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**BIOTECHNOLOGY INNOVATION ORGANIZATION**

**2020 SPECIAL 301 SUBMISSION**

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## I. OVERVIEW OF BIOSCIENCE INNOVATION INDUSTRIES

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to participate in the 2020 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 preserving strong intellectual property protections for United States' companies internationally.

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 50 States and a number of foreign countries. 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. intellectual property (IP) system, has generated hundreds of drug products, medical diagnostic tests, genetically engineered crops, and environmentally beneficial products such as renewable fuels and bio-based plastics.

The vast majority of BIO's members are small and medium sized enterprises 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 commercialize their technologies. More and more, BIO's members are looking abroad as they expand their R&D and commercialization efforts and the challenging IP policies highlighted below frustrate this growth.

### A. BIOSCIENCE INNOVATION IMPROVES THE ECONOMY

Advances in biotechnology innovation have had a transformative impact on many sectors of the economy — from advances in healthcare to improved plants that are key to feeding the world to industrial biotechnology applications that are leading to bio-based fuels, chemicals and products that can protect our environment and herald a new age of sustainable development.

Bioscience industries employed 1.74 million people in 2016 across more than 85,000 U.S. business establishments. The broader employment impact of U.S. bioscience jobs is an additional 8 million jobs throughout the rest of the economy. Taken together, these direct, indirect, and induced bioscience jobs account for a total employment impact of 9.7 million jobs.<sup>1</sup>

The industry continues to pay high wages, reflecting the high skills and education requirements of an innovative workforce, with the average U.S. bioscience worker earning nearly \$99,000 per year, or 85% greater than the private sector average. Since 2001, bioscience wages have grown substantially faster than overall private sector wages.<sup>2</sup> The bioscience industry is also well distributed geographically in the United States: 38 states and Puerto Rico have an employment specialization in at least one bioscience subsector. For U.S. metropolitan areas, 213 of 383 have employment in at least one biotechnology sector.<sup>3</sup>

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<sup>1</sup> "Investment, Innovation and Job Creation in a Growing U.S. Bioscience Industry 2018"  
[https://www.bio.org/sites/default/files/TEconomy\\_BIO\\_2018\\_Report.pdf](https://www.bio.org/sites/default/files/TEconomy_BIO_2018_Report.pdf) at 1-2.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.* 3

## **B. BIOSCIENCE INNOVATION IMPROVES HEALTH OUTCOMES**

In addition to contributing to economic prosperity, bioscience industries are delivering improved health outcomes and giving individuals who suffer from medical conditions the hope of living a fuller, healthier life. Innovations made by the bioscience industry 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.<sup>4</sup>

## **C. BIOSCIENCE INNOVATION IMPROVES AGRICULTURE AND OTHER INDUSTRIES**

In addition to health outcome improvements, significant and meaningful advances have been made in agriculture, food and industrial biotechnology.

In agriculture, genetically engineered crops have been on the market for over twenty years. During this time, 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. In addition to addressing agronomic challenges, advances in biosciences now enable farmers to 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.<sup>5</sup>

## **II. INTELLECTUAL PROPERTY ENABLES DEVELOPMENT OF BIOTECHNOLOGY INNOVATION**

Biotechnology business models (for agriculture, pharmaceutical and industrial applications) are built on collaborations between universities, small biotechnology companies, venture capital and larger private company partners. Governments support this model, and benefit from development of biotechnology innovations into products when they establish enabling environments for innovation. Experts have identified seven components of an enabling innovation environment for biotechnology: human capital, infrastructure for R&D, intellectual property protection, regulatory environment, technology transfer, market and commercial incentives, and legal certainty.<sup>6</sup>

The agricultural and pharmaceutical biotechnology industries rely heavily on patents and regulatory data protection for legal certainty needed to attract investments. The development of

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<sup>4</sup> “Innovation Saves” <https://www.bio.org/toolkit/infographics/innovation-saves>

<sup>5</sup> “Growing America’s Biobased Economy” <https://www.bio.org/toolkit/issue-briefs/growing-america%E2%80%99s-biobased-economy>

<sup>6</sup> *Building the Bioeconomy 2018*. [http://www.pugatch-consilium.com/reports/Building\\_the\\_Bioeconomy2018.pdf](http://www.pugatch-consilium.com/reports/Building_the_Bioeconomy2018.pdf) See page 12

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.

Biotechnology product development is also fraught with high risk – the vast majority of biotech medicines and therapies fail to ever reach the marketplace. In addition, while biotech health inventions are entitled to the same patent term as all other inventions – 20 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 8 to 10 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 markets that import U.S. grain, such as Europe 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 investors, and commercial banks, indicated patents were an important factor in their investment decisions.<sup>7</sup>

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 could improve conditions for export of biotech from the United States. In addition, improvements in IP would benefit those 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.<sup>8</sup> Studies show that even developing countries obtain economic benefits from increasing their IP protection.<sup>9</sup> Like in other trade areas, increased standards in IP provide a win-win situation for the United States and other nations around the world.

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<sup>7</sup> 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>

<sup>8</sup> "Building the Bioeconomy", *Supra*, 19-20.

<sup>9</sup> 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.

For well over a century, governments have recognized the need for global minimum standards that enable inventors to effectively and efficiently protect and share their inventions in a territorial system of intellectual property rights. The Paris Convention for the Protection of Industrial Property (signed in 1883) allowed inventors, regardless of nationality, to claim priority for their inventions and to take advantage of the intellectual property laws in each member country. Today, most countries are members of the Paris Convention and the Patent Cooperation Treaty (PCT) that facilitates filing patent applications globally.

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which entered into force in 1994, was a major achievement in strengthening the worldwide protection and enforcement of intellectual property rights by creating an international minimum standard of protection for intellectual property rights. Because it concerns both the definition and enforcement of rights, TRIPS is one of the single most important steps toward effective protection of intellectual property globally.

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. Some of these efforts are aimed at forcing localization of technology. While often popular they are harmful not only to the biotechnology industry but to the long-term prospects for the country's economic growth in this sector.<sup>10</sup> 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.

To help assess the IP challenges abroad that may hinder biotechnology developments, BIO has surveyed our members asking them to identify relevant IPR barriers in the identified nation's law, courts, enforcement regime, regulatory regime, import/export regime, etc. Our members have provided the information found in this submission and we have compiled the information in aggregate form.

### **III. PRACTICES THAT UNDERMINE INNOVATION**

In recent years the biotechnology industry has faced a growing number of work streams within the multilateral system that threaten to undermine future investments and innovation in biotechnology - most significant, the repeated and narrow focus on IP as a barrier to access to medicines. While IP and pricing related to new drugs and biologics have long been a source of

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<sup>10</sup> Pugatch, Localization Barriers, [http://www.pugatch-consilium.com/reports/Localization%20Paper\\_us\\_final.pdf](http://www.pugatch-consilium.com/reports/Localization%20Paper_us_final.pdf)

debate, multilateral institutions are increasingly providing fora to pursue biased work streams that cast innovators and the systems that incentivize innovation as cause of problems surrounding access to medicines. 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 regulatory systems, supply chains and delivery infrastructure and systems.

Biotechnology innovators support strong national health systems and timely access to quality, safe and effective medicines for patients who need them. Patents and regulatory data protection drive and enable the research and development that delivers new treatments and cures. These limited and temporary intellectual property rights are not barriers to access to medicines; to the contrary, they promote access to medicines, particularly when governments and the private sector partner to improve health outcomes.

BIO describes below some of these flawed approaches that should be prioritized by the U.S. government in its trade-related negotiations with foreign countries and in its dealings with multilateral organizations.

#### **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 or threatened to issue CLs that allow local companies to make, use, sell or import particular patented medicines without the consent of the patent holder. In the case of medicines, BIO strongly believes governments should grant CLs only in accordance with international rules and as a last resort in exceptional circumstances. 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.

BIO is concerned about ongoing CL challenges in middle to high income countries such as Chile and Colombia, both OECD economies, and Malaysia.

#### **B. PRICE CONTROLS**

As mentioned earlier, bringing a new biopharmaceutical product through the lengthy research and development phase to commercialization stage is increasingly costly and risky. Strong intellectual property protection is critical, but so is value-based pricing and reimbursement that is critical to ensure recognition of the impact of an innovative medicine to patients and society. In many foreign countries, where the government is responsible for health care costs, industry is under attack to lower prices and often companies accept prices that undervalue the benefits conferred in order not to delay patients access to the latest breakthroughs. Biopharmaceuticals are saving lives and curing once incurable diseases. 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.<sup>11</sup> 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 in the forefront of nations acting responsibly with appropriate valuation and reimbursement to support innovators working to improve health outcomes globally rather than free-riding off of U.S. innovators.

### **C. OTHER COMMON CONCERNS**

The intellectual property challenges described below have practical and immediate impact on the ability of BIO members to invest in discovering and transforming promising molecules and proteins into useful new applications to help heal, feed and fuel the world. These challenges hinder or prevent innovators from securing patents (patent backlogs and restrictive patentability criteria), maintaining and effectively enforcing patents (lack of mechanisms to promote efficient resolution of patent disputes, weak patent enforcement and due process) and protecting regulatory test data (regulatory data protection failures).

#### *Patent Backlogs*

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, India and Thailand are countries with persistent backlog problems.

#### *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:

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<sup>11</sup> 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>)

Argentina, Brazil, Canada, China, Egypt, India, Indonesia, Thailand, Turkey.

#### *Early Resolution Mechanism 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 the regulatory agency of a jurisdiction do not inadvertently contribute to the infringement of patent rights. China, for example, despite proposing to put in place a patent linkage mechanism, has made little to no progress in ensuring implementation. BIO is hopeful, however, that China will implement the patent linkage system in a robust and expeditious manner as agreed upon in the US-China Phase One agreement.

#### *Regulatory Data Protection Failures*

Regulatory data protection (RDP) complements patents on innovative medicines and agriculture protection products. By providing temporary protection for the comprehensive package of information biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine or of crop protection 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 so complex that it is possible for others to produce a version – or “biosimilar” – of a 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. Examples described further in the country profiles below include: Argentina, Australia, Brazil, China, India, Indonesia, Malaysia, Russia, Thailand, and Turkey.

The United States had an opportunity to significantly improve support for biotechnology innovation internationally by including at least 10 years of regulatory data protection for biologics in the USMCA. BIO regrets that the final USMCA text falls short of providing for this level of protection.

Moving forward, to address the ongoing problems with inadequate regulatory data protection, BIO members urge USTR and other federal agencies to highlight the above-listed countries and challenges in the 2020 Special 301 Report and to use all available tools to address and resolve them. The Report should also include specific engagement plans that detail USTR’s intended actions to effectively resolve these concerns.

## PRIORITY FOREIGN COUNTRY

### Canada

New pricing policies for patented medicines as well as continued patent term restoration challenges are highly concerning to BIO’s membership. Due to the lack of improvement of the overall environment for our sector and lack of predictability and transparency in policy development, BIO recommends USTR to designate Canada as a **Priority Foreign Country**.

#### Pricing for Patented Medicines

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.

Moreover, the regulations include 3 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 to develop market impact tests for medicines that are likely to pose affordability challenges for insurers due to the market size for the medicine.” Patentees would not be responsible for reporting GDP or GDP per capita. Guidelines for implementation published in November 2019 do not provide clarity on how these features will be applied and are currently open for consultation until February 14, 2020.

## **EU-Canada Comprehensive Economic and Trade Agreement (CETA)**

CETA provides for several reforms to Canada's Patent Act that will have important implications for the biopharmaceutical industry including the introduction of patent term restoration via Certificates of Supplementary Protection (CSP) and changes to Canada's linkage regime.

