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BIOTECHNOLOGY INNOVATION ORGANIZATION

2023 SPECIAL 301 SUBMISSION

I. INTRODUCTION

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to participate in the 2022 Special 301 Review: Identification of Countries under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing. We hope our contribution will assist the United States Trade Representative's (USTR) efforts in strengthening President Biden's Build Back Better agenda by preserving strong intellectual property (IP) protections for United States' innovators, companies and workers internationally.

A. USTR SPECIAL 301 REVIEW: ADVANCING A WORKER CENTRIC TRADE POLICY AND PROPELLING AMERICA'S BIOTECHNOLOGY SECTOR

The annual Special 301 Review presents a key opportunity for the U.S.-based innovative biotechnology research community to share with USTR and the broader U.S. Government interagency stakeholders the main intellectual property (IP) challenges in trading partner countries abroad that harm the competitiveness of our member companies and their workers. The examples provided throughout this submission of the absence of adequate and effective protection of U.S. IP rights serve to illustrate how the ability of U.S.-based biotech enterprises, collectively employing over 2.14 million workers in the United States,[1] that rely heavily on their IP rights to export and operate overseas is frustrated by certain policies put in place by key trading partners.

The immediate impact of the adverse global IP environment detailed in this submission is the denial of equitable market access abroad for our biotech enterprises. This directly harms their ability to innovate, invest and create jobs in the United States. Addressing these immediate concerns are critical and we encourage USTR to prioritize responding to the issues highlighted in the sections that follow.

The deteriorating IP rights scenario globally, punctuated by the ongoing COVID-19 TRIPS Waiver debate, undermines the foundational underpinnings of the biotechnology sector. Beyond the immediate impacts to our members and their workers, the unchecked deterioration of IP rights globally has significant medium- and long-term implications for the broader U.S. private sector and, consequently, for our nation's economic interests.

IP-enabled innovations contribute to the robust strength of the U.S. economy and propel the quintessentially American entrepreneurial spirit, which is the hallmark of the biotech sector, promoting economic development across sectors and leading to inclusive and high-paying jobs for American workers. Strengthening the global policy environment for the commercialization of IP-enabled innovations should, therefore, be a cornerstone of the Build Back Better agenda.

BIO, therefore, strongly urges USTR to take appropriate and proportionate actions including enforcement of existing trade agreements and U.S. trade laws to efficiently remedy the IP issues detailed below with key trading partners and ensure a fair, rule-based system globally that provides market incentives for continued IP-driven innovation. Swift and meaningful engagement on these issues is critical for our member companies' businesses abroad and is an

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

imperative to restore and achieve the important aim of the Special 301 Review.

B. 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 U.S. IP system, 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.

Bioscience industries are delivering improved health outcomes and giving individuals who suffer from medical conditions the hope of living fuller, healthier lives. Innovations made by our member companies are transforming the way we treat patients. Today, many diagnoses that were once devastating can now be cured or treated as a manageable chronic condition. For instance: Hepatitis C, which was once an incurable disease, now has cure rates above 90%; the death rate for cancer has fallen by 22% since its peak in 1991, due in large part to medicines; and HIV/AIDS death rates have decreased 85% since 1995.[2] The rich pipeline of biotech innovation comprising gene and cell therapies and genome editing provide new treatments with the potential to cure once incurable diseases.

In addition to health outcome improvements, significant and meaningful advances have been made in agriculture, food and industrial biotechnology. Advances in bioscience have enabled farmers to more effectively manage harmful pests and diseases thereby increasing crop yields, reducing environmental impacts and making agricultural production more sustainable. Farmers can now grow higher valued consumer-oriented crops, such as non-browning apples and potatoes that reduce food waste and soybeans with a more heart-healthy oil composition. Furthermore, innovations in industrial biotechnology illustrate a shift towards bio-based products is underway that is critical for environmentally sustainable development. These bio-based products are biodegradable and non-polluting and can also be applied to use in environmental remediation to clean up the legacy of our non-sustainable industrial past.[3] Consequently, any U.S. trade policy which seeks to advance the goals of global climate and environmental sustainability should place the promotion of innovation in the bio-based technologies at its core.

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

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[2] "Innovation Saves" *https://www.bio.org/toolkit/infographics/innovation-saves*

[3] *"Growing America's Biobased Economy" https://www.bio.org/toolkit/issue-briefs/growing-america%E2%80%99s-biobased-economy*

globally. Accordingly, we are committed to work constructively towards a global policy environment that provides 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.

The agricultural and pharmaceutical biotechnology industries rely heavily on patents and regulatory data protection for legal certainty needed to attract investments. The development of a single biotechnology product in both of these sectors often takes scientists more than a decade to commercialize, and hundreds of millions (and in the healthcare sector more than a billion) of dollars of capital investment, a significant amount of which comes from private sources.[4]

Biotechnology product development is also fraught with high risk – the vast majority of researched biotech therapies fail to ever reach the marketplace. In addition, while biotech health inventions are entitled to the same patent term as all other inventions − twenty years from the time they are filed – they face the additional hurdle of a rigorous pre-launch regulatory review process during which they may lose between eight to ten years of the patent life. In agricultural biotechnology, following regulatory approvals in cultivating countries such as the United States, the path to market is often delayed due to asynchronous approvals in strategic markets that import U.S. grain, such as Europe, Mexico, and China, thus eroding patent life.

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

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

investors, and commercial banks, indicated patents were an important factor in their investment decisions.[5]

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. IP reforms outside the United States would improve conditions for export of biotech products from the United States and grow American jobs, furthering a worker-centric trade policy embodied in the Build Back Better agenda.

In addition, improvements in IP would benefit foreign countries and support their ambitions to develop innovative ecosystems. An OECD study, for instance, looked at R&D expenditure and technology transfer as well as FDI and found that a 1% change in the strength of a national IP environment (based on a statistical index) is associated with a 2.8% increase in FDI in-flows, a 2% increase in service imports and a 0.7% increase in domestic R&D.[6] Studies show that even developing countries obtain economic benefits from increasing their IP protection.[7] Like in other trade areas, increased standards in IP provide a win-win situation for the United States and other nations around the world.

Through WTO accessions and regional and bilateral trade agreements, the United States and other countries have given effect to and built on the global minimum standards of protection international rules provide. U.S. trade agreements can help to drive and sustain biotechnology innovation by eliminating restrictive patentability criteria, addressing unreasonable patent examination and marketing approval delays, promoting the early and effective resolution of patent disputes and protecting regulatory test data. They have established rules and principles that, if implemented effectively, promote fair, transparent, reasonable and non-discriminatory market access for life science technologies.

Despite these achievements, certain U.S. trading partners maintain or are considering acts, policies or practices that are harming or would harm the ability of biotechnology innovators to research, develop and deliver new treatments and cures for patients and advances in agricultural and industrial biotechnology applications around the world. For example, some of these efforts are aimed at forcing localization of technology through coercive technology transfer schema linked to market approval or reimbursement for innovative biotechnology products. These

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[5] 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

[6] "Building the Bioeconomy", *Supra*, 19-20.

[7] See Cavazos, Ricardo H. & C. Lippoldt, Douglas & Senft, Jonathan, 2010. Policy Complements to the Strengthening of IPRS in Developing Countries; Minyuan Zhao, 2010. "Policy Complements to the Strengthening of IPRS in Developing Countries - China's Intellectual Property Environment: A Firm-Level Perspective," OECD Trade Policy Papers 105, OECD Publishing; ; Lee Branstetter & Kamal Saggi, 2009. "Intellectual Property Rights, Foreign Direct Investment and Industrial Development," Economic Journal, Royal Economic Society, vol. 121(555), pages 1161-1191; Branstetter, Lee & Fisman, Raymond & Fritz Foley, C & Saggi, Kamal, 2007. Intellectual Property Rights, Imitation, and Foreign Direct Investment: Theory and Evidence. 10.3386/w13033.

policies are harmful not only to the biotechnology industry but to the long-term prospects for the country's economic growth in this sector.[8] These acts, policies or practices deny or would deny adequate and effective intellectual property protection and/or fair and equitable market access for innovative biotechnology products. In many cases, they appear to be inconsistent with global, regional, and bilateral rules.

In recent years the biotechnology industry has faced a growing number of efforts within the multilateral system that threaten to undermine future investments and innovation in biotechnology - most significant, the repeated assertion of IP as a barrier to access to medicines and vaccines. While IP and pricing related to new drugs and biologics have long been a source of debate, multilateral institutions are increasingly providing fora to pursue biased work streams that cast innovators and the systems that incentivize innovation as the cause of problems surrounding access to medicines, rather than their actual role as a solution. These work streams simply serve to polarize the issue rather than advance meaningful solutions, because they are not evidence-based and fail to examine the myriad of fundamental challenges that are in fact the cause of limited access – such as poorly functioning healthcare systems, regulatory approval frameworks, supply chains and delivery infrastructure and systems. The debate around a COVID-19 TRIPS Waiver is a painful reminder of this challenging dynamic.

A. 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. In the WTO itself, there has been an extreme proposal to waive IP commitments with respect to technologies related to COVID-19. 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 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

[8] Pugatch, Localization Barriers, http://www.pugatch-consilium.com/reports/Localization%20Paper_us_final.pdf

originated by small and medium sized biotech firms.[9] There are now over a dozen approved vaccines manufactured throughout the world, collectively amounting to over 15.9 billion doses manufactured through 2022.

Furthermore, there are approximately 500 unique COVID-19 antivirals and treatments in development globally to treat COVID-19.[10] Over 50% of the innovation has originated in the United States and of the innovative COVID-19 therapeutics in development, over 86% 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.

The global IP system has facilitated unprecedented levels of collaboration around the world and scientific development in remarkably abbreviated timeframes.[11] 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 technologies have been entered into globally on a voluntary basis. 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 a TRIPS Waiver for vaccines, therapeutics, and diagnostics 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 to ensure that vaccines, therapeutics, and diagnostics are able to be manufactured and deployed in countries throughout the world.[12] 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

[9] https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker
[10] https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker
[11] See "Biopharmaceutical Innovators Lead the Charge in Fight Against Covid", https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus
[12] https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus

the health and safety of patients.

