will shy away from investing in biotech innovation, and will simply put their money into projects or products that are less risky – without regard to the great value that biotechnology offers society.

While the IP environment in the United States has contributed to the emergence of many biotechnology businesses and provided their first market opportunities, these businesses need to participate in the global economy in their search for innovations and rewards for transforming those innovations into products. Strong IP rules outside the United States improve conditions for export of biotech products from the United States and grow American jobs.

III. IP AS A TOOL TO DEFEAT COVID-19

The COVID-19 pandemic substantially impacted life as we have known it all around the world. As a result, policymakers have struggled with how to address the unprecedented crisis.

Unfortunately, there have been many unfounded claims that IP has hindered the development of tools to fight COVID-19, as well as access to those tools. As a result, there have been numerous calls for the adoption of measures to weaken IP rights counter to global commitments embodied by the TRIPS Agreement.

The global IP system has been under attack, mischaracterized and misunderstood as an impediment in the face of a global pandemic. These claims and lack of fact-based considerations have led to the adoption of a waiver of IP for COVID-19 vaccines. Unfortunately, this debate continues, and the potential extension of this waiver to therapeutics and diagnostics not only ignores current and future supply and demand, but it will also negatively impact future pandemic preparedness and the multitude of therapies in the pipeline with uses beyond COVID-19.

Despite these efforts to weaken IP rights, as we reflect on the incredible amount of innovation directed towards eradicating COVID-19, IP can objectively be viewed as an enabler of innovation and as a key factor in our collective ability to harness science for the public good.

First, IP rights built a strong private sector ready to rapidly respond to health crises. Robust IP rights mobilize large and sustained amounts of private investment that funded past research and innovations that

[10] *See "Private Sector's Critical Role in Biomedical Innovation"*, Cost & Value of Biopharmaceuticals - https://www.bio.org/toolkit

[11] Graham, Stuart J. H. and Sichelman, Ted M., Why Do Start-Ups Patent? (September 6, 2008). Berkeley Technology Law Journal, Vol. 23, 2008. Available at SSRN: http://ssrn.com/abstract=1121224

our member companies then leverage to support COVID-19 research. As a result, since the onset of the pandemic, over 1,000 R&D programs related to COVID-19 have been launched with 50% of these programs originating from the United States, 75% of which originated by small and medium sized biotech firms.[12] There are now over a dozen approved vaccines manufactured throughout the world, collectively amounting, according to Airfinity, to over 15.9 billion doses manufactured through 2022.

Furthermore, there are approximately 475 unique COVID-19 antivirals and treatments actively in clinical development to treat COVID-19.[13] In addition, a total of 24 antivirals and treatments have been approved or received Emergency Use Authorization while another 355 research programs are now inactive or failed – amounting to over 800 total research and development programs for COVID-19 therapeutics since the beginning of the pandemic.[14] Over 50% of the innovation has originated in the United States and of the innovative COVID-19 therapeutics in development, over 87% have originated from SME biotech firms. Such rapid progress in research to combat COVID-19 has been fueled by research enabled by strong global IP incentives.

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 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. Moreover, expanding the TRIPS waiver could disincentivize further research into whether drugs with other indications may treat COVID-19, thereby denying patients of additional treatments.

The global IP system has facilitated unprecedented levels of collaboration around the world and scientific development in remarkably abbreviated timeframes.[15] Multi-way collaboration between private sector members of the life sciences community with governments, universities, foundations, and non-profit entities is the hallmark of the on-going COVID-19 response. Over 300 manufacturing partnerships to scale up production and distribution of critical COVID-19 vaccine and therapeutic technologies have been entered into globally on a voluntary basis in an effort to exceed demand and provide access to patients around the world. Without reliable, predictable, rule-based IP systems globally and confidence in the rule of law upon which parties honor the sanctity of contractual obligations, these partnerships simply would not exist.