The changes negotiated in the CETA text applicable to the biopharmaceutical industry were intended to elevate Canadian intellectual property (IP) standards closer to those of the EU. BIO is concerned that the current implementation proposed in the CETA regulations will not achieve this objective.

For example, there are two main limitations with the CSPs, namely: the 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 addition, changes to damages rules for generic companies that challenge patent validity may result in windfall recoveries that harm patentees reliant on effective, non-discriminatory patent enforcement regimes.

BIO will continue to urge Canada to implement CETA in ways that improve their IP environment for biotechnology innovators and seek support from the United States in that effort.

## **Japan**

The lack of predictability and transparency in Japan's pricing and reimbursement reform, as well as its discriminatory and onerous government pricing policies, not only continues to undervalue U.S. innovation in a key market, but also significantly hinders fair and equitable market access for U.S. biomedical innovators. Furthermore, while BIO welcomed the U.S. negotiation objectives of the 2019 U.S.-Japan Trade Agreement (USJTA), specifically, to "ensure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are nondiscriminatory, and provide full market access for U.S. products, particularly under relevant Japanese measures"<sup>12</sup>, the two sides did not appear to achieve commitments or meaningful outcomes in the final agreement to address our sector's concerns. BIO and its member companies continue to support a comprehensive trade deal with Japan and urge the U.S. Government to address challenges facing the biopharmaceutical sector in the second round of trade talks. However, should the trading partner fail to enter into good faith negotiations or make significant progress in resolving the related market access challenges, BIO recommends USTR to consider designating Japan as a **Priority Foreign Country**.

Cross-border collaboration in the biopharma sector has intensified in recent years between the United States and Japan, in part because of important progress and reform within Japan's drug regulatory system that now approves products on a similar time frame as the United States. Advances in scientific research in both countries have also increased the opportunities for collaboration. However, a variety of aspects of Japan's system for pricing and reimbursing new drugs continues to threaten the innovative eco-system in Japan, and with it, opportunities that

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<sup>12</sup> United States-Japan Trade Agreement (USJTA) Negotiations: Summary of Specific Negotiating Objectives. USTR, December 2018.

U.S. small, medium-sized and large biopharma companies have to develop and launch new products in Japan. Some of these developments particularly make it difficult for small companies to consider developing and launching in Japan. Allowing the policies to continue its non-transparency, non-predictable, and anti-innovation trend will deprive innovators in the United States and elsewhere of fair remuneration for their technology, divert American technology and jobs to Japan, and otherwise undermine, as well as undervalue, American ingenuity and innovation.

### **Technology Localization and Impact on Small and Medium Sized Enterprises**

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 small and medium sized enterprises (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<sup>13</sup>. 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.

### **Non-transparent and Non-predictive Approach to Pricing and Reimbursement (P&R) Policy Making**

BIO has long been concerned with the non-transparent, and non-inclusive nature of policy making with respect to P&R for new drugs. In particular, we find the process by the Central Social Insurance Medical Council (Chuikyo) of the Ministry of Health, Labor and Welfare (MHLW) seriously defective with regard to its provision of advance notice of issues to stakeholders, and its limited opportunities for such stakeholders to engage and provide meaningful input. We believe it is unfair for one of the world's largest markets for new medicines to do such a poor job of reaching out to the U.S. biotech community – which originates a large number of all new medicines globally – for its input. Outreach to large U.S. companies located in Japan is also deficient, but even that does not include any input by our SME members, which are the backbone of this industry.

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<sup>13</sup> 2019 Emerging Therapeutic Company Trend Report, David Thomas and Chad Wessel. BIO Industry Analysis. 2019.

As discussed above, a predictable policy environment is critical for ensuring continued investment into biomedical R&D, as 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. As such, BIO is concerned by pricing policy decisions by the Japanese government that are made at a reactive and *ad hoc* manner, and that fail to adequately consult industry and employ international best practices. For example, in 2016 Japan introduced the “huge-seller” repricing policy, followed by quarterly re-pricing policy in 2018, and is expected to introduce further repricing rules in 2020. The changes were imposed with little meaningful engagement with stakeholders and are contributing to a highly unpredictable pricing environment in Japan.

### **Systemic Discrimination Against Innovative Medicines in the Budgeting Process – Undervaluation of Innovation**

BIO recognizes Japan’s continued efforts to reward innovation in its regulatory framework and to improve efficiency in its drug evaluation and approval system. BIO also recognizes that the Japanese health care system faces fiscal constraints. But time and again, we find that health care budgets disproportionately limit spending on new innovative medicines (e.g., the percentage of budgetary cuts far exceed our percentage of health care expenditures) compared to other health care services and products, despite the fact that many new medicines create significant health care savings in the longer run. Bluntly put, new medicines which are predominantly developed abroad (mostly in the U.S.) face much deeper cuts than Japanese constituents in the health care system such as doctors and hospitals. Moreover, Japan’s special expansion re-pricing (or huge-seller penalty) cuts the price of a product purely on the ground that its sales have far exceeded the sales originally projected. This significantly penalizes and undervalues breakthrough therapies as an attempt to manage budget impact. Such measures are not only unfair and discriminatory, but systemically work to undervalue new medicines and therapies, undermines IP, and stunts incentives for biopharma innovation within Japan.

### **A Rigid Health Technology Assessment (HTA) in Japan Exacerbates the Trend of Anti-Innovation**

BIO is concerned that Japan’s cost-effectiveness-based HTA system, implemented in April 2019, is constructed in ways that further disincentivizes innovation in Japan, add to costs (particularly burdensome for small companies) and can potentially delay patient access to new medicines. In addition, the methodology used by the Government of Japan in its HTA pilot, on which the HTA system is based, was not developed in a transparent process and deviates from standard methodologies aligned with the latest available science. Any future reforms to the HTA system need to encourage innovation, not be unduly burdensome, incorporate a broad set of benefits in the value framework, and not simply be used a tool for rationing care to Japanese patients.

## **Regulatory Data Protection**

In accordance with the Trade Promotion Authority Act requiring the U.S. government to leverage trade agreements to bring our trading partners in line with U.S. standards for intellectual property rights, BIO strongly believes the U.S. standards of data protection for biologic products (12 years) remains the gold standard and should be the basis for negotiations with Japan. In addition, BIO would welcome a strong patent enforcement mechanism, including patent term restoration to address patent examination delays.

BIO continues to urge the Japanese government to ensure robust and consistent stakeholder consultation as it implements the new drug pricing reform package, so to assure predictability and transparency of the drug pricing system in the Japanese market. As the United States and Japan have been engaged in intensive bilateral trade talks involving the biopharmaceutical sector for over 30 years – starting with the advent of “MOSS talks” in 1986, there is a rich record of discussions, agreement and achievements up which to build in any new Trade Agreement.

## **Malaysia**

BIO and its member companies continue to be concerned by actions of the Malaysian government which constitute a blatant disregard of patent rights protection and recommend USTR treat Malaysia as a **Priority Foreign Country**.

In September 2017, the Government of Malaysia exercised its rights under Section 84 of its Patent Act of 1983 and announced it would move forward with a “government-use license” – effectively a compulsory license - on a patented therapeutic product, despite the patent owner’s agreement to address related public health concerns through voluntary licenses. The government-use license would nullify patent rights in favor of providing marketing opportunities to local pharmaceutical companies. In addition, the government and local advocates have expressed interest in expanding the compulsory licensing scheme to include additional patented therapies. The use of compulsory licensing in Malaysia has far reaching ramifications for the biopharmaceutical industry as other governments, such as Chile and Colombia are considering similar policies that would provide broad discretion to issue compulsory license. In 2019, USTR extended the Out-of-Cycle Review of Malaysia to evaluate the extent to which Malaysia is providing adequate and effective IP protection and enforcement, including with respect to patents.

In addition to expropriation of patent rights, BIO is also concerned about the lack of effective regulatory data protection in Malaysia. Not only is the scheme narrow in scope, it also places onerous requirements on biopharmaceutical originators seeking protection for their data against unfair commercial use and disclosure. As a result, some companies have had their applications rejected on arbitrary grounds, and some face an unreasonably curtailed protection period.

The intellectual property challenges faced by BIO member companies in Malaysia are egregious. The compulsory licensing scheme, coupled with lack of meaningful regulatory data protection, will adversely affect the incentives for companies to develop and to introduce new therapies in Malaysia, and the spread of these practices will weaken U.S. companies’ ability to compete globally, and, ultimately, put American jobs at risk.

## **Compulsory Licensing**

In September 2017, Malaysia's Ministry of Health, under the Administration of former Prime Minister Najib Razak, announced that the Cabinet approved a government-use compulsory license on a patented breakthrough therapy developed by a U.S. biopharmaceutical company. The compulsory license would permit local firms in Malaysia to import and manufacture generic versions of the patented product for sale at public hospitals without the consent of the patent owner. Prior to the announcement by the Malaysian Ministry of Health, the patented treatment, which is a medical breakthrough for hepatitis C virus (HCV) patients, had been approved by Malaysia's own regulators and available to patients in Malaysia for two years, since September 2015. In addition, the patent owner had committed to include Malaysia in its voluntary licensing program, which would address the Malaysian Government's procurement needs while providing patients with affordable quality-assured products in a timely manner. Instead, the Government of Malaysia moved forward with compulsory licensing, and its sudden announcement provided little opportunity for the patent owner to give timely feedback, nor for the input to be meaningfully considered.

Malaysia's compulsory licensing scheme lacks sufficient transparency, due process, and dialogue, as the patent owner was given inadequate notice and limited opportunities to respond to the government's decision. Furthermore, the Ministry of Health continues to entertain recommendations by advocacy groups to impose compulsory licenses on additional therapeutic areas, which would allow local companies to import, manufacture, sell, and distribute generic versions of patented products. Using compulsory licensing to promote the importation of 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 the Malaysian government, which has identified biotechnology as one of its strategic growth sectors. In March 2019, the Ministry of Health announced that Malaysia will begin domestic production of a hepatitis C treatment, which is a combination variant of the drug under compulsory license. The aim, according to Malaysia's Deputy Minister Lee Boon Chye, is to promote local pharmaceutical industry.

Despite being named for Out-of-Cycle Review by USTR in 2018, again in 2019, and despite renewed efforts by the U.S. innovator to engage in in-depth negotiation with the new Administration under Prime Minister Mahathir Mohamad to address Malaysia Government's procurement needs under its voluntary licensing program, the Ministry of Health nevertheless moved forward to enable third-party manufacturers, which have not demonstrated compliance with Good Manufacturing Practices, to manufacture and import the patented products for use in 22 public hospitals. It is also disappointing that the Malaysian Government has taken no meaningful steps to improve transparency and the lack of procedural fairness in pricing and procurement negotiations. Malaysia's baseless decision to expropriate patent rights of a U.S. manufacturer through a process that lacked transparency, and in the absence of any justified access problem, is deeply troubling to BIO and our members.

Compulsory licenses should be granted in accordance with international agreements and only in exceptional circumstances. Furthermore, compulsory licensing decisions 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. BIO feels strongly that compulsory licensing is not an effective nor sustainable way to address a country's healthcare needs, nor is it an indication of a strong national healthcare system, one that ensures patient access to safe and quality medicines while supporting continued development of innovative treatments. BIO urges the Government of Malaysia to uphold its commitments to protect the intellectual property rights of foreign patent holders and to ensure that current, as well as future, patients have access to innovative medicines.