B. 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 and is consistent with a worker-centric U.S. trade policy that prioritizes American workers and jobs.

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/CSBA/BIO 2022 Report on the Bioscience Economy[13], the U.S. bioscience industry employs 2.14 million people across more than 127,000 U.S. business establishments, with the industry growing its employment base by 11% since 2018, while the 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 jobs in the country. 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. It is also a concern to BIO that the WHO is contemplating IP measures which remains a competency of other UN bodies, namely the WTO and the World Intellectual Property Organization. BIO urges USTR and the U.S. Government to encourage the WHO to focus on its core competencies and mission as a global technical authority in public health matters.

[13] *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

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, 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. Accordingly, we strongly encourage USTR to play an active role in these multilateral fora to guide the international community towards constructive solutions that genuinely address real access barriers without compromising the underlying IP legal regime that has enabled life-saving innovation and facilitated hundreds of deep research and manufacturing collaborations around the globe.

III. SYSTEMIC IP CHALLENGES THAT UNDERMINE THE ECOSYSTEM FOR BIOTECHNOLOGY INNOVATION

BIO has surveyed our members asking them to identify relevant IP barriers globally that frustrate their business and R&D operations. We are presenting issues that impact our sector thematically and have chosen to focus our efforts on the issues that we believe should be prioritized by the U.S. government in its trade-related engagements with foreign countries and in its dealings with multilateral organizations.

Our comments below reflect the input of our membership and, through this non-exhaustive list of examples of the IP challenges our members experience abroad, we aim to provide USTR with perspectives that accentuate the impact global IP developments have on the entrepreneurial journey across the spectrum of the life sciences sector and the challenges SME biotechnology firms face as they expand research, collaboration, and commercialization globally.

We are hopeful that through this exercise, we encourage greater collaboration globally in the life sciences for the benefit of all people, while recognizing the important role of the global IP system in enabling cutting edge R&D efforts.

A. COMPULSORY LICENSES

Under the guise of TRIPS flexibilities, non-government organizations and some international organizations are actively encouraging governments to avoid granting IP rights, force biotechnology companies to transfer technology to local companies, or regularly resort to compulsory licenses (CLs) for biopharmaceutical products.

Some governments have issued and several more have threatened to issue CLs that allow local companies to make, use, sell or import patented medicines without the consent of the patent holder. BIO strongly believes governments should grant CLs only in accordance with international rules and as a last resort in exceptional circumstances. Longstanding WTO rules require that decisions should be made on public health emergency grounds through fair and transparent processes that involve participation by all stakeholders and consider all the facts and options, including less harmful but effective alternatives to CLs.

As BIO's membership expands globally, our members are particularly struck by the compulsory licensing threats from middle- to high-income countries such as Argentina, Chile, Colombia, Hungary, India, Indonesia, and Malaysia, some of which are OECD economies or hopefuls.

LACK OF FAIR AND TRANSPARENT PROCESSES WITH THE IP RIGHTSHOLDER

Compulsory licensing decisions are largely avoidable and should be made through a fair and transparent process that involves participation by all stakeholders. Priority should be given to a partnership or mutually accepted resolution with the patent holder. In fact, industry experience clearly demonstrates that collaborative access policies enable significantly better treatment access outcomes.

Nevertheless, one consistent challenge BIO members face when under a threat of compulsory licensing measures is that fact patterns around the world can be characterized by their lack of procedural fairness, due process, dialogue, and transparency.

USE OF COMPULSORY LICENSING THREATS TO ADVANCE INDUSTRIAL POLICY AND FORCE DRUG PRICING NEGOTIATIONS

Using compulsory licensing measures to promote the import, export and/or local production of medicines, at the expense of innovators and manufacturers in the United States and elsewhere, appears to be a key industrial policy strategy for governments around the world and is also in contravention of TRIPS. Some countries, for instance, have provided through their patent legislation broad authority for the issuance of compulsory licenses on the basis that the patent products are not "worked" or manufactured in a specific territory. Accordingly, a compulsory license under these circumstances would be avoided if the IP rightsholder shared its relevant IP with local manufacturers or invested in local manufacturing. The examples below illustrate the uncertainty globally for patent holders and how these provisions may be broadly interpreted and used to initiate compulsory licensing procedures.

In addition to using CLs to advance industrial policy narratives, the threat of a CL has been leveraged to force pricing negotiations with the IP rightsholder. This takes several forms and, in some countries like in Argentina, Chile, and Colombia, there are recently introduced legislation or pending bills that promote the use of compulsory licensing measures precisely for these concerns.

COMPULSORY LICENSING DURING THE COVID-19 PANDEMIC

Even during the COVID-19 pandemic, while BIO members have been dedicating resources to

develop treatments and vaccines, threats to undermine IP have done nothing to advance R&D efforts and have only served as a distraction.[14] BIO recognizes lawful, proportionate, and temporary exercise of government emergency powers is available to respond to genuine emergencies or other extraordinary circumstances that cannot be addressed collaboratively between a government and an IP rightsholder. However, new drugs and vaccines are being developed and brought to patients to address the COVID-19 pandemic with unprecedented speed driven by a collaborative approach that respects IP rights, bolsters access, and leverages their positive impact on innovation rather than through coercive approaches suggested by some policymakers.

Despite industry effort to make medical innovation available urgently, some countries have sought to use CLs as a tool to wrongfully promote local industry to further their national industrial policy objectives during a pandemic even when imports of COVID related products are sufficient to meet patient need.

For instance, a BIO member entered voluntarily into a number of royalty-free agreements with Indian generic drug manufacturers to scale up manufacturing and distribution of a rheumatoid arthritis drug with a restricted emergency use as a COVID-19 therapy. One of the Indian companies had also sought a compulsory license to develop this same drug to treat rheumatoid arthritis, its original indication, and has since begun marketing a generic version of the drug in India and abroad. This unfortunately illustrates how in some cases, including in times of a pandemic, CLs or the threat of CLs may be inappropriately leveraged to further national industrial policy rather than a defined and narrow public health emergency.

B. TECHNOLOGY LOCALIZATION MEASURES AND THEIR IMPACT ON MARKET ACCESS AND PRICING DECISIONS

Forced technology transfer measures, R&D localization policies and local manufacturing or working requirements to maintain the validity of patents held by foreign IP rightsholders are common strategies employed globally to undermine the IP rights system. These policies often create market access barriers for foreign IP rightsholders and, in some cases, also influence pricing decisions, as illustrated below.

TECHNOLOGY LOCALIZATION MEASURES

Technology localization measures present significant challenges to the global innovative biopharmaceutical sector. SME biotech firms are particularly vulnerable to forced localization measures as they lack the resources necessary to manage global operations in their initial push to expand globally and bring their technologies to the world. Regardless of size of the biotech enterprise, forced localization measures add to the costs and complexities to manage, secure, and leverage IP rights globally to drive innovation.

As illustrated above, compulsory licenses may be threatened or issued should a company not localize manufacturing or transfer their IP to a local enterprise. In addition to CL measures, forced localization policies also seek to compel a foreign entity to engage in local manufacturing,

[14] See https://www.bio.org/press-release/proposed-trips-waiver-wrong-way-attack-global-access-vaccines-developing-countries and https://www.bio.org/press-release/support-trips-waiver-sets-dangerous-precedent

local R&D investments, or the transferring of IP to local enterprises in order to ensure market access or to ensure a reasonable price for their innovative technologies. Forced localization measures introduce logistical challenges with respect to locally manufactured products and manufacturing inefficiencies by losing economies of scale to fulfil global demand. The transfer of IP to local entities may compromise the global IP portfolio and create a challenging business dynamic globally that is difficult for biotech firms of all sizes, particularly emerging SME companies, to navigate.

i. R&D Localization Policies Impact Market Access and Drug Pricing Decisions –Japan and South Korea

Under Japan's Price Maintenance Premium (PMP) program, eligible companies must satisfy specific criteria in order to receive the full pricing premium, including requirements on the level of R&D conducted in Japan. Eligible companies that do not meet the requirements would receive a reduced level of the premium. Such policy would not only provide preferential treatment to domestic firms at the expense of foreign ones, but furthermore, it conditions the preferential treatment on R&D localization, as firms will be judged on the number of localized clinical trials. It is particularly concerning that eligible biopharmaceutical firms that are SMEs are expected to be excluded from the full pricing premium under the program, as SMEs typically have a lower level of R&D activities and investments in Japan compared to large drug developers.

The restrictive PMP criteria, which effectively discriminate against SMEs, appear to be contrary to the pro-innovation policies of the Japanese government. SMEs, which constitute the vast majority of BIO's member companies, are a critical innovation force in the biomedical industry. These life sciences start-ups and emerging biotech companies are responsible for 73% of the global clinical pipeline and 85% of all Orphan-designated products in development.[15] As the eligible SMEs lack the necessary resources and pipeline to satisfy the localization requirements, exclusion from the full pricing premium may encourage U.S. based SMEs to out-license early stage drug development and transfer technology and intellectual property to enterprises in Japan in order to ensure their innovative products are appropriately valued.

Similarly, South Korea conditions preferential pricing policies on a number of performance requirements, including, localized manufacturing and local or joint R&D initiatives with domestic firms.

ii. Manufacturing Localization Policies Impact Market Access and Drug Pricing Decisions - Argentina, India, and Turkey

In the previous section, developed economies such as Japan and South Korea are leveraging R&D localization policies to increase early-stage R&D efforts in their countries. In the examples below, BIO presents situations where developing economies, rather than focusing on the localization of early-stage R&D, use localization policies to drive their local manufacturing industries and life science infrastructure.

[15] *2019 Emerging Therapeutic Company Trend Report*, David Thomas and Chad Wessel. BIO Industry Analysis. 2019.

Some countries require local production in order for drugs to be listed in their drug formulary. In Turkey, for instance, the Medical Devices and Medicine Agency and Social Security Institution (TITCK) leads the Turkish Government's industrial policy with respect to the pharmaceutical sector and they have established a number of arbitrary rules for local production, such as delisting imported medicines from the medical reimbursement scheme as a penalty for not meeting local production requirements.