Coercive measures to compel licensing or suspend or eliminate IP rights, as promoted by an IP Waiver, have not been needed to drive global collaboration. In fact, they would undermine collaboration. Since the beginning of the pandemic, there have been scores of public announcements illustrative of how our global innovative biotechnology community, comprising large and SME biotech firms, has partnered with entities

[12] https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker
[13] Id.
[14] Id.
[15] *See "Biopharmaceutical Innovators Lead the Charge in Fight Against Covid"*, https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus

to ensure that vaccines, therapeutics, and diagnostics are able to be manufactured and deployed in countries throughout the world.[16] We are seeing how treatments and vaccines will be deployed more efficiently in a collaborative rather than coercive manner, where IP rights are respected and where technology and know-how are negotiated in a collaborative fashion amongst partners for the health and safety of patients.

IV. IP AS A TOOL FOR ECONOMIC RECOVERY IN THE POST-PANDEMIC CONTEXT

Two key characteristics of the biotech industry set it apart and make this sector so vital in meeting the challenges of the pandemic: 1) the innovative capacity of the bioscience sector to address global challenges from human health, to food production and security, to clean energy and sustainability and 2) the bioscience sector's role as a consistent economic stalwart, with a track record of generating high-quality jobs in a range of fields from research to manufacturing and near continuous growth that has acted as a key buffer during prior economic recessions. A robust global IP system is core to this innovation and economic growth.

The biotechnology sector as an innovation and economic driver has never been more important, both for our health and our economic recovery. According to the TEConomy/BIO 2022 Report on the Bioscience Economy[17], the U.S. bioscience industry employs 2.14 million Americans across more than 127,000 U.S. business establishments, with the industry growing its U.S. employment base by 11% since 2018, while the U.S. overall economy shed 1.5% of its jobs base due to steep job losses experienced during the initial pandemic wave and economic shutdowns of 2020. Through indirect and induced effects, the industry supports nearly 8.2 million additional American jobs. The bioscience industry's average wages have also been growing and the sector stands out as a major job generator among knowledge- and technology-driven sectors for the U.S. economy. Our sector's economic impact on the U.S. economy totaled $2.9 trillion dollars in 2021, as measured by overall output.

IP rights not only have supported the innovation to help get us out of this pandemic but will drive economic recovery in the post-pandemic world. A myopic approach to curtailing IP protections in the midst of a pandemic may have significant long-term implications and may hurt the ability of the private sector to contribute to crisis responses in the future.

Sadly, as an example of troubling myopic policymaking that runs counter to public health goals, the World Health Organization (WHO) is entertaining curtailing IP protections in the proposed WHO Pandemic Accord currently under negotiation. More specifically, the WHO is proposing time-bound waivers of IP as a tool to address future pandemics. There is demonstrably no evidence that IP has been a barrier to manufacturing of pandemic response products during the COVID pandemic and a weakening of the IP system globally would not lead to a better pandemic response but rather, with forced compulsory licensing measures, would lead to reduced R&D expenditures and commitment from private sector to contribute innovative solutions.

Threats to the global IP system, such as the recent effort with the WHO Pandemic Accord that go beyond the scope of addressing the current pandemic, create significant challenges for the global biotechnology community to continue raising critical investment capital and frustrate the ability for firms to partner globally and advance scientific R&D efforts with the potential to dramatically improve lives. Ultimately,

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[16] https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus

[17] *The U.S. Bioscience Industry: Fostering Innovation and Driving America's Economy Forward 2022,* TEConomy/BIO, https://www.bio.org/value-bioscience-innovation-growing-jobs-and-improving-quality-life

undermining IP protections abroad will weaken U.S. companies' ability to compete globally, put American jobs and the workers who rely on them at risk, and impede scientific advances from reaching society.

Indeed, the mere discussion of potentially undermining IP protections in multilateral fora have already had a significant impact on the biopharmaceutical sector. Stocks for SME biopharmaceutical companies with COVID-19 related R&D projects, on average, recently performed worse than the average U.S. stock and the average SME biotech not working on COVID-19 related R&D (-73% vs. -55% on average), since February 2021. Ensuring U.S. leadership in the life sciences and as a global leader in future pandemic preparedness requires robust protection of IP assets – the efforts to undermine IP rights at the WTO and, more recently, at the WHO through the Pandemic Accord are a disincentive and compromise U.S. scientific leadership.