BIO is further concerned that Malaysia's denial of proper IP protection for patent holders may set a destructive precedent that will erode the spirit of the TRIPS Agreement and ultimately dilute the global intellectual property regime. Other government authorities are aware of the actions taken by the Malaysian government, and are closely monitoring stakeholder reactions, including that of the U.S. government. Malaysia's compulsory licensing decision and the potential expansion of expropriations through licensing within, as well as beyond, Malaysia's borders will harm American companies and place American jobs at risk. BIO therefore requests intervention by the Office of the USTR and the U.S. interagency to defend the IP rights of and to preserve fair and equitable market access by U.S. biopharmaceutical innovators.

## **Regulatory Data Protection**

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".

BIO member companies invest a significant amount of resources to develop research data to prove the safety, efficacy, and quality of originator products. The lack of adequate regulatory data protection scheme in Malaysia 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.

## **South Korea**

In September 2018, BIO and its member companies welcomed the revised U.S.-Korea Free Trade Agreement intended to secure free, fair and reciprocal trade for U.S. workers. Notably, under the agreement, Korea committed to revising its drug pricing and reimbursement policy so that it is aligned with existing KORUS commitments and to ensure fair and equitable treatment for U.S. exports. While the Government of Korea took subsequent steps, including revising the Premium Pricing Policy for Global Innovative Drugs, BIO is concerned that the revisions have done little to correct the challenges facing U.S. innovators in the Korean market. The policies of the Government of Korea continue to result in unfair practices that are inconsistent with relevant KORUS provisions and, furthermore, U.S. originators continue to be denied fair remuneration for their innovative products in Korea. Accordingly, BIO recommends that USTR consider South Korea a **Priority Foreign Country** and to seek consultations with the trading partner with the objective to address policies inconsistent with the spirit of KORUS aimed to ensure fair treatment for U.S. pharmaceutical exports.

### **Pricing and Reimbursement Policies**

BIO member companies are concerned with the lack of robust implementation of the KORUS provisions on innovation, IP and market access. Despite commitment under KORUS to value U.S. innovation appropriately, S. Korea continues to restrict the pricing of innovative medicines through an unreasonable valuation scheme. For example, the government seeks to significantly reduce the price of innovative products by linking prices of newly patented products to the discounted prices of off-patent and generic products. In addition to the lack of recognition of IP in its pricing and reimbursement scheme, the Korean government also conditions preferential pricing policies on various performance requirements, including localized manufacturing and R&D, joint partnerships with domestic firms, as well as “social contribution”.

BIO applauds the U.S. Government in its efforts to improve KORUS through negotiations and for securing an outcome on pharmaceutical reimbursements in 2018 that calls on the S. Korean Government to amend its Premium Pricing Policy for Global Innovative Drugs to make it consistent with Korea’s commitments under KORUS and to ensure non-discriminatory and fair treatment for U.S. pharmaceutical exports. Subsequently, in Spring 2019, Korea’s Health Insurance Review and Assessment Service (HIRA) implemented a revised pricing policy. However, BIO is concerned that the new criteria would effectively continue to exclude innovative pharmaceuticals from the premium pricing regime and is therefore inconsistent with the spirit of the updated KORUS agreement to ensure non-discriminatory and fair treatment for U.S. innovative pharmaceutical exports.

## **Burdensome Data Requirements for Patent Applications**

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, the applicant/patent owner is not allowed to 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. 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.

## **Patent Linkage**

Our members continue to express concerns regarding South Korea's implementation of their patent linkage obligations under their Free Trade Agreement 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 far from automatic. MFDS can decline to impose a stay even if patents are duly listed in the Green Book.

## **Patent Term Restoration Challenges**

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

These practices add uncertainty to IP protections for both innovators and generic manufacturers and are inconsistent with Korea's obligations under the FTA.

## PRIORITY WATCH LIST

### Algeria

Due to issues surrounding weak patent enforcement and regulatory data protection failures, as well as market access barriers such as import restrictions and forced localization, BIO recommends the continued placement of Algeria on the **Priority Watch List**. BIO members are hopeful that collaborative relationships are formed with the new Algerian government and that pro-business, pro-innovation reforms will be top priorities.

#### **Weak Patent Enforcement and Regulatory Data Protection**

Algerian regulatory authorities, despite the existence of laws and regulations to the contrary, continue to grant marketing approval to copies of patent protected products while the original patent is still in effect. In some cases, this occurs many years in advance of the original product patent expiration despite the owners repeated attempts to alert the authorities and present documentation confirming that the product is under patent in Algeria. This issue is compounded by the absence of effective judicial remedies for preventing the infringement of basic patent rights, including the lack of injunctive relief. Furthermore, Algeria fails to protect pharmaceutical test and other data from unfair commercial use and disclosure.

#### **Market Access Barriers**

Since 2009, Algeria has prevented the importation of many products that compete with similar products that are being manufactured locally. Further measures taken in 2015 to restrict the importation of products not manufactured locally contradict the government's aspirations to attract more investment by the innovative biopharmaceutical industry, and for Algeria to accede to the WTO. BIO continues to be concerned by the Ministry of Health's procedures to promote forced local manufacturing. Such actions have a negative impact on patients and unfairly discriminate against BIO members. Repealing such policies should be a prerequisite for Algeria's ascension to the WTO.

### Argentina

BIO members continue to face a challenging IP environment in Argentina, highlighted by persistent patent backlogs, lack of patent term extension, narrow patentability requirements and lack of regulatory data protection. Accordingly, BIO recommends Argentina remain on the **Priority Watch List**.

#### **Restrictive Patentability Criteria and Patent Prosecution Practices**

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.

### **Regulatory Data Protection**

Argentina does not provide protection for data submitted in support of marketing authorizations to establish that agricultural biotech or biopharmaceutical products are safe and effective. 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. This practice violates an obligation of Argentina under article 39.3 of the TRIPS Agreement that requires such data to be protected against "unfair commercial use."

### **Discriminatory Procurement Policies**

Law 27.437 establishes margins of preference of between 8-15% for goods of national origin in public tenders. Furthermore, if a foreign company wins a public tender and the purchase of imported goods exceeds a threshold provided for in the Law, the company must sign a productive cooperation agreement committing to acquire local goods and hire local services linked to the object of the tender. This forced localization creates significant challenges for BIO members and discourages foreign entities from entering the Argentine market.

### **Proposed Amendments to the Seed Law and IP Enforcement Challenges**

Proposed amendments 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 amendments have been proposed in a bill from the Agriculture Commission of the Lower Chamber of the Argentine Congress and remains pending through March 1, 2020.

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.

### **Compulsory Licensing**

Finally, there is a new risk of compulsory licensing under Art. 70 of the Emergency Economic Law passed in December 2019. This law empowers the Ministry of Health to establish a compulsory or mandatory licensing mechanism in the event of potential problems of availability or unjustified/unreasonable price increases that may affect the population's access to medicines. Given how recent the law is, this provision has not yet been implemented. Nevertheless, it permits expanded use of compulsory licenses and will be closely monitored.

## **Brazil**

Although there are still persistent problems that hinder Brazil from fully achieving a positive IP environment across technology sectors, particularly with respect to the biotechnology sector, there have been several improvements to its protection of IP over the years. It is still too early to measure the impact of these policy developments, however, and to ensure that Brazil can continue to strengthen its IP regime to support innovation, BIO recommends that USTR place Brazil on the **Priority Watch List**.

### **Restrictive Patentability Criteria and Patent Prosecution Practices**

Over the years, the Brazilian Patent Office (INPI) has developed patent examination guidelines for biotech inventions across the health, agriculture, energy, and industrial biotech sectors. The patentability guidelines address some issues but continue to reflect a restrictive approach to defining patent eligible subject matter and have a narrower interpretation of patentable subject matter than standards adopted in other innovative countries. The biotechnology patentability guidelines are currently being revised by the INPI and BIO would welcome updates to the guidelines that reflect recommendations made in BIO's public submission to INPI in 2019.

The INPI also has restrictive patent prosecution standards which presents challenges to innovative companies that seek patent protection in Brazil. For example, there are significant obstacles for patent applicants when looking to present amendments, add new claims and/or alter the scope of protection of claims for patent applications under review.

In addition to restrictive patentability criteria and challenging patent prosecution rules that are at odds with global best practices, there are several bills before the Brazilian legislature that may negatively affect the IP environment, such as, for example, Bill 139/1999, Bill 5402/2013 and their complementary bills which seek to, among other things, reduce patent term in Brazil by not allowing for any patent term adjustment.

### **Patent Backlog**

INPI has currently an unacceptable backlog – more than 200,000 patent applications pending for approximately 270 examiners, which extends the examination for more than 10 years. There is no doubt that the number of patent's examiners is blatantly insufficient, including for applications related to biotechnology. In this sense, it remains a great challenge for INPI to increase and improve its staff and examiners properly. INPI presents every year new plans to deal with this huge backlog, which results have been continuously unsatisfactory.

The backlog problems may be exacerbated if Bill 139/1999 (5402/2013) before the Brazilian legislature is passed. The bill seeks to reduce patent term by not allowing for patent term adjustment, essentially removing the guarantee that a patent will have at least 10 years of patent term. Patent applicants may effectively expect less than a 10-year patent term considering that patent applications in the biotech space almost invariably take more than 12 years to issue. Patent applicants should not be penalized on obtaining meaningful patent term for patent backlog delays caused by the INPI.

BIO members, however, welcome the concrete efforts underway at INPI to significantly reduce the backlog by streamlining the patent examination process and through Patent Prosecution Highway (PPH) agreements with the USPTO and other leading global Patent Offices. More specifically, we are hopeful that the renewed PPH with the United States which is effective as of December 1, 2019 will help alleviate the backlog and facilitate more collaboration, reducing workload and duplication of efforts and strengthen patenting practices and institutional know-how. Recognizing the PPH is inclusive of all technical areas, which BIO representing agriculture, environment, animal health, and human health companies greatly appreciates, the PPH is, however, limited to 400 applications per year (one application per month for each applicant). We are hopeful this will be expanded.

Furthermore, we welcome the INPI's July 2019 proposal to reduce their patent backlog by 80% in the next two years. If successful, the INPI claims they will be able to examine patent applications within two years from filing. These developments provide some promise to the global innovative biotechnology community that the patent backlog is being addressed. Preliminary information from the INPI suggest there are positive developments; however, the progress of these initiatives will need to be followed closely. Again, BIO appreciates these efforts to address this longstanding problem and welcome the signal this brings to the global innovative ecosystem about how innovation and IP rights may be protected in Brazil for the years to come.

## **ANVISA's Questionable Role in Reviewing Patentability Criteria**

Brazilian law establishes that the regulatory authority (ANVISA) must provide prior consent on the grant of a pharmaceutical patent before the INPI issues a patent. ANVISA had interpreted this requirement as an obligation to review patentability criteria (novelty, non-obviousness, and utility). BIO, however, recognizes ANVISA's recent efforts to minimize its role in the patent review process and restrict their review to questions of public health and not base decisions on a review of substantive patentability requirements.

BIO maintains that ANVISA's review of patent applications should, at most, address public health issues and ANVISA should not, under any circumstance, review patentability requirements since this is a function that is squarely and solely within the purview of the INPI.

The Federal Attorney General shares this opinion and determined that ANVISA's review should be restricted to an analysis of the sanitary risks of the patented product to health.<sup>14</sup> Inter-ministerial guidance has opined on this issue and have attempted to iron out procedural processes for the exchange of files between ANVISA and INPI.

In 2017, the acting President Michel Temer participated in the signing of an agreement between the Ministry of Health, Ministry of Development, Industry and Foreign Trade, ANVISA and the INPI in which a compromise on prior consent was made. The agreement establishes that ANVISA will only review patentability requirements for drugs considered "strategic" to the Universal Healthcare System and only if a patent application is considered "strategic" may ANVISA assess patentability requirements. The agreement further stipulates that the ANVISA opinion on patentability, however, is ultimately non-binding and that the final decision on patentability rests with the INPI.