In Argentina, local laws establish up to 15% margins of preference for goods of national origin in public tenders. Law 27.437 establishes that if a foreign company wins a public tender and the purchase of imported goods exceeds a threshold provided for in the Law, a company must sign a productive cooperation agreement committing to acquire local goods and hire local services linked to the object of the tender of up to 20% of its amount, which for the biotechnology sector presents significant challenges.

As aforementioned in the section on Compulsory Licensing, other mechanisms that some countries use to compel technology transfer or local manufacturing is through provisions in their patent laws which would allow for the invalidation of a patent should the invention claimed not be manufactured locally. These "working requirements" have been used in India to issue a compulsory license and to also force IP rightsholders to consider manufacturing the object of their patents in India.

Such draconian measures and discriminatory practices in government procurement systems to compel local manufacturing and forced technology transfer compromises U.S. leadership in the sciences and disincentivizes investment in the sector. These policies also frustrate the ability for biotech firms of all sizes to expand globally and offer their innovative treatments to people around the world that are in need.

iii. Coercive Data Localization and Data Sharing Measures – China, European Union and India

Article 59 of China's Biosecurity Law enacted in October 2020 requires that foreign biotech firms when accessing data related to human genetic resources in China must partner with local Chinese entities in the R&D process and that the Chinese partnering entity must participate substantively in the entire course of research and share in any relevant interests. Similar elements restricting the cross-border data transfers, establishing onerous government oversight when accessing certain types of scientifically relevant data, and requirements to localize data and establish technology partnerships with Chinese entities are also found in the Human Genetic Resources Administrative Regulation (HGR) promulgated in May 2019 and the draft Personal Information Privacy Law.

BIO is concerned that collectively these regulations have an adverse impact on BIO member companies' ability to conduct global biotech research and clinical studies. For instance, in the case of the HGR, the ability to access and obtain data to drive biomedical research that includes Chinese human genetic resources is significantly impinged and subject to violations at the discretion of Chinese regulators. The 2019 HGR Regulation also mandates that an overseas entity must collaborate with a Chinese institution and is required to grant the Chinese partner full access to and complete copies of all records, data and other information in the research process,

regardless of whether the Chinese partner is a collaborating organization or a subcontractor that does not contribute to the research efforts. The provision of concern also requires the foreign entity to include its Chinese partner on any patent applications arising from the results of the collaboration.

These coercive measures requiring local arrangements and partnership do not promote biosecurity, public health, or advance Chinese citizen's privacy rights. They also do not accelerate global R&D efforts but, rather, create challenges to cultivate long-term collaborative scientific relationships and deter global partnerships. In addition, the required approval process under the HGR, Biosecurity Law, the Cybersecurity Law, and the draft Personal Information Privacy Law, adds to the onerous regulatory requirements and undermines the biotech sector's ability to bring innovative vaccines and therapies to global patients in a speedy manner.

Finally, in addition to the examples in China related to coercive data sharing measures, a number of other key markets are proposing similar policies that amount to the forced sharing of data and IP with local entities. For instance, Recommendation 5 of the Report by the Committee of Experts on Non-Personal Data Governance Framework constituted by the Ministry of Electronics and Information Technology of India suggests that certain entities may be compelled to share data and satisfy a third party request for proprietary data if determined by a Non-Personal Data Authority of the Indian Government that such data would confer "social/public/ or economic benefits." Recommendation 5 adds that for "core public interest purposes" data may be requested for "community uses/benefits or public goods, research and innovation." Science and healthcare are expressly listed as core public interest purposes that would, according to this Committee, justify a compelled sharing of data and proprietary information. Beyond the impact on our memberships' ability to conduct meaningful scientific R&D with partners in India, this policy framework could set an international precedent and lead to unintended consequences if other countries follow suit and put in place similar policies.

BIO is also concerned about data sharing provisions in the European Commission's proposed European Health Data Space (EHDS). We commend the European Commission for their efforts to establish a policy framework for health data that supports the delivery of the highest quality of care to patients in the EU and which also aims to promote cutting edge research endeavors in the life sciences. Collectively, these efforts to construct a Health Data Space within the context of the broader European Commission Strategy for Data have the potential to be immensely powerful drivers of public health, economic growth, innovation, and prosperity.

However, preserving a strong IP system should be a priority of the EHDS and provisions on the compelled disclosure of proprietary information in Paragraph 40 of the Whereas clauses, Articles 33 (paragraph 4), Article 34 (paragraph 40) and Article 46 (paragraph 11) present significant concern to BIO membership about the potential to undermine private sector IP protections.

Research partners need to be able to share confidential commercial information over the course of the R&D process in a reliable and secure fashion. For instance, confidential commercial information is often developed and used by real world data providers to generate real world evidence that supports regulatory decision-making – a highly technical process that takes many years. These datasets need to be treated confidentially as proprietary information and need to be protected from data sharing requests until the study results and data become publicly available.

Significant resources and innovation support the curation of data sets, anonymization, and ultimately transformation of data into usable information that accelerate biomedical R&D.

The EHDS framework should provide safeguards to protect the forced disclosure of proprietary information and confidential datasets and should recognize and reinforce the crucial role that IP protections play in driving biomedical innovation.

Navigating these policy frameworks to establish meaningful and long-lasting scientific collaborations will be a complex and time sensitive endeavor for BIO members, particularly our innovative, pre-commercial companies. Obstacles to cross-border scientific collaboration would undermine scientific advancement and, more importantly, does a disservice to the global public health and the development of treatments to benefit all of mankind.

TRADE SECRET MISAPPROPRIATION

Related to the previous section dealing with the forced sharing of data and proprietary information, BIO notes with significant concern the evolving international legal landscape around trade secrets and how countries characterize misappropriation of trade secrets and afford access to legal redress in the event of a misappropriation.

Trade secrets are an increasingly important form of IP that secure proprietary information. Trade secrets are critical for investment and innovation and encourage collaboration between institutions to engage in early-stage research projects. Some policies globally overtly seek to compel disclosure of confidential know-how, such as through the initial COVID-19 TRIPS Waiver proposal. BIO members have noted other more nuanced policies, such as those illustrated in the subsection above, that may covertly lead to the misappropriation of trade secrets through forced data localization and data sharing measures.

Policies aimed at requiring technology localization or some degree of data localization pose threats to the international biotech research community. Such policies lead to situations where confidential proprietary information and know-how may be more susceptible to cybersecurity threats, for instance. Furthermore, a lack of adequate legal recourse in many jurisdictions present challenging situations for biotech companies globally that have identified potential cases of a misappropriation of trade secrets.

BIO encourages USTR to pursue strong trade secret commitments in future bilateral trade agreements, consistent with the Defend Trade Secrets Act and provisions in the USMCA.

MARKET ACCESS BARRIERS AND PRICING POLICIES

Bringing a new biopharmaceutical product through the lengthy research and development phase to commercialization stage is increasingly costly and risky. As independent data consistently shows, these new treatments not only save lives, but also can lower overall health care costs. Unfortunately, longer-term savings and population health and productivity gains are often overlooked for short-term budgetary gains, and the value of biopharmaceutical innovations and their IP are being unreasonably restricted by countries. As indicated in a recent study, price controls devastate the emerging biotech sector by impacting the ability for small and emerging

biotech companies to obtain venture capital funding to support their R&D endeavors.[16]

In particular, BIO is concerned about such practices by developed economies such as Canada, Japan, and South Korea. These developed countries, with strong economies and capacities of their own and high standards of living, should be at the forefront of nations acting responsibly with appropriate valuation and reimbursement to support innovators working to improve health outcomes globally. BIO is concerned with the non-transparent and non-inclusive nature of policy making with respect to pricing and reimbursement for innovative therapies as well as arbitrary and inconsistent approaches to pricing decisions. We welcome meaningful stakeholder engagement to reform Health Technology Assessment (HTA) methodologies so as to enable the prioritization of transformative technologies with the potential to cure severe conditions in targeted patient populations.

In June 2017, Health Canada released a consultation document proposing to change the current mandate of the Patented Medicines Review Board (PMPRB) from ensuring "non-excessive" prices to ensuring "affordable" prices, and to change its pricing regulations accordingly. Subsequently, in August 2019, Canada published the final Patented Medicines Pricing Regulations to come into effect by July 2020. The new regulations are expected to cost the innovative biopharmaceutical industry over $3 billion annually. Amendments include removing the United States and Switzerland from the basket of reference countries and to target OECD median prices.

In addition, the regulation requires patentees to report price and revenues, net of all price adjustments (e.g., confidential rebates). Specifically, the reform requires patentees to report confidential rebate data and contains additional language on the potential use of these data. This provision raises several concerns, including how the PMPRB intends to maintain confidentiality of data, and whether the collection of this data is within PMPRB's jurisdiction under the Patent Act. The disclosure of confidential rebates has been deemed unacceptable through two different court proceedings, both Judicial Review and Constitutional Review of PMPRB's mandates.

Moreover, the regulations include three new economic factors that PMPRB must consider in determining whether prices are excessive: "pharmacoeconomic value"; market size; and GDP measures. For pharmacoeconomic value, PMPRB will use analysis prepared by an existing publicly funded Canadian organization (CADTH) and there would be an obligation on patentees to submit most recent cost-utility analyses, but there would be no obligation on the patentee to prepare a cost-utility analysis if one does not exist. However, no final details on potential cost-effectiveness thresholds are provided. How the PMPRB implements "pharmacoeconomic value" remains a significant source of uncertainty. For market size, it is noted the "Canadian price could be assessed against international prices and prevalence (number of people with the disease) levels in an effort to evaluate the price-volume relationship and establish a reasonable market impact test. Including the size of the market as a factor would also allow the PMPRB to reassess the prices of patented medicines over time." For GDP, it is noted this could "enable the PMPRB

[16] International Reference Pricing under H.R. 3 Would Devastate the Emerging Biotechnology Sector, Leading to 56 Fewer New Medicines Coming to Market Over 10 Years (http://vitaltransformation.com/wp-content/uploads/2020/01/Vital-Trans-HR3-Exec-Summ-11-22-2019-30JAN20.pdf)

to develop market impact tests for medicines that are likely to pose affordability challenges for insurers due to the market size for the medicine."