V. CONCLUSION

BIO and our members stand ready to serve as a resource to support the USITC's efforts in this investigation. In addition to studying the market dynamics as requested by USTR in its December 16, 2022 letter, we encourage the USITC in its investigation to consider the broader economic consequences of an IP waiver and its impact on U.S. competitiveness and leadership in the life sciences and future pandemic preparedness efforts.

We look forward to providing oral testimony and answering your questions.

ANNEX A

SEPTEMBER 26, 2022 BIO LETTER TO PRESIDENT BIDEN

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.[1]

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.[2] 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

[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/
[2] 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.[3] 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."[4] 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,

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

[3] 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

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

ANNEX B

Covid companies, on average, suffered more than the average stock in the US, and more than the average SME biotech not working on Covid R&D (-73% vs. -55% on average), since Feb 2021.

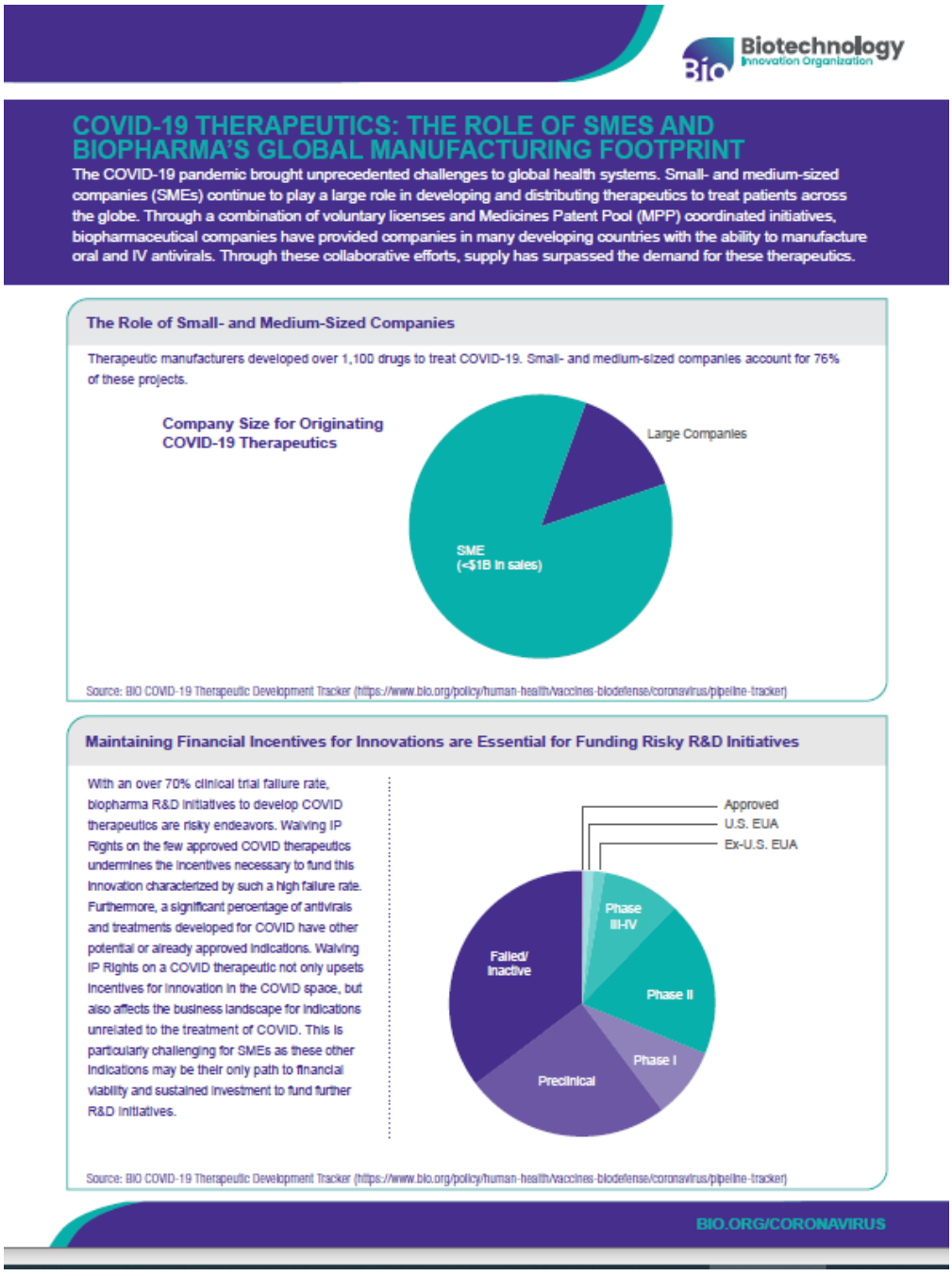
Feb 10th, 2021 - Nov 1, 2022

Type	N	Mean Return
US SMEs working on Covid	98	-73%
US SMEs NOT in Covid R&D	458	-55%