Although this illustrates some advancement on the issue and acknowledgement of INPI's primary role in reviewing patent applications, ANVISA's presence in the process still presents concern to BIO membership and is inconsistent with global IP standards. ANVISA is still notified of patent applications that refer to a "strategic" drug and ANVISA will still carry out a patentability assessment, albeit a non-binding opinion. In addition, the list of "strategic" drugs can be updated on an ad hoc basis at any moment without any public consultation. Giving ANVISA a say on patentability remains inconsistent with its mandate and may lead to undue interference in patent examination process. Until ANVISA is clearly removed from the patentability process in Brazil, BIO members will continue to express their concern. As an example, Senate Bill 437/2018 illustrates BIO's continuing concern and seeks to, among other things, legislate the authority of ANVISA to review substantive patentability criteria. Therefore, the issue for our members persists, providing unnecessary uncertainty and insecurity with respect to a patent applicant's pending patent applications.

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<sup>14</sup> Accessed on February 4, 2020 and found at:  
[http://translate.google.com/translate?sl=auto&tl=en&u=http://www.agu.gov.br/sistemas/site/TemplateImagenTextoThumb.aspx?idConteudo%3D153676%26id\\_site%3D3](http://translate.google.com/translate?sl=auto&tl=en&u=http://www.agu.gov.br/sistemas/site/TemplateImagenTextoThumb.aspx?idConteudo%3D153676%26id_site%3D3)

## **Enforcement and Royalty Payments**

For BIO members fortunate enough to navigate the complicated IP environment and ultimately obtain a patent, it is concerning that there remain additional obstacles to effectively enforce the acquired IP right.

For example, the 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. Furthermore, INPI can dictate terms prohibiting parties from freely negotiating contracts and restricting IP owners from fully exploiting their patents by, for instance, stipulating royalty rates.

There are also concerning developments with respect to the enforcement of IP in the agriculture sector. Brazil is a member of the UPOV and has enacted a plant variety protection (PVP) law. A plant may be protected by the PVP law, whereas a gene inserted therein and other related technologies may be protected by the patent law. Intellectual property rights provided by patent protection and PVP are thus complementary. However, the PVP law does not have a clear provision on its different and complementary scope of protection, which allows local farmers and agricultural cooperatives/associations to challenge payment of royalties on the use of GMO seeds based on a supposed conflict between the IP law and PVP law regarding protection of plants and plant-related technologies. In view of this, a recent decision on a leading case from the Superior Court of Justice ruled on the independence and coexistence of the PVP law and the IP law in Brazil. The Superior Court of Justice ruled that PVP law does not extinguish one's right from enforcing patents or collecting royalties on saved biotechnology seeds. The Superior Court of Justice understood that to allow the farmers' claims would frustrate commitments assumed by Brazil under Article 28.1 of the TRIPS Agreement. Our members appreciate how this decision creates important case law and judicial precedence in Brazil, and more broadly for the region, in favor of the position recognizing the relevance of IP rights and enforcement mechanisms in the agricultural biotech field.

## **Lack of Regulatory Data Protection**

Brazilian law (Law 10.603/02) provides data protection for veterinary, fertilizer, and agrochemical products, but does not provide similar protection for pharmaceutical products for human use, resulting in discriminatory treatment. Contrary to TRIPS Article 39, Brazil continues to allow Government officials to grant marketing approval for pharmaceuticals to competitors relying on test and other data submitted by innovators to prove the safety and efficacy of their products. Additional efforts are needed to provide certainty that test and other data will be fully protected against unauthorized use to secure marketing approval for a fixed period of time.

## **Proposals to Restructure the Patent Office**

Finally, Technical Note 8623/2019 published by the Ministry of Economy in November 2019 seeks to alter the legal status of the INPI as a government entity and combine it with an existing quasi-governmental agency, ABDI (Brazilian Agency for Industrial Development), to create ABDPI, the Brazilian Agency for Development and Industrial Property. The proposal seeks to

address longstanding fiscal concerns around the INPI and BIO recognizes this is part of a broader effort in the Brazilian government to administer its budget and provide greater financial autonomy to the INPI while improving its efficiency. BIO will continue to monitor these developments to ensure that existing, pending, and future IP rights are not put at risk as these proposals are debated and ultimately as any eventual changes to the legal status and structure of the INPI are enacted.

## Chile

Recent developments regarding the potential use of a compulsory license of patented therapeutic product would nullify patent rights in favor of providing market access to local generic drug companies, despite patent holder's willingness to negotiate an outcome that would avoid a compulsory license. Due to the increasing threats of a compulsory license, as well as other long unresolved IP issues such as with respect to data protection for biologics, U.S.-Chile Free Trade Agreement (FTA) noncompliance, lack of patent term adjustment or patent term restoration, BIO requests that Chile be placed on the **Priority Watch List** and to conduct an **Out of Cycle Review** to monitor the changing IP and potential compulsory license developments.

### Compulsory Licensing

On January 11, 2017, the Chilean Chamber of Deputies of the National Congress passed Resolution No. 798 to expand the scope and discretion available to the Chilean government to issue compulsory licenses. That resolution calls on the Ministry of Health (MOH) to "incorporate and use the compulsory licensing mechanism provided in Article 51(2) of Chile's Industrial Property Law ... to facilitate [medicines] acquisition at competitive prices." It also calls for the prioritization of certain classes of medicines to be considered for compulsory licensing and highlights the price reductions realized by certain countries after issuing compulsory licenses on biopharmaceutical products. In addition, the Chilean Congress is currently considering the "Medicines II Bill," which has recently returned to the Senate after a lengthy analysis in the Lower House. That bill, which has been declared as a legislative priority for the government, seeks to amend Article 99 of the Sanitary Code to establish that access to medicines is not adequate "when there are economic, financial, geographic or opportunity barriers that prevent access to a medication." The bill also broadens the procedural discretion for compulsory licence petitions. Furthermore, in January 2018, the Chamber of Deputies approved Resolution No. 1014 seeking to establish that access to certain Hepatitis C medicines is not consistent with the constitutional right to health, thus warranting a compulsory license.

BIO is extremely concerned that actions such as Resolution No. 798, the pending Medicines II Bill, and Resolution No. 1014 inappropriately expand, or seek to expand, the scope of compulsory licensing provisions to pursue cost-containment efforts inconsistent with international obligations. Moreover, Bill 12.135-0 introduced in October 2019 - separate and unrelated to the pending Medicines II legislation - contains a number of proposed amendments to Chile's Industrial Property Law that would further erode the country's intellectual property environment. This includes ambiguous language on patent working requirements as well as lack of notice for compulsory licenses.

In addition to these developments at the legislative level, the Chilean Ministry of Health on March 9, 2018 issued a declaration of public interest, citing sufficient “public health reasons to support a compulsory license on a drug for the treatment of Hepatitis C. The declaration was issued on the last effective day of the Bachelet administration.

On August 28, 2018, Chile’s Minister of Health issued Resolution 1165, dismissing the legal arguments put forward by the patent holder against the declaration of public interest, formalizing the current administration’s position with respect to a potential compulsory license and establishing a formal pathway to proceed with a compulsory license of a Hepatitis C drug. Since the issuance of a declaration of public interest (DPI) by the Chilean Minister of Health on March 9, 2018 the patent holder has not been allowed to explore alternative paths to avoid a potential compulsory license with senior officials responsible for this policy.

The continued and combined efforts at the legislative and executive level of the Chilean government to issue a compulsory license without reasonable discussion of alternative mechanisms to address access concerns with the patent holder is of chief concern to BIO and its membership.

Compulsory licenses should be granted in accordance with international agreements and only in exceptional circumstances. Furthermore, compulsory licensing decisions 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. Compulsory licensing is not an effective nor sustainable way to address a country’s healthcare needs, nor is it an indication of a strong national healthcare system, one that ensures patient access to safe and quality medicines while supporting continued development of innovative treatments. BIO strongly urges the Government of Chile to uphold its commitments to protect the intellectual property rights of patent holders and to ensure that current, as well as future, patients have access to innovative medicines.

### **Lack of Adequate Data Protection**

Chile 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. This protection is needed to justify introduction of biopharmaceuticals and encourage sustained investments in further innovation. Chile does currently provide data protection for new *chemical* entities for 5 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 either FTA with the United States or provisions of the TRIPS Agreement.

## **Insufficient Patent Term Restoration**

Chile's patent laws 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 9 months from the filing of the extension request to the final ruling by the Industrial Property Court, creating further delay in extending patent terms.

The patent law in Chile also excludes transgenic plants and animals from patent protection, thereby limiting the availability of meaningful protection for valuable biotech innovations. To the extent that protection is available, significant backlogs delay ability to obtain rights essential to adequately protecting these inventions.

## **Patent Linkage and Enforcement Challenges**

Chile is not in compliance with its obligations under Article 17.10.2 of the US Chile FTA to refrain from granting marketing approval for a drug to a third party prior to expiration of a relevant patent. This is highly important to prevent infringement and devaluation of intellectual property assets of BIO member companies. The lack of protection is particularly troubling in light of Chile's clear obligations under the FTA.

## **China**

On January 15, 2020, U.S. President Trump and Chinese Vice Premier Liu He signed the U.S.-China Phase One trade deal, which include promising provisions to improve market access and IP enforcement for agricultural biotechnology and biopharmaceuticals. BIO commends both sides for the agreement and looks forward to supporting the implementation and enforcement of the provisions.

China's large consumer market presents opportunities for U.S. biotechnology companies to increase exports and create jobs in the United States. However, failure to adequately protect and enforce U.S. IPR greatly affects BIO's members. The China National Medical Products Administration (NMPA) in May 2017, took initial steps to improve China's IP environment by proposing to establish new forms of regulatory data protection and patent linkage systems in China. However, without coordination with the Chinese National Intellectual Property Administration (CNIPA) to ensure corresponding revisions to China's Patent Law, the effectiveness of the patent linkage system to facilitate early resolution of patent disputes prior to market entry of the follow-on product may be undermined. In addition, BIO continues to advocate for China to align its patent administration practices with that of other patenting jurisdictions, including regarding the treatment of supplemental data submitted in support of pharmaceutical patent applications. Finally, while BIO welcomes NMPA's proposal to provide six, six, and twelve years of data protection for innovative drugs, new orphan and pediatric drugs, and innovative therapeutic biologics, respectively, it is important to ensure the implementing measures take into account industry recommendations for best practices and do not discriminate against foreign businesses, including small and medium-sized biopharmaceutical enterprises.

BIO and our member companies applaud China's commitment in the IP Chapter of the Phase One agreement to establish a system for early resolution of patent disputes, effectively a "patent linkage" system where patent holders, licensees, and marketing authorization holders can seek "expeditious remedies", such as preliminary injunctions, prior to the marketing approval of an allegedly infringing follow-on product. Most notably, the scope of the system would include both small molecule drugs as well as biologics, as well as cover product and method of use patents. In addition, China would allow patent term extensions and to allow patent applicants to supplement data to meet patentability requirements during judicial and administrative proceedings. While the IP Chapter did not include actionable provisions pertaining to the implementation of regulatory data protection for biopharmaceuticals in China, BIO welcomes the Fact Sheet of the IP Chapter noting that United States and China have agreed to address regulatory data protection in future negotiations.

BIO calls on both sides to ensure an expeditious and robust implementation of the agreement, and to make continued progress to achieve concrete and meaningful outcomes that effectively address trade and investment barriers. As such, BIO recommends that China be placed on the **Priority Watch List**.