C. REGULATORY DATA PROTECTION

Regulatory data protection (RDP) complements patents on innovative medicines and agricultural products. By providing temporary protection for the comprehensive package of information biotechnology innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine or of agricultural biotech products for marketing approval, RDP provides critical incentives for investment in new treatments and cures.

RDP is particularly critical for biologic medicines, which may not be adequately protected by patents alone. Derived from living organisms, biologics are very complex and difficult to manufacture. One important distinction from chemically synthesized small molecule products is that follow-on biologics, known as biosimilars, are not identical in molecular structure to an innovator reference product, whereas small molecule, chemically synthesized generic drugs are identical to innovator small molecule products. Thus, it is possible for others to produce a biosimilar of an innovator medicine that may not be covered within the scope of the innovator's patent. For this reason and others, Congress included provisions in the Affordable Care Act providing twelve years of RDP for biologics. This was not an arbitrary number, but rather the result of careful consideration and considerable research on the incentives necessary to ensure biopharmaceutical innovators and the associated global scientific eco-system are able to sustainably pursue groundbreaking biomedical research.

Unfortunately, many U.S. trading partners do not provide adequate, if any, RDP. This is clearly contrary to WTO rules, which require parties to protect regulatory test data against both disclosure and unfair commercial use.

Moving forward, to address the ongoing problems with inadequate regulatory data protection, BIO members urge USTR and other federal agencies to reference in the 2023 Special 301 Report and respond, using all available tools, to some of the specific issues provided in the paragraphs below.

U.S. FTA TRADING PARTNERS WITH INADEQUATE RDP

i. Australia, Chile, Colombia, and Mexico

There are, unfortunately, a number of countries relevant to BIO members' global efforts that do not provide an adequate level of RDP. One would not expect, however, that OECD member countries that have Free Trade Agreements (FTAs) with the U.S. containing RDP provisions do not have sufficient RDP in their countries. Nevertheless, this is precisely the case in Australia, Chile, Colombia, and Mexico.

Australia does not provide additional regulatory data protection relating to the registration of new formulations, combinations, indications, or dosage forms of currently registered therapeutic goods. Indeed, the absence of any such protection is in direct contravention of Australia's obligations under art 17.10(2) of the U.S. – Australia Free Trade Agreement

(AUSFTA), which mandates that the Parties provide at least three years of RDP protection from the date of marketing approval in circumstances where new clinical information must be submitted to obtain regulatory approval of the relevant new therapeutic good (other than information relating to bioequivalence). In addition, Australia only provides five years RDP for biological products, the same period provided for small molecule medicines, which for reasons mentioned above we believe is inadequate given how different biologics are compared to traditional, small molecule therapeutics.

In contrast, in 2014, amendments to the Agricultural and Veterinary Chemicals Code Act 1994 became effective increasing the provision of data exclusivity for various categories of veterinary chemicals to 10 years. For the first time this includes those benefitting companion animals --- for which data exclusivity increased by 10 years (up from zero). The debate on that Bill recognized that '… these measures ensure that innovators can obtain a fair return on their research investment.' BIO encourages that data exclusivity protections applied to medicines for humans should receive the same protections as those for veterinary products.

Chile also does not provide adequate protection of data that is required for submission in support of applications for marketing authorization for biopharmaceuticals consistent with its obligations under Article 17.10.1 of the U.S.-Chile FTA. Further, Chile does not provide data protection for biological medicines as required under the same Article of the FTA and as required under TRIPS. Chile, like Australia, does provide data protection for new *chemical* entities for five years. However, for small molecules, the Chilean laws undermine this protection by placing onerous conditions on the availability of this protection. They also provide that such protection may be revoked for a broad range of poorly defined grounds, including "reasons of public health, national security, [and] public non-commercial use," among other circumstances. Although to date it has rarely been invoked, such laws create uncertainty with respect to data protection and patent enforcement that are not consistent with Chile's obligations under their U.S. FTA.

In addition, while Colombia offers a five-year RDP term, this is often not fully implemented or enforced consistently. Moreover, the Colombian health agency INVIMA applies narrow interpretations to recognize new chemical entities. For instance, new molecules that have some "structural similarity" or "analogy" with active ingredients of medicines already approved in Colombia are not recognized as new chemical entities, because they are analogues of molecules already known and marketed in Colombia. On these questionable grounds, Colombian authorities seldom grant any RDP. BIO encourages USTR to revisit this issue and ensure Colombian implementation of RDP for small molecules and biologics.

Finally, Mexico continues to inadequately implement its obligations relating to test data required by regulatory agencies to obtain marketing approval for pharmaceuticals. Mexico has obligations to provide protection for pharmaceutical test data against unfair commercial use under the U.S.-Mexico-Canada Agreement (USMCA) Article 20.48 1(b) and, previous to USMCA, under North American Free Trade Agreement (NAFTA) Article 1711 section 6 for a period of at least five years after marketing approval. Despite these commitments embodied in an FTA with the U.S., Mexico does not provide protection consistent with these obligations. The Industrial Property Law states that Mexican law will implement requirements under its various international obligations; however, we are not aware of any implementing regulations or practices that provide for a minimum five-year term of non-reliance consistent with Mexico's international obligations.

BIO would like to stress the importance of seeking a high standard of RDP in future trade negotiations and supporting American innovators through the enforcement of existing standards, such as the importance of Mexico implementing the minimum USMCA obligations that include five years of RDP for biologics. Moving forward, to address the ongoing problems with inadequate regulatory data protection, BIO members urge USTR to enforce RDP provisions with Mexico and ensure RDP for biologics.

OTHER KEY TRADING PARTNERS WITH INADEQUATE RDP REGIMES

i. No RDP for Biopharmaceuticals or Agricultural Biotech – Argentina and Brazil

Most countries have some degree of RDP for biotech products. Argentina and Brazil, however, are two key trading partners and important countries for agricultural and pharmaceutical biotech that fail to provide any level of RDP for innovative biotech products. In Argentina, Law 24,766 and Decree 150/92 permits the regulatory body ANMAT to indirectly rely on innovator's data to approve other similar or identical products as soon as the innovator product is itself approved. The companies which introduce other similar products in Argentina may also rely indirectly on marketing approval of an innovative product in other countries or in Argentina to support their Argentine filing. Similarly, in Brazil, Law 10.603/2002 establishes data protection for veterinary, fertilizer, agrochemical products but does not provide similar protection for biopharmaceutical or agricultural biotechnology products.

As illustrated in the examples below, even in countries that have some degree of RDP for biotechnology products, the ability for the global innovative biotechnology sector to benefit from meaningful regulatory data protection may prove to be quite difficult from a practical standpoint due to arbitrary rules establishing how entities qualify for RDP.

ii. No Legislated RDP – Japan

While Japan's system has the effect of providing protection that is similar to eight years of regulatory data protection, it has not formally established such protection through legislation. Establishing a high standard RDP system in law would help create more certainty and predictability for innovators, which would encourage more meaningful scientific collaboration between U.S. based biotech enterprises with Japanese counterparts.

iii. Inadequate Implementation of RDP Provisions – China and Malaysia

The previous sections illustrated situations in which there is either no legislated or no effective RDP for biopharmaceuticals or agricultural biotech products. The following examples demonstrate how local laws in several countries may provide for some degree of RDP for biotechnology products, however, due to a number of factors effective RDP term for foreign IP rightsholders may be limited or undermined by certain policies.

For example, Malaysia's policy on data exclusivity severely limits the protection afforded to biopharmaceutical originator's proprietary data submitted to the Ministry of Health. In particular, BIO is concerned that Malaysia's data exclusivity guidelines effectively exclude data protection for biological products. Under Malaysia's regulatory data protection regime, the Ministry of

Health restricts eligibility of originators to receive data protection by requiring originators to submit the new drug application within eighteen months from the date the product is first registered or granted marketing authorization globally. For new indications, the time limit to apply is only twelve months. Such an arbitrary time limit for seeking marketing approval in order to qualify for data protection unfairly discriminates against smaller and medium-sized biotech firms that may not have the resources or the expertise in global marketing of products. Furthermore, companies may have a valid reason to postpone launch in the Malaysian market, such as additional testing for safety concerns due to adverse events in another market.

Malaysia's policy on data exclusivity unreasonably curtails the protection period of regulatory data by starting the clock of the protection period from the date the product is first registered or approved and granted data exclusivity in the country of origin. Thus, the only instance in which an innovator can receive the full five years of RDP in Malaysia is if they seek marketing approval in Malaysia first. Furthermore, BIO is concerned with the lack of transparency, due process, and stakeholder consultation in the Ministry of Health's decision to deny regulatory data protection to originators. Even where the strict criterion laid-out by the government is met, and the government should be therefore granting data exclusivity under its own policy, there is no certainty that the government will in fact grant RDP. Companies have recently reported government denial of RDP based on the summary conclusion that denial of such protection would "improve access to medicine for the interest of public health".

No foreign drug products have effectively received data exclusivity from China, and biological products are expressly excluded from the system. This is despite a commitment made over twenty years ago when joining the WTO. China has proposed a series of reforms to establish a reasonable RDP period for biologics and small molecule drugs; however, little progress has been made. Moreover, the proposal would condition the terms of IP protection based on number of locally conducted clinical trials, as well as requiring foreign companies to launch the innovative product first, or simultaneously, in China – which could potentially delay the introduction of new therapies in other jurisdictions. Reforms that establish effective periods of RDP for all pharmaceutical products without these conditions are critical.

In line with international best practice, RDP should be granted for any new product that is "new" to China, not "new" to the world. China is the second largest pharmaceutical market in the world, and BIO member companies are incentivized to seek marketing approval promptly in China without the need for onerous regulatory requirements. Moreover, as noted, imposing an arbitrary window for seeking marketing approval in order to qualify for full RDP could have negative effects. For example, some companies may have an important reason for delaying entry into the China market, such as a need to conduct additional testing to address safety concerns due to an adverse event in another market. Furthermore, emerging biomedical SMEs may not have either the resources or the expertise in global marketing of products to meet the RDP requirement.