Index	N	Price Return
S&P Biotech (equal wt)	151	-51%
Nasdaq Biotech (Mcap wt)	365	-24%
S&P 500 (Mcap wt)	500	-1%

ANNEX C

COVID-19 Therapeutics: The Role of SMEs, Global Manufacturing Footprint, Supply vs. Demand



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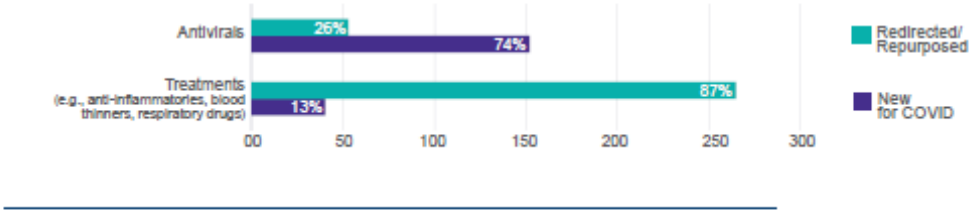
New and Repurposed Treatment Status by Therapy Type

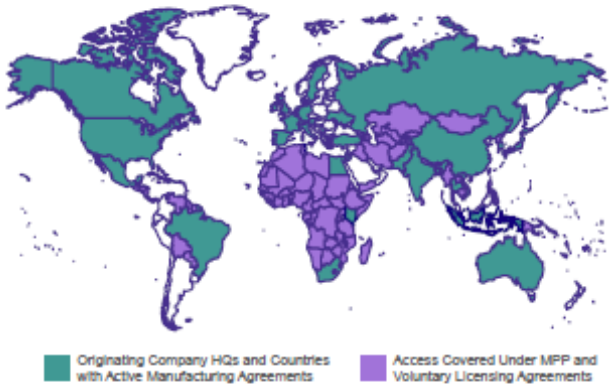


Repurposed: Drugs originally approved for other indications; repurposed for COVID.
Redirected: Drugs not yet approved for other indications; research redirected toward COVID.

Source: BIO COVID-19 Therapeutic Development Tracker (https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker)

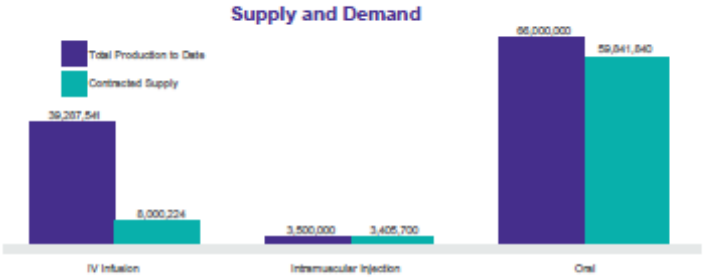
Global Footprint of COVID-19 Therapeutic R&D, Licensing, and Manufacturing Collaborations

Oral antivirals are the highest in demand COVID-19 therapeutics in the developing world. In addition to countries with originating company manufacturers, many developing countries can voluntarily access IP of the two oral antivirals. Both Lagevrio and Paxlovid are available for licensing through the Medicines Patent Pool (MPP). In addition, the IV-administered antiviral, Veklury, has multiple voluntary licensing agreements with manufacturers in Egypt, India, and Pakistan to supply its antiviral to 127 countries.



Supply of Therapeutics Exceeds Demand

Manufacturers are currently supplying therapeutics at a rate that outpaces demand.



Source: Airfinity, September 15, 2022

ANNEX D

Representative, Non-Exhaustive List of Global COVID-19 Therapeutic R&D and Manufacturing Collaborations (updated as of September 2022)

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