### **Restrictive Patentability Criteria**

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. BIO welcomed China's commitment at the 2013 U.S.-China Joint Commission on Commerce and Trade (JCCT) plenary meeting to address this concern, but China's implementation was mixed. In April 2017, China released its Amended Patent Examination Guidelines clarifying that examiners must consider in their examination process certain post-filing supplemental data.

While the amended Guidelines are an important step forward, BIO members are concerned that post-filing data is still not consistently being considered in connection with inventive step or other issues associated with the adequacy of a patent application's disclosure. As such, BIO welcomes China's commitment under the Phase One agreement to permit pharmaceutical patent applicants to rely on supplemental data to satisfy relevant requirements for patentability during patent examination proceedings, patent review proceedings, and judicial proceedings. BIO hopes that this new provision 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.

In biotechnology applications, it appears that CNIPA does not consider the use of percent identity or hybridization conditions unless they are specifically used in the working examples to define breadth. 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. BIO urges China to consider harmonizing its approach to this issue more closely to that taken by other major countries.

## **Effective Patent Enforcement**

Chinese law currently requires that the products actually be sold in China before a patent holder can bring an infringement action. It is not enough to produce the infringing product, or secure regulatory approval of the infringing product. 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.

In 2017, NMPA finalized its priority review policy that provides accelerated regulatory review and approval to eligible drug applications. One of the eligibility categories is if the drug application meets “urgent and unmet medical needs.” However, to date, China has not provided a definition for “urgent and unmet medical needs”. Furthermore, BIO is concerned that generic drug applications may be granted priority review and approval by NMPA in cases where another party holds a valid patent.

BIO became further concerned when, in 2019, China’s NMPA removed provisions in the Provision for Drug Registration Administration that would effectively provide a basic mechanism requiring the follow-on applicant to submit a “statement of non-infringement” to NMPA, and, in cases where another party holds a valid patent, to only allow generic applicants to submit their application no earlier than 2 years before the expiry of the patent.

As such, BIO is encouraged by Article 1.11 of the Phase One U.S.-China agreement whereby China would put in place an effective mechanism for early resolution of patent disputes. It will be critical that the commitment is reflected in relevant laws and procedures, including the Patent Law, to ensure meaningful outcome and enforcement.

## **Patent Term Restoration**

Another challenge for biotechnology companies in China involves the lack of patent term restoration provisions to compensate for regulatory review and patent office delays. The patent examination backlog at CNIPA and regulatory review delays at NMPA significantly curtail the effective rights of IP owners. Many other nations include patent term adjustments for patent review delays and patent term extensions to compensate for the time it takes to gain regulatory approval for pharmaceutical and agricultural products. This is particularly true of China, which permits development of a follow-on pharmaceutical product free of patent infringement allegations (so-called Bolar provision). This attribute of China’s legal regime makes it more important for innovators to be able to recoup the effective patent term lost as a result of regulatory and patent office reviews.

In January 2019, China’s National People’s Congress announced draft amendments to the Patent Law for public notice and comment, and BIO is encouraged by the proposal to authorize patent term extensions for patents covering pharmaceuticals. However, timing of the promulgation of the amendment is unclear and the proposal contains concerning conditions, including potentially restrictive eligibility criteria, which warrant further clarification and revision. Given the

commitment under the Agreement to provide patent term extensions, BIO urges both sides to ensure a timely and effective implementation of the policy.

### **Genetic Resource Disclosure and IP Sharing Requirements**

On May 28, 2019, the People’s Republic of China State Council promulgated the Human Genetic Resources Administrative Regulation (HGR). BIO and our member companies are concerned that this Regulation will have an adverse impact on BIO member companies’ ability to conduct global biotech research and clinical studies, as 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 mandates that an overseas entity must collaborate with a Chinese institution and is required to grant the partner full access to and complete copies of all records, data and other information in the research process, regardless of whether the 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.

BIO also continues to be concerned that Article 5 of China’s Patent Law prohibits patents for inventions “relying” on genetic resources where the acquisition or use of those resources is contrary to the “relevant laws and administrative regulations.” It is disappointing that the ongoing Patent Law revisions do not appear to address this issue. This provision is ambiguous and could result in the rejection of applications for deserving new and useful inventions, or even the revocation of granted patents later found inconsistent with these provisions.

Furthermore, 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 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. Including human genetic resources however makes the disclosure obligations of even greater concern to BIO members.

The amendments concern BIO as they could 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. Alternatively, if the rules remain in force, we suggest that the initial burden shift to the examiner to first identify which material the applicant must show “direct” and “original” sources for. Without such initiative by the examiner the disclosure requirement should not apply. It is also suggested that any disclosure requirement be limited to the disclosure of the direct source from which biological material - that is directly claimed in the patent application – is obtained.

## **Regulatory Data Protection**

Despite having an RDP system, no foreign drug products have effectively received data exclusivity from China. China proposed a series of reforms in 2017 and 2018, including China Food and Drug Administration (CFDA) Circular 55 - “Relevant Policies on Protecting Innovator’s Rights to Encourage New Drug and Medical Device Innovation”, released in May 2017, to strengthen its regulatory data protection regime and to establish a patent linkage system. In April 2018, NMPA released the draft “Measures on the Implementation of Drug Clinical Trial Data Protection (For Trial Implementation)”, which, as written, would provide six and twelve years of data protection for innovative pharmaceuticals and biologics, respectively. While BIO welcomes this positive movement, the proposal also includes concerning location- and time-based eligibility requirements. Specifically, 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 can potentially delay the introduction of new therapies in other jurisdictions. More importantly, for small emerging biotech companies that are responsible for more than 70% of the medicines in the innovation pipeline in the U.S. biopharmaceutical industry, these proposed onerous requirements could inhibit market access.

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 companies that are small and medium-sized enterprises (SMEs) may not have either the resources or the expertise in global marketing of products to meet the RDP requirement.

## **Counterfeit Products**

While China has taken steps to combat online sale of counterfeit and substandard medicine, Chinese law requires proof that violations in counterfeit activity exceed threshold values before authorities take any action. Although this provision does seem to recognize the limited resources and prioritization of Chinese enforcement, violators have adjusted by operating in diffuse networks to make enforcement more challenging.

In addition, China requires U.S. companies to pursue enforcement actions related to counterfeit products at the provincial level with no central coordination. This allows suspects to escape prosecution through the use of diffuse networks to sell counterfeit goods. Local politics also makes it difficult to affect change. Enforcement authorities generally are skeptical or dismissive of infringement claims by local competitors and usually try to dissuade any attempt to use the courts, preferring “local arbitration or mediation,” which tends to produce few results.

China is the world’s top manufacturer of pharmaceutical ingredients and is a leading global exporter of active pharmaceutical ingredients (API). In China, manufacturers of bulk chemicals that can be used as APIs are required to register with CFDA if the product manufactured is

intended for use in medicinal products. However, if a company manufactures a bulk chemical that can potentially be used as an API but does not intend or declare that the bulk chemical will be used in a finished pharmaceutical product, then CFDA would not serve as the competent authority.

Furthermore, Chinese manufacturers that only export their products are not subject to regulatory oversight or review. As a result, industry and media sources report that many bulk chemical manufacturers produce and export API with little regulatory oversight. While these export shipments may be legal, non-controlled products can be used for the manufacturing of precursor drugs or counterfeit and substandard medicine at third countries, then exported to other destination markets, including China. Company representatives were able to purchase counterfeit goods in China and in jurisdictions outside of China indicating inadequate supply chain and distribution controls. Internet pharmacies and other illicit distribution routes allow the counterfeits to enter foreign markets with intellectual property protection for those products. As part of the 2020 Phase One agreement, China agreed to take effective enforcement action against counterfeit pharmaceuticals and related products, including active pharmaceutical ingredients, and to increase enforcement action to stop the manufacture and distribution of counterfeit products with significant health or safety risks. BIO applauds the provisions and welcomes an opportunity to support effective policy frameworks and enforcement directed to combat the manufacturing and distribution of precursor chemicals and counterfeit medicines in China.

### **Plant IP Protections**

China has a plant variety protection (PVP) law in force, and its patent law excludes patent protection for plant varieties. SIPO Guidelines 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 SIPO 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 SIPO 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.

## **Colombia**

The Colombian patent law, inadequate regulatory data protection, and government initiatives around compulsory licensing raise a number of concerns for BIO's members. In light of these concerns, BIO recommends that Colombia be placed on the **Priority Watch List** and that USTR conduct an **Out of Cycle Review** to monitor the changing IP and potential compulsory license developments.

### **Compulsory Licenses**

In 2015, Colombia passed laws based on the National Development Plan (NDP) which includes a mandate to the Ministry of Health requiring review of patents for possible compulsory licensing. These provisions are directed to the healthcare sector, especially those relating to pharmaceuticals. In 2016, the Ministry of Health, citing the laws passed under the NDP, issued

declaration 2475/2016 which declared a single drug product, imatinib, of public interest. The declaration recommended that the National Pricing Commission make a mandatory price reduction of the product. While this is not technically a compulsory license, such action effectively undermines the patent rights of the innovator in a similar way.

In December 2017, the Colombian Ministry of Health and Social Protection issued Resolution 5246 in response to a petition filed by Fundación IFARMA on October 28, 2015 (hereinafter “petition”). That Resolution initiated the procedure for declaring public interest (DPI) over patents covering direct acting antivirals for the treatment of Hepatitis C. The DPI, if granted, will effectively destroy the value of patents to which it is applied.

A DPI directed to a broad category of medicines, namely “antivirals for treatment of Hepatitis C” is unreasonable and should not be permitted; the implementation of such an extreme measure covering a broad range of products based on unspecified patents raises several issues of due process and, moreover, would not be consistent with the international obligations of Colombia, including those obligations under the TRIPS Agreement. We also understand that Hepatitis C drugs have been subjected to significant price reductions from the government and that there is no indication that a health-related emergency regarding Hepatitis C exists in Colombia. The Petition on the Resolution therefore appears to be deficient. BIO believes that the Resolution should therefore be withdrawn or grant of a DPI refused.

Although to date the compulsory license has not been issued, the threat to BIO’s members remains and presents considerable concern and risk. Colombia will compromise the integrity of its intellectual property regime if it proceeds with these measures, thereby undermining the introduction of future scientific innovations. BIO therefore encourages USTR to use all available means to minimize this threat to a harmonious IP environment with an important trading partner.

### **Restrictive Patentability Criteria and Burdensome Patentability Requirements**

There are other government initiatives that make obtaining IP rights difficult. For example, 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. 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. These practices appear to be inconsistent with the requirements of Article 27.1.

Andean Decision 486 also 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. As noted above, these types of requirements cause great uncertainty over potentially valuable patent rights that result in significant risks for BIO’s members. These requirements may result in the outright denial of patent protection for valuable inventions. In addition, such requirements appear to be inconsistent with Colombia’s obligations under the TRIPS Agreement.

## **Patent Infringement Adjudication**

Colombia has not effectively implemented provisions of its Free Trade Agreement with the U.S. that require mechanisms for resolving pharmaceutical patent disputes before entry of a follow-on product. To implement these provisions effectively Colombia would need to provide mechanisms for challenging patent validity in courts while applications for generic or biosimilar marketing approvals are pending.

## **Regulatory Data Protection**

While Colombia offers a five-year RDP term, this is often not fully implemented or enforced consistently. Moreover, Colombian health agency INVIMA applies narrow interpretations to recognize new chemical entities. For instance, new molecules that have some “structural similarity” or “analogy” with other active ingredients in their chemical composition with medicines already approved in Colombia are not recognized as new chemical entities, because they are analogues of molecules already known and marketed in Colombia, and therefore implying that these innovators cannot count on the protection of clinical study data in the country. Such a narrow interpretation breaches INVIMA’s obligations as prescribed under Decree 2085/2002--the structural similarity of a molecule with another already approved is not a cause to determine that such molecule is not a new chemical entity. BIO encourages USTR to revisit this issue and ensure Colombian implementation of RDP for small molecules and biologics.