BIO member companies invest significant resources to develop research data to prove the safety, efficacy, and quality of originator products. The lack of adequate regulatory data protection regimes in key countries undermines the competitiveness of biomedical innovators in the United States and elsewhere by allowing other firms to rely on originator-generated data to obtain market approval. As we see in these previous examples, U.S. and other foreign biotech firms,

particularly SME biotech enterprises, qualify for little to no effective RDP with key trading partner countries.

D. PATENT ACQUISITION OBSTACLES

In this section, we present obstacles BIO members face globally to obtain meaningful patents abroad. The challenges described below have practical and immediate impacts on the ability for our members to collaborate globally and efficiently advance their R&D efforts to bring innovation to people in need around the world. The lack of clarity, for example, around a patent portfolio may delay collaborations with researchers in other jurisdictions, may affect the ability to raise capital and drive R&D efforts, and may affect how biotech firms expand globally to deliver their technologies to farmers and patients around the world.

As aforementioned, our SME biotech firms investing in R&D efforts at the cutting edge of biotechnology are primarily pre-commercial and, thus, rely heavily on their IP portfolio as one of their key assets. Challenges to secure patents abroad frustrate the entrepreneurial journey and add to the risks of an already complex endeavor to invest in biotech research.

Some of the issues to be explored below relate to administrative delays and patent backlogs, unreasonable data supplementation rules and patent specification requirements, and highly restrictive patentability criteria.

RESTRICTIVE PATENTABILITY CRITERIA

To transform valuable new innovations into products that people can use, innovators must be able to secure patents on all inventions that meet the basic TRIPS requirements of being new, involve an inventive step and are capable of industrial application. National laws, regulations or judicial decisions that prohibit patents on certain types of inventions or impose additional or heightened patentability criteria prevent innovators from building on prior knowledge to develop valuable new and improved technologies. Some of the most serious examples of restrictive patentability criteria challenges facing BIO members in countries around the world include Argentina, Brazil, Chile, Colombia, China, and India.

i. Restrictive Subject Matter Eligibility – Argentina, China, Colombia, India

Argentina has one of the most restrictive regimes for obtaining biopharmaceutical and agricultural biotechnology patents in the world.

Regulation 73/2013, Joint Regulations 118, 546, 107 of 2012, and Regulation 283/2015 collectively restrict as patent eligible subject matter most innovations that are essential across all biotech sectors. Under the guidelines, for example, pharmaceutical patents are not granted for inventions to formulations, salts, polymorphs, combination products, active metabolites and pro-drugs, enantiomers, species selection of a genus of compounds and others. These inventions represent around 80% of all pharmaceutical innovations.

Furthermore, Regulation 283/2015 imposes additional patentability criteria beyond those of demonstrating novelty, inventive step and industrial application for biotechnology inventions. This Regulation is also discriminatory and not in line with international norms. BIO strongly

encourages Argentina to respect international standards for novelty, inventive step and industrial applicability and abrogate the internal regulations that establish new patentability criteria that has no support in TRIPS, the Patent Law and its Regulating Decree.

Argentina is also one of the few remaining trading partners with the US that has still not become a member of the Patent Cooperation Treaty (PCT). Implementing this widely accepted agreement would be a positive step toward reducing unnecessary expenses and facilitating the procurement of patent applications not only for BIO's members but also for local inventors.

Andean Community Decision 486, which applies in Colombia, denies patents to inventions of "biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing." The Andean Decision excludes the patenting of use claims as well. In addition, application of Decision 486 denies BIO's members protection in Colombia for inventions in chemical polymorphs and isolates that are commonly patented in other jurisdictions.

With respect to more advanced biotechnology patent applications, BIO sees restrictive patentability requirements that limit the extent to which protection may be afforded. For instance, the Chinese Patent Office, the China National Intellectual Property Administration (CNIPA), does not consider the use of percent identity or hybridization conditions unless they are specifically used in the working examples in the patent specification. As a result, bio-informatics methods of defining sequence scope deemed acceptable in the patent systems of many countries are not recognized in China. This difference is problematic as biotech research is expensive and developing the number of working examples necessary to cover all embodiments may not be possible. In addition, therapeutic treatment method patent claims (e.g., new dosage regimens and new administration routes) are not allowed in China regardless of any claim type formatting. Therapeutic treatment methods are generally acceptable in most major jurisdictions. BIO urges China to consider harmonizing its approach to these issues more closely to that taken by other major countries.

Finally, in India, Section 3(d) of the Indian Patents Act explicitly excludes from patentability new forms of a known substance that does not result in "enhancement of the known efficacy of that substance." This requirement, interpreted by India's Supreme Court to mean "therapeutic efficacy," excludes from patentability many significant inventions in the biopharmaceuticals area, such as new forms of known substances with improved heat stability for tropical climates, or having safety or other benefits to patients that may not result in "enhanced clinical efficacy" per se. This provision appears to be inconsistent with India's obligations pursuant to Article 27 of the TRIPS Agreement, which requires that patents be made available to "any inventions … in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application." Further, Section 3(d) effectively creates an additional hurdle to patentability that is applied only to certain biopharmaceutical products, and therefore appears to violate the non-discrimination clause with respect to field of technology set forth in TRIPS Article 27. BIO members have seen other countries attempt to incorporate this doctrine in their IP law, such as Indonesia, which effectively amounts to a fourth substantive hurdle to patentability for biopharmaceuticals with no justification in international law.

ii. Lack of Adequate IP Protections for Plants – Argentina, Brazil, Chile, China, and India

The Argentine, Brazilian and Chilean patent laws exclude transgenic plants and animals from patent protection, thereby limiting the availability of meaningful protection for valuable biotech innovations in key agricultural producing markets and trading partners of the United States.

China has a plant variety protection (PVP) law in force, and its patent law excludes patent protection for plant varieties. Guidelines issued by the Chinese Patent Office, CNIPA, however have broadened the patent exclusion to any animal and any plant claimed in generic terms (i.e. beyond plant varieties). As a consequence, the CNIPA has created a significant gap in intellectual property protection for inventions in the field of agriculture. Innovators of plant-based inventions cannot obtain adequate protection for their inventions either with patents ("plants" broadly excluded from the Guidelines) or from PVP (only applicable to plant varieties). Amending the CNIPA Guidelines by limiting the patent exclusion to "plant varieties" instead of "plants" (and "animal races" instead of "animals") should remove this gap in protection for agriculture innovations.

India adopted a plant variety protection (PVP) in 2005 but, as in China, excludes patent protection for plants. Therefore innovators of plant-based inventions cannot obtain adequate protection for their inventions either with patents ("plants" broadly excluded) or from PVP (only applicable to plant varieties but not all crops). Amending Section 3(j) of the Patent Act by limiting its exclusion to "plant varieties" instead of "plants" (and "animal races" instead of "animals") should, as we have suggested in the case of the Chinese Patent Office's Guidelines, positively remove this gap in protection for agriculture innovations.

PATENT BACKLOG AND OTHER ADMINISTRATIVE BURDENS

Long patent examination and approval backlogs harm domestic and overseas inventors in every economic sector. Backlogs undermine incentives to innovate across sectors and prevent timely patient access to valuable new treatments and cures while also contributing to delay in introduction of new agricultural innovations. Because the term of a patent begins on the date an application is filed, unreasonable delays can directly reduce the value of granted patents and undermine investment in future research. For biopharmaceutical companies, patent backlogs can postpone the introduction of new medicines. They create legal uncertainty, for research-based and generic companies alike, and can increase the time and cost associated with bringing a new treatment to market. Brazil and India are countries with persistent patent backlog problems and other administrative challenges that delay the issuance of patents.

Another concern involves extensive delays in examination that sometimes occur because of opposition procedures. Companies often wait for years for a patent application to enter the examination process only to have the claims opposed in a pre-grant proceeding. The additional delay in the process results in applications being held up indefinitely, resulting in the loss of the majority of the effective patent term. Companies have also reported delays in the post-grant opposition proceedings, waiting years for a decision. The existence of both pre- and post-grant opposition proceedings – as they are currently applied - create problems as a U.S. company that

survives a pre-grant opposition proceeding can then later face a post-grant proceeding from the same opponent.

This has led to many frivolous multiple pre-grant oppositions being filed by third parties or individuals, many of such frivolous pre-grant oppositions being filed just near the prosecution hearing proceedings or before the grant of patent or near the issuance of Examination Report. This had led to significant delay in grant of patent and can be considered a delaying tactic by third parties.

The Indian generic industry routinely uses this opposition process to delay the grant of U.S. biotechnology patents to produce their own legal copies of products that otherwise should be enjoying meaningful patent protection in India as they do in other countries. Patent term extensions to compensate for such losses do not exist in India, further exacerbating the problem.

Due to the broad nature of post-grant challenges, unlimited pre-grant opposition should be curtailed to better reflect international practice. Unlike in the United States, any person may challenge a patent application in India at any time before a patent is granted. This has allowed parties with political, ideological, and other non-technical opposition to patent applications to unduly delay the process by raising numerous pre-grant challenges. These challenges increase costs and unnecessarily complicate the ability obtain a patent in India.

DATA SUPPLEMENTATION REQUIREMENTS IN PATENT SPECIFICATIONS

Data supplementation refers to the submission of affidavits, declarations, or experimental data following the original filing of a patent application. At the time of filing, the benefits of the invention may not be fully delineated and patent offices around the world are increasingly challenging patents based on insufficient disclosure of inventions needed to substantiate claims.

Similarly, patent offices around the world are also requiring applicants disclose genetic resource information in their patent applications with proof that the acquisition of those resources was done in accordance with relevant laws and administrative regulations. Should a patent applicant fail to provide adequate information at the time of filing, a patent office could reject the patent application on formal grounds prior to any substantive examination and may lead to the revocation of those patents that have already been granted.

i. China's Implementation of the Phase One Agreement regarding Data Supplementation

The Chinese Patent Office, CNIPA, issued in December 2020 draft amendments to the Patent Examination Guidelines to address data supplementation concerns to meet China's obligations under Article 1.10.1 of the Phase One Agreement, which provides that "China shall permit pharmaceutical patent applicants to rely on supplemental data to satisfy requirements for patentability, including sufficiency of disclosure and inventive step." The Amendments, which took effect in January 2021, address some concerns around the examination of supplementary data for meeting the requirement of sufficient disclosure; however, there are still several issues around how data supplementation rules will be implemented. BIO encourages USTR to monitor developments to ensure China upholds commitments from the Phase One Agreement.

Our companies have reported that CNIPA has imposed inappropriate limitations on the use of post-filing data to satisfy inventive step requirements under Article 26.3 of China's Patent Law in the past. While the commitments from the Phase One Agreement are an important step forward, BIO members are concerned that post-filing data may still not consistently be considered in connection with inventive step or other issues associated with the adequacy of a patent application's disclosure.

BIO hopes that this commitment to allow for data supplementation in patent applications will be implemented in such a way that supplemental data can be relied upon to successfully respond to an examiner's rejection based on adequacy of the applications to meet disclosure requirements such as industrial utility and enablement. BIO further urges USTR and other U.S. agencies to work with China to ensure effective implementation of rules related to consideration of supplemental data.

ii. Burdensome Data Requirements in U.S. FTA Trading Partners - South Korea

South Korea's overly burdensome data requirement for patent applications continues to be of concern to BIO and our member companies. BIO strongly urges the Government of South Korea to modify its rules of practice to allow companies to supplement the data contained in original patent applications during patent prosecution and post-grant validity challenge proceedings, as is allowed in most other countries.

For example, the extreme pharmacological data requirement in Korea creates unfair, discriminatory obstacles for innovative biopharmaceutical companies. Moreover, almost all other countries' patent offices do not require that amount of pharmacological data in the original application, or those offices allow submission of such data during patent prosecution. Consequently, many biopharmaceutical inventions that are patentable in other countries are not patentable in South Korea for failure to meet South Korea's data requirement.

Another problematic aspect of South Korea's data requirement is related to prior art references. During the original patent prosecution or in post-issue invalidation proceedings, if a prior art reference is cited against the application or patent in making an obviousness argument, for a general compound invention, the applicant/patent owner can submit any comparison data, or any other data, between the invention that is the subject of the patent and the compounds in the prior art reference in order to rebut the obviousness argument, as long as the effect supported by the data is described in or can be inferred from the specification.

However, for a selection invention (i.e., a species compound selected from known genus compounds for a qualitatively distinct or qualitatively the same, but quantitatively superior effect), comparative data cannot be submitted if the claimed species compound has a qualitatively same, but quantitatively superior effect over the prior art compound, and the original specification does not clearly describe such superior effect in a quantitative manner (e.g., the claimed compound provides three times higher efficacy than the compound of the prior art). This means that unless the patent applicant provides comparison data in the original patent application to essentially every single reasonably close prior art compound, which in many cases is a practical impossibility, it is unlikely that the patent will issue in South Korea or, if the patent issues, survive a post-grant validity attack.

BIO recognizes that the South Korean Supreme Court rendered a decision in April of 2021 that selection invention should be reviewed under the same general inventiveness criteria as all other inventions and we, therefore, encourage the Patent Office's practice in reviewing such patent applications to reflect the Supreme Court's recent decision.

iii. Genetic Resource Disclosure Requirements – China, Colombia, India, and Indonesia

In China, Article 26 of the Patent Law requires patent applicants to indicate the "direct source" and the "original source" of genetic resources if the completion of the claimed invention relies on an access to genetic resources. These provisions are intended to implement provisions of the Convention on Biological Diversity (CBD) relating to access to genetic resources and equitable sharing of benefits from utilization of these resources. These special disclosure requirements are ambiguous and as a result impose unreasonable burdens on patent applicants, subjecting valuable patent rights to great uncertainty. Moreover, the Implementing Regulations define "genetic resource" to include "material from the human body." This goes beyond the scope of the CBD, which excludes human genetic resources; however, including human genetic resources makes the disclosure obligations in China of even greater concern to BIO members. Provisions in the Patent Law could, therefore, prevent the issuance of patents for new and useful biotechnology inventions, or perhaps the revocation of granted patents later found to not fully comply with these provisions. Thus, BIO suggests that these requirements should be deleted.

More recently, the Second Draft of Amendments to the Patent Examination Guidelines Following the Amended Patent Law in China from December 2022 contains troubling new provisions that further links compliance with the Biosecurity Law and Human Genetic Resource Regulation to patent eligibility. This newly proposed requirement will generate confusion about when the use of certain data from clinical trials in China might affect a patentability assessment, especially considering the ambiguities and inconsistent implementation of the HGR. This creates significant uncertainty for BIO's members operating in China and creates additional, unreasonable hurdles for foreign biotech firms to obtain patent rights in China.

Similarly, India's Patents Act requires applicants to disclose the source and geographical origin of biological materials used to make an invention that is the subject of a patent application. Failure to correctly identify the geographical source of a biological material can result in revocation proceedings. These special disclosure requirements and the scope of what constitutes a genetic resource are at best ambiguous, subjecting the validity of valuable patent rights to damaging uncertainty.

Separately, Indonesian Patent Law requires disclosure of the origin of genetic resources or traditional knowledge "related" to inventions. In addition, while a new ministerial regulation issued in 2020 provides clearer guidelines and flexibility for overseas material transfers, the approval and monitoring process remain rigid. These requirements introduce uncertainties into the patent system that inhibit innovation in relevant technologies and undermine the potential of benefit-sharing. The current proposed amendments to the Patent Law do not adequately address this concern and BIO, therefore, suggests the elimination of these disclosure requirements.

As a final example, Andean Decision 486, which applies in Colombia, requires that patent applications include requirements relating to the acquisition or use of genetic resources if the

relevant inventions "were obtained or developed from" genetic resources originating in one of the Andean Community countries (Bolivia, Peru, Ecuador, or Colombia). It similarly applies to inventions derived from traditional knowledge originating in the Andean Community.

PATENT TERM ADJUSTMENT AND PATENT TERM EXTENSION

Patent Term Adjustment (PTA) is designed to restore a portion of the patent term for unreasonable delays by the governmental agency during examination of a patent application, including any period of reexamination and any appeal filed against the decision of the patent reexamination board that may occur during the pendency of the patent application.

Patent Term Extension (PTE) is designed to restore a portion of the patent term lost to clinical development and pre-market regulatory review of a biopharmaceutical or agricultural biotech product. PTA and PTE both help patentees restore the effective term of eligible patents, and PTE, is a critical measure for preserving the economic incentives for developing innovative therapeutic products.

i. China's Implementation of PTA/PTE Commitments from the Phase One Agreement

China's amended Patent Law became effective on June 1, 2021. In line with commitments made in the Phase One Agreement, Article 42.3 of the amended legislation allows for PTE for new pharmaceutical-related inventions which have been approved for marketing in China. We believe, however, that certain aspects of these proposed amendments need to be revised and clarified to both bring the provisions in line with the Phase One Agreement's requirements under Article 1.12 and to ensure that the PTA and PTE mechanisms encourage innovation, particularly with respect to the development of biotherapeutic products.

In particular, detailed implementing regulations that are consistent with commitments made in the Phase One Agreement will be necessary to define how PTA and PTE will be determined and calculated in order to ensure that the PTA and PTE mechanisms will function as intended. In August 2021, CNIPA issued the draft Amendments to the Patent Examination Guideline, which limits PTE eligibility to innovative or improved new drugs first launched in China. This overly restrictive scope of PTE is inconsistent with international standards, and if promulgated in its current form, would discriminate against all innovative pharmaceutical products first introduced in the United States or other markets. The December 2022 Second Draft of Amendments to the Patent Examination Guidelines continues to contain ambiguities on this point and thus it remains a concern to BIO members. A "new to the world" approach would be inconsistent with the Phase One Agreement, PTE should be available for drugs or improvements that are new to China.

ii. Inadequate Patent Term Restoration with U.S. FTA Partner Countries – Canada, Chile, Singapore, and South Korea

In South Korea, BIO member companies report due process concerns in PTA and PTE procedures. For example, if the Patent Office determines a certain duration of PTA and PTE that is less than the full amount requested by the patentee, and the patentee challenges that determination and subsequently loses the challenge, no PTA and PTE is granted despite the fact that Patent Office had itself determined that some level of PTA and PTE was justified. This "all-or-nothing approach" significantly undermines a patentee's right to appeal, effectively deterring

appeals of erroneous calculations. In addition to the due process concerns, the scope of PTE is narrow. For example, the PTE calculation should include all relevant essential clinical trials. Collectively, these practices add uncertainty to IP protections for both innovators and generic manufacturers and are inconsistent with Korea's obligations under the FTA.

Chile's patent laws also do not provide sufficient patent term restoration, consistent with obligations under the FTA, to fully compensate for unwarranted delays in the marketing approvals process. Chile has established a system where requests for extension must be filed within six months of the approval and no additional term is available unless the marketing approval process lasts more than 1 year. The procedure itself lasts around nine months from the filing of the extension request to the final ruling by the Industrial Property Court, creating further delay in extending patent terms.

Singapore's existing PTE regime only covers the delay caused by the administrative regulatory approval process and does not include the delay caused by clinical trials. The PTE regime is capped at two years, which is seldom passed, effectively resulting in no awarded PTE. Similar regimes have been copied by other trading partners, including New Zealand, undermining commitments to ensure meaningful PTE.

Finally, the EU-Canada Comprehensive Trade Agreement (CETA) provides for several reforms to Canada's Patent Act that have had important implications for the biopharmaceutical industry including the introduction of patent term restoration via Certificates of Supplementary Protection (CSP), as well as changes to Canada's patent linkage regime.

The changes negotiated in the CETA text applicable to the biopharmaceutical industry were intended to elevate Canadian IP standards closer to those of the EU; however, BIO is concerned that the implementation enacted in the CETA regulations has not achieved this objective.