## **India**

While we support the Indian Government’s efforts to create a stronger business environment, lack of concrete improvements and lack of resolution of long-standing IP concerns continue to create a challenging and risky environment for BIO members. Accordingly, we recommend USTR place India on **Priority Watch List** with an **Out of Cycle Review**.

With an estimated 142 billion in traded goods and services in 2018, India is undoubtedly an important U.S. trading partner. As such, it is important that the policy environment in India be amenable to U.S. business interests. BIO is pleased to see the continued prioritization of intellectual property protections in the U.S. and India trade discussions as well as the Indian government’s attempt at addressing Form 27 biases, though no such amendments were included in the final rules. In addition, BIO has noted some promising developments recently that may improve the protection and enforcement mechanisms of IPRs. Efforts, for example, to advance with Patent Prosecution Highway agreements with foreign Patent Offices are welcomed by BIO membership and movement on these agreements, beyond a single PPH with Japan that only relates to limited technologies, would send a positive signal to the global biotechnology community about the IP environment in India. BIO also recognizes recent amendments to the Drug Price Control Order (DPCO) which exempts innovative drugs from price caps for five years and a High Court decision ruling for the validity of a patent protecting a genetically modified cotton seed. While these are positive first steps, they do not address the fundamental problems within the Indian IP system.

## **Restrictive Patentability Criteria**

Section 3(d) continues to be one of main IP issues 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 chemical products, and therefore appears to violate the non-discrimination clause with respect to field of technology set forth in TRIPS Article 27.

This section is applied in a very generalized manner without providing any objective reasoning by the Indian Patent Office (IPO), especially with respect to new chemical entities (NCE), wherein the said NCEs are neither mere discovery of new form of known substance or nor new use of known substance. The Patent Act also does not provide for an innovator to submit after-filed data generated in testing activities of the substance that may be highly relevant in evidencing the novelty and inventiveness of the substance to satisfy the burdensome higher threshold requirement that only applies to the technical area of pharmaceutical substances.

BIO has expressed concern that the Patent Guidelines as applied are biased against pharmaceutical patents and the Controller General (CG) indicated that the IPO would reconsider the Guidelines to ensure that they do not result in a negative bias toward pharmaceutical patents. This situation has in fact encouraged third parties to continue to misuse this section during opposition, appeal and revocation proceedings. There seems be no efforts by the IPO to provide any further guidelines or clarifications in interpretation of this section during the examination procedure.

Moreover, we have noted that there has been a significant increase in objections under Section 3(e) by the IPO, which deals with patenting of admixture. The existing guidelines with respect to this section in Manual of Patent Office Practice and Procedure (MPOPP) are incomplete and inadequate. The IPO continues to have a more individualistic approach in analysis, interpretation and decisions while dealing with Section 3(e). All of this indicates that there is an increasingly unpredictable environment for obtaining IPRs.

## **Patent Disclosure Requirement**

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 identify correctly 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.

## **Plant Intellectual Property Protection**

India adopted a plant variety protection (PVP) in 2005 but excludes patent protection for plants per se in broad terms. As a consequence, 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 positively remove this gap in protection for agriculture innovations.

## **Regulatory Data Protection**

India still has not implemented any meaningful protection for the data that must be generated to support efficacy and safety claims of pharmaceutical and agricultural chemical products. Under Article 39.3 of the TRIPS Agreement, in addition to providing trade secret protection, governments must separately prevent unfair commercial use of regulatory test data.

The absence of regulatory data protection (RDP) is a significant problem for BIO members because India's drug regulatory agency approves generic company applications to market generic drugs based on an abbreviated submission that includes reliance on the innovator's safety and efficacy data. This creates an unfair commercial advantage for Indian generic companies. BIO urges India to implement effective and meaningful periods of regulatory data protection for small molecules and biologics.

## **Patent Enforcement and Patent Linkage Deficiencies**

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. CDSCO's recent effort to reform the SUGAM initiative under draft Notification GSR 629(E) provides an opportunity to facilitate the notification of manufacturing applications between government agencies and patent holders. 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 marketing and manufacturing applications filed with central and state regulators.

The Indian Courts have taken steps to issue Preliminary Injunction (PI) during litigation proceedings, however, there still appears to be substantial inconsistency in the manner in which PIs are issued. The courts issue PIs by inconsistent application of the "status quo doctrine". In many instances, the courts have misapplied the legal doctrine by treating the infringement that precedes or accompanies the request for preliminary relief as part of the "status quo" and thus rejecting the issuance of an injunction or even limiting its scope. Consistency in determining PIs will encourage investment decisions and will also enable pre-litigation negotiations between the litigating parties.

## **Counterfeit Medicines**

There is also a lack of a proper mechanism for controlling, stopping and prosecuting entry of counterfeit patented non-approved drugs in India through its porous borders. There has been a significant number of counterfeit drugs entering from Bangladesh and Sri Lanka in India.

## **Compulsory Licensing**

Provisions of the Indian Patents Act provide broad authority for the issuance of compulsory licenses, including authority on the basis that the patented products are not “worked” (manufactured) in India. In a 2012 case involving a BIO member, a compulsory license was issued on these grounds. This decision was not overturned on appeal. Recent cases have since been brought, however, courts seem to have moved from this working doctrine as the justification for a compulsory license. Nevertheless, the lack of any clear guidelines/clarifications from the IPO, still presents a challenge and the threat of compulsory licenses remains.

For instance, the Patent Office requires all patentees submit a yearly “statement of working” that proves that the patentee is exploiting its invention in India.<sup>15</sup> If the company does not comply, the government may issue a compulsory license. This provision may result in the loss of intellectual property rights in India when a biotechnology company cannot “work” a medicine due to extraneous conditions (such as an FDA “clinical hold”). There remain uncertainties as well as to whether the importation of patented drugs satisfies the working requirement.

BIO members are also concerned about the Ministry of Agriculture requirement prohibiting the licensor of an approved genetically modified agricultural technology to refuse grant of a license to any eligible seed company wanting to incorporate it into its own hybrids or varieties, which has the practical effect of a compulsory license. BIO encourages further discussions around this topic.

## **Pre-grant Oppositions, Administrative Burden and Delay**

Another concern involves extensive delays in examination that sometimes occur as a result of opposition procedures. Companies often wait for years for a patent application to enter into 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. Companies have reported waiting years for a decision. The existence of both a 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.

For example, pre-grant opposition procedures under Section 25 of India’s Patents Act have created significant uncertainty and delayed the introduction of new inventions by undermining patent office efficiency and delaying patent prosecution – exacerbating India’s already significant patent examination backlog. The provision of Pre-grant opposition allows, any party to file a pre-grant opposition, any time after the publication of patent application till the grant of patent. This has led

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<sup>15</sup> [http://www.ipindia.nic.in/iponew/publicNotice\\_21January2015.pdf](http://www.ipindia.nic.in/iponew/publicNotice_21January2015.pdf)

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 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 in order 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. The ability of third parties to submit references prior to patent grant are sufficient and should be the preferred method of challenge pre-grant. These challenges increase costs and greatly complicate the ability obtain a patent in India.

The Patent Division of the IP Appeal Board (IPAB) continues to remain non-functional despite the appointment of a new chairman in January 2018 primarily because the position of patent technical member remains vacant. This lack of functionality in the IPAB patent division has not only significantly increased the backlog of pending patent appeals but it has significantly impeded the issuance of many patents. BIO strongly urges that a patent technical member be appointed as soon as possible so that Patent Division of IPAB becomes functional.

## **Indonesia**

In addition to discriminatory IP policies and heightened concern over compulsory license threats, BIO urges USTR to place Indonesia on the **Priority Watch List**.

BIO members have concerns with listing decisions that take into account price and the Social Insurance Administration Organization's budget and do not reflect all of the evidence submitted, including scientific data demonstrating drugs' safety and efficacy. Furthermore, Halal certification represents a mandatory labeling requirement that could have unexpected negative implications on patient health. BIO's concerns for specific provisions of the new patent law are summarized below.

### **Restrictive Patentability Criteria**

The 2016 Patent Law precludes patents on new uses and establishes an additional patentability criterion of "increased meaningful benefit" for certain forms of innovation prominent in biopharmaceutical technology (i.e. new salts or new dosage forms). These restrictions undermine support for important innovations and appear to conflict with existing international obligations by imposing additional or heightened patentability criteria that discriminate against classes of technology.

TRIPS requires that patents be available for inventions that are new, involve an inventive step, and are capable of industrial application. The Patent Law impermissibly adds a fourth substantive criterion for chemical innovations of "increased meaningful benefit" to the three criteria set forth in Article 27 of TRIPS. Adding a fourth substantive hurdle to patentability for specified

technologies is discrimination that harms members of BIO and should not stand scrutiny under Indonesia's international obligations.

Article 27 of TRIPS also requires grant of patents in "all fields of technology, provided they are new, involve an inventive step and are capable of industrial application". This prevents discrimination against a field of technology and barring patents on new uses or indications violates that prohibition. These are misguided policies that discriminate against innovators who build on prior knowledge to develop valuable new and improved treatments that can improve health outcomes and reduce costs by making it easier for patients to take medicines and improving patient adherence to prescribed therapies.

In addition, Indonesia's Patent Law states that a patent holder shall produce a product or use processes in Indonesia – such policies are inconsistent with Indonesia's international trade commitments and are designed to force localization and technology transfers that benefit the domestic industry at the expense of foreign innovators.

### **Compulsory Licensing**

In September 2012 Indonesia issued a decree authorizing government use of patents for nine patented pharmaceutical products as a group without dealing with the products and relevant licenses on a case-by-case basis. This raises significant concerns about consistency with Indonesia's TRIPS obligations and other international norms. TRIPS Article 31(a) requires such licenses be considered on a case-by-case basis rather than as a group. Article 31(i) also requires the ability to appeal the compulsory license to a judicial or other independent body. No such appeal seems to be available in Indonesia.

The indiscriminate use of compulsory licenses draws investment away from the biotechnology sector that is heavily reliant on patents to generate investment funding. Indonesia's actions on compulsory licensing are inconsistent with their stated desire to create an enabling environment for innovation in the life sciences.

The current Patent Law creates additional uncertainty by discouraging voluntary licensing agreements between private parties and by promoting compulsory licensing on grounds that are vague or appear to be inconsistent with Indonesia's international obligations. Provisions of the new law appear to require disclosure of private license agreements and allow compulsory licensing if a patented product subject to the agreement is not manufactured in Indonesia. Requiring disclosure of private agreement terms would in itself discourage entry into such agreements to the detriment of Indonesia. That is compounded by a local manufacturing requirement that also appears to contravene Indonesia's national treatment obligations pursuant to which manufacturers should be able to meet the "local working" requirements through importation.

In December 2018, the Ministry of Law and Human Rights issued a regulation on the procedure for granting compulsory licenses, which implements concerning localization requirements under the Patent Law, including providing the granting of compulsory license if a patent holder does not implement the requirement to manufacture products or use processes in Indonesia within 36 months from when a patent was granted. In December 2019, Indonesia issued a proposed revision to the Procedures for Granting of Compulsory Patent Licensing, Regulation No. 30/2019. The

draft continues to have localization requirements and, further, appears to require compulsory licenses to be granted based on the principle of expediency/use and further attempts to define expediency and what constitute emergency situations.