For example, there are two main limitations with CSPs, namely: CSPs only allow for a maximum two-year period rather than a five-year maximum and BIO members need to apply for regulatory approval in Canada within one year of other major jurisdictions in order to obtain any CSP at all. In addition, CSPs are also subject to an "export" exception that means they do not provide a level of protection commensurate with the protection afforded by the patent on which they are based. Furthermore, the export exception provisions do not contain safeguards, such as notification provisions, to help innovators ensure that the terms of the permitted exceptions are respected. BIO will continue to urge Canada to amend its CETA implementation in ways that improve Canada's IP environment for biotechnology innovators and seek support from the United States in that effort.

iii. Supplementary Protection Certificates in the EU

BIO members' concerns with the ongoing Incentives Review process have been heightened in light of recent EU legislation in 2019 that weakens Supplementary Protection Certificates (SPC). The adopted exemption to SPC rights[17] frustrates the fundamental purpose of these rights, i.e., to compensate innovators for lost standard patent term that results from costly and lengthy

[17] Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products. http://data.europa.eu/eli/reg/2019/933/oj

development and regulatory approval timelines. As stated in the SPC Regulation, "[m]edicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favorable rules that provide for sufficient protection to encourage such research."[18]

The current EU intellectual property rights-based incentives framework, including full SPC protection and orphan medicines, has fostered a robust ecosystem of innovation and generic competition within Europe. The adoption of the proposal for a manufacturing waiver during the SPC term undermines the rights-based framework that has and is making new healthcare solutions available.

In addition to changes to the SPC regime, BIO remains concerned about potential changes to IP incentives in Europe that would reduce incentives associated with the development of orphan and pediatric medicinal products. BIO and its member companies are very concerned that the continuing Incentives Review could further weaken existing incentive mechanisms that support biopharmaceutical innovation. In fact, the recent Inception Impact Assessment on Medicines for Rare Diseases and Children[19] from the European Commission identifies four concrete options to modify such incentives – yet all appear to envision weakening, rather than safeguarding or enhancing the innovation environment in Europe. Failure to effectively safeguard these incentives in one of the world's largest markets for innovative medicines would harm American companies developing new treatments and cures for these under-served patient populations in Europe and around the world. Furthermore, any changes that adversely affect investment and innovative output are unlikely to address any affordability or access issues among the EU Member States. Such issues are often dependent on factors related to the diversity of healthcare systems across the EU, such as different reimbursement processes, bureaucratic timelines and regulatory hurdles. Jeopardizing the existing EU legislation by reducing the incentives in place will not help solve such concerns. The EU Orphan Regulations has already been proven successful since its adoption in 2000 with increased investments in R&D for rare diseases and subsequent approvals of orphan medicines. Rather than fixing what is not broken, policymakers should explore areas for reform where targeted incentives can address unmet needs, which remain high in the area of rare diseases.

Furthermore, we note with concerns plans by the European Commission announced in the Pharmaceutical strategy to include conditionalities of incentives "to support broader access for patients".[20] This means that a company's IP would be reduced (or eliminated) if its product is not made available in most/all EU markets within a certain period. This approach assumes that it is up to pharmaceutical companies when and where their drugs are launched. However, in a context of price controls, there are a number of reasons determining patient access to medicines, such as the level of regulatory requirements, differences in medical practices, the speed of pricing and reimbursement negotiations, the ability to achieve an adequate price acceptable for both payers and industry, the level of health expenditures (and general wealth), external reference pricing, or

[18] Council (EC) Regulation No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products; *see also* Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (no longer in force).

[19] The Inception Impact Assessment is available here: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12767-revision-of-the-EU-legislation-on-medicines-for-children-and-rare-diseases.

[20] https://eur-lex.europa.eu/legal-content/en/txt/pdf/?uri=celex:52020dc0761&from=EN, p.6

the requirement to see a product reimbursed in other markets (as is mandated by law in some markets). Most of these elements are outside of the hands of companies: this is why the Commission's plans to link IP incentives to actual launches seems to be both disproportionate and ineffective.

Thus, BIO urges the U.S. Government to work with the EU to reconsider the implementation of the SPC waiver and to safeguard and enhance, rather than weaken, the incentives for innovators to bring new therapies to patients suffering from orphan and pediatric diseases.

E. PATENT ENFORCEMENT CHALLENGES

EARLY RESOLUTION MECHANISMS FOR PATENT DISPUTES

A mechanism that allows for effective early resolution of disputes concerning patents of innovative drugs benefits both the innovator and follow-on manufacturers by creating clear rules for resolving costly patent disputes in an efficient manner. It also contributes to improving patent enforcement by ensuring a particular jurisdiction's regulatory agency does not inadvertently contribute to the infringement of patent rights.

i. China's Implementation of Patent Linkage Commitments from the Phase One Agreement

Article 76 of China's amended Patent Law, which became effective on June 1, 2021, provides an initial framework to establish patent linkage in China. In Article 1.11 of the Phase One Agreement, China committed to establishing an early patent dispute resolution system if it permits a follow-on product to obtain approval by relying on evidence or information concerning the safety and efficacy of a previously approved product.

This early patent dispute resolution framework must include: a system to provide notice to the patent holder of the approved product that the follow-on product applicant seeks to market its drug during the term of an applicable patent that claims the approved product; adequate time and opportunity for the patent holder, to resolve patent infringement or validity disputes; and, procedures for judicial or administrative proceedings and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measures.

In July 2021, the National Medical Products Administration (NMPA) and CNIPA released the "Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial)". The NMPA-CNIPA Measures are a step in the right direction; however, ambiguities and omissions in the provisions leave significant uncertainties about how patent linkage will be realized, particularly for biological products. The system as proposed seems incapable of achieving its goal of providing a mechanism for sponsors of new pharmaceutical products (biological products and new drugs) to prevent the marketing of follow-on pharmaceutical products (i.e., generic drugs and biosimilar products) that infringe valid patents.

We are also concerned that, even since the Phase One Trade Deal Agreement was concluded, NMPA has continued to grant marketing approvals to local drug companies to make infringing copies of innovative medicines while the reference products in each case are still subject to

patent protection. Moreover, at least a few of these infringing products were included on lists that passed preliminary review for inclusion on recent National Reimbursement Drug Lists and the national volume-based procurement program. BIO would welcome the opportunity to provide additional public input to clarify and revise the patent linkage provisions to create a more effective patent linkage system and to more effectively encourage the development and marketing of innovative biotherapeutics in China.

For example, in the recently released Second Draft of Amendments to the Patent Examination Guidelines Following the Amended Patent Law, we would recommend CNIPA broaden language relating to patent invalidation cases involving the early patent dispute resolution mechanisms in Article 76 of the Patent Law. Ensuring that the patent linkage system functions as intended and that Article 76 invalidation cases are not used intentionally or mistakenly to bypass the patent linkage system would be an improvement welcomed by BIO membership. CNIPA should require all patent invalidity applicants certify or otherwise notify CNIPA if they have submitted or do submit during the course of the invalidation proceeding any patent statement to the NMPA with respect to the challenged patent.

ii. Patent Linkage Concerns with U.S. FTA Trading Partners – Australia, Chile, Colombia, Mexico, South Korea

Amongst U.S. FTA trading partners, there is a significant range in patent linkage regimes that we will briefly illustrate below.

For instance, Chile lacks a patent linkage system and is therefore not in compliance with its obligations under Article 17.10.2 of the U.S. Chile FTA to refrain from granting marketing approval for a drug to a third party prior to expiration of a relevant patent.

Likewise, Australia and Colombia have not effectively implemented provisions of their Free Trade Agreements with the U.S. that require mechanisms for resolving pharmaceutical patent disputes before launch of a follow-on product. To implement these provisions effectively both Australia and Colombia would need to provide mechanisms for enforcing patents in courts prior to any launch of the follow-on product and while applications for generic or biosimilar marketing approvals are pending.

A patent linkage system exists in Mexico; however, it is dysfunctional and unreliable, despite commitments in the USMCA that include a functioning patent linkage system. Recent concerning statements by the Mexican Sanitary Regulatory Agency, COFEPRIS, suggest that the regulatory agency will only apply its existing patent linkage to patents directed to a pharmaceutical active ingredient per se. Several court decisions have ordered the publication of formulation and use patents to satisfy linkage requirements, but the Mexican Patent Office refuses to publish these patents without litigation and the regulatory agency has shown reluctance to observe these patents. This is not consistent with "best practices," such as those employed in the United States. It is important that linkage is applied not only to compound patents but also in non-compound patents reflecting investment in targeted innovation, such as formulation and "use" patents, that deliver significant benefit to patients.

Finally, our members continue to express concerns regarding South Korea's implementation of their patent linkage obligations under their FTA with the United States. South Korea's interpretation of its obligations is quite narrow and leads to inequitable results. Moreover, the Ministry of Food and Drug Safety (MFDS) may publish its own version of listed patent claims, rather than the actual claims that the company submitted as part of the application process. The MFDS does not provide applicants with a formal opportunity to comment on any changes to the listed claims, although we understand they are informally notifying the company of any changes. During appeals of these MFDS interpretations, extrinsic evidence is accepted only in limited cases. In addition, the limited nine months stay against a generic filer is not automatic. Finally, MFDS can decline to impose a stay even if patents are duly listed.

iii. Patent Linkage Deficiencies with non-FTA Trading Partners – India and Japan

In India, central government and state regulatory authorities are not required to verify or consider the remaining term of any existing patents. Accordingly, generics are approved without regard to patent term of originator product. BIO supports development of a notification and early resolution mechanism for patent disputes to give innovators security in knowing that their efforts in creating a new drug will be respected for the duration of the patent period similar to patent linkage in the U.S.

BIO members urge the Ministry of Health and Family Welfare (MOHFW) to take immediate steps to increase transparency and cooperation between central and state medicines regulatory authorities. At a minimum, MOHFW should ensure all biopharmaceutical manufacturers, the relevant Indian authorities and the broader public have timely notice of follow-on product marketing and manufacturing applications filed with central and state regulators.

In Japan, actions by the Ministry of Health (MHLW) have undermined the predictability of patent protections. While MHLW has acknowledged that it should not arbitrate patent disputes, in 2020 it undermined the patent of an innovative product by approving multiple generic versions even though the Japan Patent Office had upheld two of the four claims on the underlying method of use patent. Moreover, while the innovative manufacturer in this instance has initiated patent infringement suits against each of the approved generics, due to the action of the MHLW, potentially infringing products were permitted to enter the market as of December 2020, before the manufacturer could secure injunctive relief. Such relief can take months to secure in Japan's legal system, thereby frustrating the ability of the innovator to seek an injunction before infringing products enter the market and creating uncertainty for innovator and generic manufacturers alike. This system equally harms patients, who could be prescribed products that ultimately must be withdrawn from the market based on the outcome of the pending litigation. It is exactly this uncertainty and disruption that well-functioning and effective patent enforcement systems are designed to avoid.

Additionally, in Saudi Arabia, BIO members continue to face challenges related to patent linkage. Although Saudi Arabia introduced a patent linkage system in 2013, the Saudi Food and Drug Authority (SFDA) has effectively overridden the country's linkage regime by granting market approval for a follow-on product to a patented medicine. Instead of providing the rightful legal action, the Saudi government has put the onus on the innovator and infringing company, a local Saudi manufacturer, to deal with the situation.

GENERAL PATENT ENFORCEMENT CONCERNS

For BIO members fortunate to navigate the complicated IP environment globally to ultimately build a robust global patent portfolio, there is an expectation that reasonable enforcement mechanisms exist. However, as illustrated below, there are some significant enforcement challenges globally that impact the biotechnology sector.

i. Litigation Damages for Unsuccessful Bona Fide Patent Infringement Lawsuits - Australia

Australia's government has been seeking significant litigation damages from companies that legitimately seek to enforce their patent rights, putting Australia out of step with the rest of the developed world and key U.S. FTA trading partners regarding its treatment of IP rights.

The government has intervened in at least seven patent infringement suits in Australia's Federal Court, claiming damages from the innovator for alleged losses the government says it suffered as a result of the delay of statutory price reductions under Australia's Pharmaceutical Benefits Scheme ("PBS"). This derives from the delay in listing a generic drug on the PBS as a result of the court granting the innovator a preliminary injunction to prevent infringement of its patent by the generic drug, in circumstances where the innovator has ultimately been unsuccessful in that litigation.

The Australian government is, in effect, disregarding the critical and long-held distinction between patent abuse cases and bona fide patent enforcement cases, that is, between cases where: (1) an innovative biopharmaceutical company acts without good faith or vexatiously or unreasonably by seeking to abuse its patent rights to prevent the entry of a generic onto the market, on the one hand ("patent abuse cases"), and (2) the innovative biopharmaceutical company acts in a bona fide and reasonable manner in seeking to act to enforce its patent to prevent infringement, but ultimately loses the case, on the other ("bona fide patent cases").

Moreover, the patent right that the innovator is seeking to enforce is one that is granted by the Australian government and, it is the Australian government that defines the circumstances under which price reductions under the PBS occur. This also challenges the legal principle of equity, whereby an innovator incurring the statutory price reduction but then successfully challenging the generic entry in the courts has no mechanism to be compensated for the lost revenue from the statutory price reduction.

The Australian government's approach is inconsistent with the spirit and letter of Australia's international obligations relating to the protection of intellectual property rights. The Australian regime does not meet these obligations because it deters bona fide and reasonable patent enforcement by innovative biopharmaceutical companies through the use of litigation to pursue government compensation claims or via threats to do the same. This approach is a major and inappropriate shift in policy and practice by the Australian government.

Innovative biopharmaceutical companies should be able to commence bona fide patent cases under the system set up by the government, in order to enforce patents examined and granted by the government – including seeking preliminary injunctions – without the government later

seeking damages from the innovator in the event that the bona fide patent case is ultimately unsuccessful.

Enforcing patent rights obtained also remains unnecessarily complicated by the Federal Court of Australia's failure to abolish the "Promise of the Patent" doctrine. This requires patentees to fulfill "the promise" of the patent made in the specification regardless of whether the invention has a viable alternative use. This is similar to recent jurisprudence which has been rejected in Canada.

Further, in a line of cases including the Federal Court of Australia's full court decision in Bristol-Myers Squibb Co v. Apotex Pty Ltd, (2015) 228 FCR 1, Australian courts have created hurdles that preclude exclusive licensees from enforcing their patent rights. By ruling that in order to be an exclusive licensee, a party must have all rights to the patent and be exclusive even vis-à-vis the patentee itself, the courts have made it impracticable for international pharmaceutical companies to enforce their and their affiliates' rights in Australia. The importance of this issue is underscored by the absence of a patent linkage regime and the consequent need to establish irreparable harm to obtain a preliminary injunction.

ii. General Enforcement Challenges – Brazil, China, Mexico, and South Korea

For foreign IP rightsholders faced with potential infringement lawsuits or other related IP legal matters, it is often a challenge to establish standing or present a recognizable legal claim to initiate a lawsuit.

For example, in Brazil, the IP Law requires registration of license agreements before they can be enforced against third parties or before royalty revenues can be sent overseas. In addition, royalty payments cannot be sent overseas unless an actual patent is granted which places some restrictions on BIO members to license pending patents.

Chinese law currently requires that follow-on products (generics or biosimilars) actually be commercialized in China before a patent holder can bring an infringement action. It is not enough to produce the potentially infringing product, or secure regulatory approval of the potentially infringing product to initiate an infringement action. Additionally, the Supreme Peoples' Court has cautioned lower courts from issuing preliminary injunctions for 'complicated' technologies (like biotechnology). As such, BIO has long advocated that China needs to adopt amendments to the Patent Law that facilitate early initiation and resolution of IP disputes in the pharmaceutical context before follow-on products are marketed. Although a patent linkage system to resolve early drug patent disputes is in place, as discussed earlier in our submission, the system needs significant improvement.

In some jurisdictions, even when foreign IP rightsholders establish standing and initiate legal proceedings, often extensive periods of time pass before patent infringement cases are decided. This is the case in Mexico, for example.

Companies report that IP enforcement cases proceed in two stages before the Mexican Patent Office that can last 4-5 years. Two additional appeal stages then follow before a final decision is made in the case. This problem in Mexico is particularly acute as the possibility to recover damages is delayed until after all appeals are exhausted. Once a patent holder emerges

victorious from the lengthy patent infringement lawsuit, innovators are not allowed to receive damages in court and must then initiate a second proceeding before a civil court to receive a damage award. While some may argue that injunctions prevent this problem, the infringer can post bond without providing evidence of non-infringement and have the injunction lifted and allow the infringing products to remain on the market. This causes extensive delay that can last up to 10-12 years between initiation of proceedings and recovery of damages. This process is extremely costly and inequitable to the innovator and to the broader innovative biotech ecosystem that relies on efficient and fair legal systems globally to enforce their IP rights.

Finally, South Korea presents another troubling patent enforcement development where biotech firms, after successful patent litigation proceedings brought against infringing companies, are unable to obtain adequate remedies and damages. Not only are the damages insufficient to cover the innovator's losses by market entry of an infringing product, but the inadequate damages also fail to serve as a deterrent to further infringements by other parties. More specifically, the Seoul High Court in September 2020 ruled that innovators could not seek an injunction to suspend the automatic price cut, triggered when a generic enters the market, as part of a patent infringement proceeding, arguing that the innovator could simply sue to recover damages. However, the South Korean Supreme Court in November 2020 held that generic companies were not liable for damages caused by this mandatory price reduction to a patented product even if the generic drug, determined to have infringed valid patents held by the innovator, illegally entered the market with a patent infringing product. Collectively, this presents a scenario that does little to deter infringements and runs counter to South Korean commitments to support IP rights and strengthen patent enforcement mechanisms.

iii. Plant PVP and Patent Enforcement Considerations – Argentina

Proposed amendments in Argentina to the Seed Law 20,247, and its implementing decree 2183/91, may significantly frustrate the ability for agricultural biotechnology innovators to enforce plant variety protection (PVP) and patent rights, which are independent and coexisting forms of IP rights critical to sustain agricultural biotechnology innovation.

The proposed amendments establish a system by which the IP holder can only effectively collect royalty payments and monetize their IP at a single transaction for a five-year term upon sale of seed, essentially attempting to extinguish all other IP rights in the seed. Furthermore, the amendments would create a system where the National Seed Institute would have sole authority for determining minimum thresholds for detecting biotechnology in seeds and, thus, control the extent to which IP rights violations may be detected in seed sales. In addition to disregarding the coexistence of PVP rights with patent rights, the proposed bill would expressly bar IP holders from enforcing their rights against family farmers registered at the National Family Registration, farmers from native population communities, and small business farmers, as defined by local law.

Over the past several years a number of bills have been introduced seeking to amend the Seed Law and it is with great concern that we monitor these developments as they would significantly compromise the enforcement of any available agricultural biotechnology IP rights in Argentina.

BIO is hopeful that recent jurisprudence from the Brazilian Supreme Court, which ruled that PVP law does not extinguish one's right from enforcing patents or collecting royalties on saved biotechnology seeds, will support the position recognizing the relevance of IP rights and enforcement mechanisms for agricultural biotechnology and influence partner agricultural economies in the region.

IV. CONCLUSION

BIO appreciates the opportunity to comment on the IP rights issues affecting U.S. biotechnology companies abroad. We hope that our submission helps the efforts of the U.S. Government in monitoring IP rights and related market access barriers internationally. Throughout this submission, we have attempted to succinctly identify foreign countries with laws, policies, and practices that fail to provide adequate and effective IP protection and enforcement for the benefit of the global innovative biotechnology community. Based on the experiences of our members and the significance of the IP concerns raised in this submission, we suggest the countries listed in Annex I be added to the USTR 2023 Special 301 Report.

BIO believes that swift and meaningful U.S. Government engagement on these issues are necessary to promote U.S. jobs, entrepreneurship, and U.S. leadership in the life sciences. Strong USTR action addressing these IP issues is consistent with a Worker Centric trade policy and is foundational to successful implementation of the Build Back Better agenda.

Annex I

SUGGESTED COUNTRY DESIGNATIONS

PRIORITY WATCH LIST

Argentina

Brazil

Canada

Chile

China

Colombia

India

Indonesia

Japan

Mexico

South Korea

WATCH LIST

Australia

European Union

Annex II

INDEX OF COUNTRIES AND ISSUES