BIO has not completed its analysis of this new regulation and will comment as member input matures. At present we urge USTR to continue to urge Indonesia to align its regulations more closely to international standards.

BIO members believe that CLs are not a sustainable or effective way to address healthcare needs. Voluntary arrangements independently undertaken by member companies better ensure that current and future patients have access to innovative medicines. BIO members urge Indonesia to work with BIO members to develop sustainable solutions to access problems while maintaining support for IP mechanisms fundamental to development and dissemination of new medicines to patients in Indonesia.

### **Regulatory Data Protection**

Indonesia does not provide adequate regulatory data protection that prevents “unfair commercial use” of regulatory data on pharmaceutical and agricultural chemical products as required by Article 39.3 of the TRIPS Agreement. The introduction of effective data protection for regulated pharmaceutical and agricultural chemical products would contribute significantly to providing adequate and effective protection of intellectual property rights in Indonesia for BIO’s members.

### **Patent Term Extension**

In addition, there are no provisions for patent term extension in appropriate circumstances. This has a detrimental effect on the value of biopharmaceutical patents in Indonesia.

### **Counterfeit Medicines**

BIO’s members also report problems with counterfeit medicines, despite recent steps taken by Indonesia that include the establishment of a National Anti-counterfeiting Task Force. The lack of expertise and resources in the courts and law enforcement agencies create problems for BIO companies. Corruption at the local police level is another challenge in Indonesia when trying to enforce a patent. BIO requests that USTR further engage with Indonesia to put in a place a system that provides adequate and effective protection for intellectual property rights.

Counterfeit biopharmaceuticals produced in Indonesia also pose a substantial safety risk for patients. More international oversight is required to regulate the normal distribution channels of counterfeits including internet pharmacies. Enhanced education in the medical sector could help warn of the dangers of obtaining dangerous counterfeit medicines from unauthorized suppliers.

### **Annuity Fees**

The Indonesian Patent Office recently issued invoices for past annuity payments on previously abandoned patents which were not expressly withdrawn from the patent office. Annuity payments are the renewal fees innovators pay to maintain a granted patent. The invoices received from the Indonesian patent office represent up to 3 years of annuities as well as back

taxes if due. The amounts are significant and if companies do not pay, they have been threatened with property seizure. This practice is not in line with the major patent offices and it is one that USTR should raise in anticipation of potential negotiations with the Government of Indonesia.

### **Plant Variety Protection**

In addition, while Indonesia has implemented a plant variety protection (PVP) system, BIO members report that the level of protection is inconsistent with the International Convention for the Protection of New Plant Varieties. The lack of appropriate protection for new plant varieties remains a crucial issue for BIO's agricultural members.

## **Russia**

BIO members continue to experience IP and market access challenges in Russia and thus recommend USTR place Russia on the **Priority Watch List**.

### **IP Enforcement**

Patent enforcement against infringing companies remains a large concern, especially against local Russian companies. In Russia, for example, an innovator cannot sue for patent infringement upon first learning of a request for generic marketing approval. Rather the patent-holder must wait until the generic drug is approved. Russian courts compound this problem by not typically granting preliminary injunctions or even permanent injunctions in litigation proceedings.

### **Regulatory Data Protection**

The Law on the Circulation of Medicines sets forth the basic regulations for biologics and biosimilars. A revision to Federal Law 61 allows follow-on manufacturers to apply for registration of a generic drug four years following marketing authorization for original small molecule drugs and three years for an original biologic medicine. Without adequate enforcement mechanisms, the generic can be placed on the market prior to the expiration of the six-year data protection period. The biopharmaceutical industry is concerned that the amendments to Federal Law 61 will further weaken RDP in Russia.

### **Compulsory Licenses**

More recently, senior Russian government officials have indicated a desire to more systematically use compulsory licensing to address access and pricing. For example, the Russian Federal Antimonopoly Service (FAS) is seeking expanded compulsory licensing provisions, which would mean pharmaceutical companies could lose their exclusive rights to certain products. Additionally, under TRIPS Art. 31(l), codified under article 1362 of the Civil Code, a Court may grant a compulsory license if the invention claimed in a second patent (the dependent patent) involves a technical advancement or has economic advantages over the first patent. The courts in Russia have misapplied this law. Multiple cases were filed by local firms for the local production of generic versions of innovator oncology drugs based on their own dependent patents. We are also concerned about the recently proposed compulsory licensing amendment and explanatory note on Article 1360 of the Civil Code of the Russian Federation. The amendment seeks to expand the government's discretion to issue a compulsory license "to ensure

national security or protect human lives or health, in case of emergency.”. These actions raise serious concerns about the ability of innovators to meaningfully enforce patents in Russia and will discourage investors and innovators from bringing products into the market. We urge the USTR to monitor this situation closely and to encourage their Russian counterparts to avoid misuse of this tool.

### **Unclear Regulatory Standards for Orphan Drugs**

Access to the Russian market for orphan drugs is also impacted by unclear and changing regulatory standards. Since 2013, the Russian Ministry of Health (MOH) has amended the rules for the inclusion of drugs into the Vital and Essential Drugs List (EDL). The amendment process delayed the updating of this list to include new drugs. The regulation went through several drafts with changes to the submission template, assessment timelines and criteria, and the information requirements until it was finalized in May 2014.

### **Parallel Importation**

The Eurasian Economic Union (EAEU) comprised of Russia, Belarus Kazakhstan, Armenia, and Kyrgyzstan, entered into force on January 1, 2015. The EAEU envisages the gradual integration of the former Soviet countries' economies, establishing free trade, unbarred financial interaction and unhindered labor migration. The first sector which it plans to integrate is the pharmaceutical sector through creation of a single pharmaceutical market. There is discussion of using the framework to facilitate parallel importation of cheaper medicines into the Union. On November 16, 2016, the EAEU Intergovernmental Council approved the main suite of regulations necessary to set up a common pharmaceutical market in the EAEU so the regulations must now be approved and implemented at the national level. The potential reliance on parallel importation and the counterfeit and economic problems it can bring are concerns for BIO members that warrant further attention.

### **Government Procurement**

Despite statements expressing support for accession to the WTO Agreement on Government Procurement (GPA), Russia continues discriminatory practices in its government procurement system. Russia has adopted a regulation that bans foreign participation in tenders in cases where two or more companies from the Eurasian Economic Union (EAEU) have bid to supply medicines included on Essential Drugs List. Moreover, Russia has maintained its policy of providing locally made pharmaceuticals a 15% price preference in government procurement tenders and is considering legislation that would disqualify imported products from the tender process if local active pharmaceutical ingredient (API) is available. These discriminatory practices are a significant concern for the biopharmaceutical members of BIO.

### **Saudi Arabia**

BIO members continue to face significant IP challenges and cannot rely on regulatory data protection in Saudi Arabia. Accordingly, BIO recommends USTR place Saudi Arabia on the **Priority Watch List**.

## **Patent Linkage Shortcomings**

Though Saudi Arabia introduced a patent linkage system in 2013, we have seen some significant issues with intellectual property in the Kingdom. 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 settle the issue.

## **Inadequate Regulatory Data Protection**

While Saudi law provides for regulatory data protection, in practice it is not applied effectively. Specifically, Article 5 of a Council of Ministers' Trade Secrets Protection Regulation (decision No. 50, dated 25/2/1426 H, April 4, 2005), states that the submission of confidential tests or other data, obtained as a result of substantial efforts, for the approval of the marketing of drugs or agricultural products which utilize a new chemical entity, shall be protected by the competent authority against unfair commercial use for at least five years from the approval date.

Unfortunately, the Kingdom of Saudi Arabia has not complied with its own regulation and WTO commitments which gave rise to the regulations.

Saudi Arabia confirmed during its accession to the WTO that:

"[Its] Regulations provided for protection of undisclosed tests and other data submitted to obtain approval of a pharmaceutical or agricultural chemical against unfair commercial use for a minimum period of five years from the date of obtaining the approval including the establishment of the base price. No person other than the person who submitted such data could, without the explicit consent of the person who submitted the data, rely on such data in support of an application for product approval. Any subsequent application for marketing approval would not be granted a market authorization unless the applicant submitted its own data, meeting the same requirements applied to the initial applicant, or had the permission of the person initially submitting the data to rely on such data." <sup>16</sup>

Member companies have approached Saudi authorities concerning the need to enforce their regulations on regulatory data protection; yet authorities insist they are not sharing the content of the drug registration file of the innovator product.

To illustrate these concerns, BIO members have reported a situation where the Saudi Food and Drug Authority (SFDA) granted marketing authorization and set prices for two unauthorized generic copies of a medicine to two local companies, apparently relying on test data submitted by the innovator. Compounding the problem of patent infringement, the Ministry of Health proceeded with procurement of one of the infringing products despite multiple appeals from the

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<sup>16</sup> Report of the Working Party on the Accession of the Kingdom of Saudi Arabia to the World Trade Organization, WT/ACC/SAU/61 (Nov. 1, 2005) ¶ 261.

innovator company. A local company is now distributing this unauthorized copy to the Ministry of Health and selected hospitals.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) imposes more than a non-disclosure obligation that the Saudi authorities rely on. TRIPS Article 39.3 additionally requires WTO member states to implement an effective system of pharmaceutical drug registration, which prevents “unfair commercial use” of data generated by others.

This is fulfilled by preventing reliance on regulatory test data and approvals based on such data for a fixed period of time. In other words, the data may not be used to support marketing approval for follow-on products for a set amount of time unless authorized by the original submitter of the data.

Considering these issues, BIO welcomes the establishment of the Saudi Authority for Intellectual Property (SAIP) and its review of the country’s RDP obligations through the draft proposal on the “Development of Regulations for the Protection of Confidential Business Information.”. This draft outlines the protection and enforcement of trade secrets and proposes changes to the regulatory data protection for certain agricultural and pharmaceutical products. This positive step to review RDP obligations may be compromised, however. For example, there is lack of clarity on the scope of products covered, as well as exceptions and limitations including on compulsory licenses, effectively shortening the term and reducing the number of products covered. The draft also ties RDP protection to the date of first global approval. The industry remains concerned that unchanged these policies will fail to bring Saudi RDP obligations in line with international obligations and best practices.

## **Thailand**

BIO recognizes the Royal Thai Government’s efforts to create task forces dealing with IPR. However, we remain concerned with policies relating to compulsory licensing of patents, as well as the lack of significant progress relating to patentability of medical use claims and other secondary inventions, regulatory data protection, and the need for a robust patent resolution mechanism to prevent regulatory approval of generic versions of biopharmaceutical products that are still covered by a valid patent. As such, we urge USTR and the U.S. interagency to continue to engage relevant Thai authorities to address outstanding bilateral trade concerns affecting the U.S. biopharmaceutical industry, including via the U.S.-Thailand Trade and Investment Framework Agreement (TIFA), and to further strengthen the bilateral trade and economic relationship between the two countries.

For 2020, BIO recommends Thailand be placed on the **Priority Watch List**.

## **Patentability**

BIO recognizes the Thai government’s efforts to create task forces dealing with IPR and appreciates this positive action. However, Thailand has undermined positive movement on IPR with patent examination guidelines for pharmaceutical products that limit the patentability of medical use claims and other secondary inventions similar to Argentina’s new guidelines.

With regard to protections for plant innovations, Thailand has taken steps to implement a plant variety protection (PVP) system, but the level of protection is inconsistent with the International Convention for the Protection of New Plant Varieties. Strengthening the level of protection for new plant varieties is critical for many BIO members.

### **Compulsory Licenses**

The Thai Government's continued support of compulsory licensing of patented pharmaceutical products as part of its trade policy also contradicts positive efforts and indicates a continued disregard for intellectual property rights that are critical for the development of new medicines. In particular, BIO's members are concerned that this policy denies adequate and effective protection of intellectual property rights for innovative biotechnology products.

The Thai Government's defense of compulsory licenses for drugs that treat non-communicable diseases is of concern, given that many of BIO's members' research and development efforts target such chronic diseases. These policies go well beyond the letter and spirit of the Doha Declaration, which was meant to provide a mechanism for governments to deal with public health crises and impact the ability of biotechnology research and development efforts to recoup their massive investments. These extraordinary compulsory licensing measures should not be used systematically to facilitate budgetary planning. BIO continues to believe that the most effective global solutions will result from policies that respect and encourage innovation.

### **Regulatory Data Protection**

Thailand also fails to provide meaningful protection for the pharmaceutical test data required to demonstrate safety and efficacy of new drug products. The implementing regulations for the Trade Secrets Act provide a five-year term of protection for "maintenance of the trade secrets" of pharmaceutical test data. However, the regulations do not appear to provide the data protection against "unfair commercial use" in a manner consistent with Thailand's obligations under Article 39.3 of the TRIPS Agreement. This protection is critical to biopharmaceutical companies and their ability to successfully launch a product in a particular market.

### **Patent Linkage**

Thailand also does not provide a formal system to prevent regulatory approval of generic versions of pharmaceuticals that are still covered by a valid patent. The lack of such a "patent linkage" mechanism facilitates patent infringement in the Thai market, leading to potential loss of exclusivity for patented inventions in the biopharmaceuticals area and increased enforcement costs.

### **Counterfeit Medicines**

Our members report growth in availability of counterfeit pharmaceutical and other biotechnology products in the Thai market. This trend is connected to a regional proliferation in the trade of counterfeits, starting in Indonesia, Malaysia and the Philippines, but moving towards the territory corridor of South East Asia. This raises a number of significant concerns and constitutes not only a risk to the valuable intellectual property rights of BIO's members, but a serious health risk to the Thai public.

## Pricing

Arbitrary and inconsistent pricing decision and discrimination of foreign companies in tenders continue to hamper the investment climate in Thailand. Thai regulations require public hospitals to purchase drugs and medical supplies from the state-owned Government Pharmaceutical Organization (GPO), which utilizes a “Median Price or Maximum Procurement Price” (MPP) system to set ceiling purchase prices for procurement. However, the arbitrary and inconsistent calculation method utilized to determine the price ceilings not only create market distortions and unfair price differentials that could adversely impact originators, but furthermore, such policies have the potential to undermine patient access and the innovative environment in Thailand. The U.S. biopharmaceutical industry has encouraged the Royal Thai Government to improve the MPP mechanism in a manner that would reward innovative drugs and to enter into dialogue to facilitate a resolution that would ensure transparency, predictability, and fairness in the market, but, to date, there has been no meaningful opportunity for industry to participate or provide input.

## Turkey

BIO supports the progress Turkey has made on improving the legal framework particularly on the protection of intellectual property and on PIC/S membership. However, the government’s continued delisting efforts to force local production of pharmaceuticals as well as a host of additional issues are concerning and continue to weaken market conditions for BIO members. BIO recommends that USTR place Turkey on the **Priority Watch List**.

## Patentability

Industrial Property Law 6769 has been accepted by Turkish Parliament and was published in the official gazette on January 10, 2017. The fourth section of the Law is dedicated to the protection of the patent rights. The new Industrial Property Law is a significant step towards harmonizing the national patent law with the provisions of the European Patent Convention (EPC). However, certain areas, such as defining and ruling biotechnological inventions explicitly and second/further medical use claims, are both not addressed by the law. As a member of the EPC, Turkey should grant patents on such inventions. However, whether Turkey will enforce such patents and protect them against third parties remains unclear.

## Compulsory Licenses

Another critical concern in the Industrial Property Law relates to its compulsory license provisions. Article 130(2) of this law provides that “at the end of three years after publication of a patent grant [...] any interested party can request the issue of a compulsory license if at the date of application [of the compulsory license] the following applies (i) The patented invention is not being used or (ii) The level of current use does not satisfy domestic demand. The threshold for assessing the use of an invention is not explicitly described. For instance, Article 132 of the IP Law enables third parties to seek a compulsory license when relevant patents are used, but “the use does not satisfy domestic market’s demand.” This provision is vague, subjective, creates tremendous uncertainty for patent holders, and may be abused by competitor third parties.

## **Regulatory Data Protection**

Data protection is undermined by regulatory delays in Turkey. Currently, regulatory approval times exceed 850 days and will likely reach four years with the implementation of international GMP standards in Turkey. The 6 years of guaranteed data protection is further undermined by the fact that data protection begins when Marketing Authorization is first granted in any Customs Union Member State, which includes the European Union. Thus, a large part of the 6 years have lapsed before the drug is approved in Turkey. In addition, Turkish legislation indicates if a product has a Turkish patent, the data exclusivity will end when the patent expires, even if this is earlier than six years.

## **Non-Trade Barrier: Forced Localization**

Another major non-trade barrier concerns “forced localization” practices in the pharmaceutical sector. The Health Industry’s Localization Committee has taken a number of decisions on ‘localization’ pursuant to Action 46 of the 64th Government Action Plan-2016. This action is part of the Structural Transformation of the Health Care Industry Program of the 10th Development Plan (2014-2018) and it aims to “take new measures to promote local pharmaceutical manufacturing and exporting of drugs which are compatible with international regulatory standards”

The Turkish Medical Devices and Medicine Agency and Social Security Institution (TITCK) is the lead on the localization decisions. TITCK has established arbitrary rules for local production, delisting imported medicines from the medical reimbursement scheme as a penalty for not meeting local production requirements.

## **Market Access Barriers: GMP requirements, Pricing and Reimbursement**

One of the issues in Turkey involves the requirement by the Ministry of Health to perform Good Manufacturing Practices (GMP) inspection at every pharmaceutical production facility. Although, TITCK allows parallel submission for prioritized applications, requirements still occur for most of the products before the product registration application in Turkey, resulting in significant registration delays for BIO companies. While the Ministry of Health does allow for GMP certificates from other competent authorities, that acceptance is conditioned on other countries recognizing Turkish GMP certification. Nonetheless, with Turkey’s recent accession to PIC/S (Pharmaceutical Inspection Convention and Cooperation Scheme), which dictates international GMP standards, Turkey should begin to recognize GMP certificates issued by any of the current 52 PIC/S members. This positive development and further agreements with countries are expected to overcome the GMP hurdle and improve regulatory timelines.

Although there have been significant improvements in the pricing environment, including resolving the pricing freeze, regular price increases in line with changes in the foreign exchange rate and no additional price cuts and discounts introduced since 2014, pricing still remains a challenge for our members. Namely, the ongoing issue is around the reimbursement decision criteria, which are not clearly defined, and involve a large amount of time to conclude the process (on average 36 weeks).<sup>17</sup> A newly implemented, yet poorly defined and nontransparent

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<sup>17</sup> Association of Research Based Pharmaceutical Companies (AIFD) Market Access Survey, 2015

alternative reimbursement process increases the uncertainty on top of existing challenges. Other challenges include the lack of officially published medical evaluation decisions for the new technology being considered for reimbursement as well as the lack of pre-defined medical evaluation criteria in the regulation and non-inclusion of patients, NGOs or physician associations during evaluation process. The reimbursement system should be revised, and evaluations should be conducted based on globally respected criteria.

### **Orphan Drugs**

Orphan drugs have not been thoroughly addressed by Turkish legislation. Collaborative studies have been ongoing on draft “Orphan Drug Guideline.” Expediting the adoption and implementation of an EU-compliant Orphan Drugs Regulation with the EU definition of rare diseases would be of crucial importance to ensure Turkish citizens have faster access to new medicines.

## **WATCH LIST**

### **Australia**

BIO’s members continue to face unique IP challenges in Australia and, accordingly, BIO requests that the U.S. Government place Australia on the **Watch List**.

### **Patent Damages Policies, Patent Linkage and Patent Enforcement Challenges**

Australia’s government is 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 regarding its treatment of intellectual property 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. In the first claim that will proceed to judgement, a number of claims have been settled, the government is claiming more than AUD \$400 million in damages from the innovator.

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.

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.

### **Weakening of IP Rights**

In 2016, the Australian Productivity Commission issued a report on Australia's IP arrangements, making a number of recommendations which, if implemented, would have the practical effect of weakening IP rights in Australia and which would lead to the deterioration of the innovative climate in Australia. In 2017, the government launched a series of consultations seeking feedback on certain recommendations. In November 2018, the Australian government published its response to the consultation on inventive step, objects clause and crown use. The report subsequently spurred a hearing at the Senate Legislation Committee in Fall 2019, after which the Committee recommended that the *Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019* to be passed. The Bill proposes the innovation patent system (IPS) to be phased out, and the introduction of an objects clause in Australia's Patent Act.

While some of the more concerning proposals did not proceed, the frequent reviews and inquiries initiated by the Australian government on IP issues over the past decade or so have created an uncertain and unstable policy and legal environment for BIO's members.

### **Lack of Regulatory Data Protection**

Australia does not provide any regulatory data protection (RDP) relating to the registration of new formulations, combinations, indications, populations 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 simpler, small molecule medicines.

## **Egypt**

In recent years, Egypt has taken some steps to enhance the environment for life science and biopharmaceutical companies in particular. These steps include suspension of onerous pricing regulations, and reforms that have accelerated new medicines reviews and decreased regulatory delays that inhibit patient access to promising new medicines. There have also been instances of cooperation to prevent patent infringement, and both the quality and frequency of consultation between industry representatives and policymakers have greatly improved. There has been progress in border enforcement and biosimilars regulation. Furthermore, BIO acknowledges recent progress in dialogue with the government to address the gaps in Decree 499 and to find a path forward for the pricing of new innovative products.

The challenge remains however that despite public statements of support for the sector and these positive signals and some tangible progress, the government has continued to struggle to advance policies into implementation and enforcement. Critical issues, such as patentability of certain biotechnology innovations, patent linkage and regulatory data protection, have not been resolved. In addition, BIO members have faced pricing challenges due to the devaluation of the Egyptian Pound. Thus, BIO recommends the placement of Egypt on the **Watch List**.

### **Patentability**

The Egyptian patent law prohibits patent protection for many valuable biotechnology innovations. Inventions that strike at the core of the life sciences sector--in the subject matter areas of organs, tissues, viable cells, natural biologic substances, and genome-- are expressly excluded from patentability.

These are areas of subject matter that must be extended protection according to the obligations contained in the TRIPS Agreement, provided the material in question is new, involves an inventive step and is industrially applicable. While TRIPS Article 27.3 does recognize some

permissible areas of exclusion from patentability, these provisions of the Egyptian patent law do not fall within the permissible exclusions.

In addition, Egypt precludes the patenting of genetically modified plants and animals. In sum, the Egyptian law precludes patenting of a wide range of basic commercial products and processes in the biotechnology industry.

### **Patent Linkage and Regulatory Data Protection**

Egypt also does not provide patent linkage or regulatory data protection, and despite progress in 2017, the approval of new medicines continues in an overly opaque system. BIO urges Egypt to adopt an effective patent linkage system and to extend RDP for at least five years.

### **Market Access Barriers**

Following the liberalization of the foreign exchange rate in November 2016 and the subsequent devaluation of the Egyptian Pound, BIO members suffered tremendous financial losses in Egypt as prices of medicines are fixed. Price adjustments have been implemented but have created and continue to present challenges as the currency devaluates. Such financial burdens have made it difficult for BIO members to operate in the Egyptian market.

## **European Union**

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). While BIO is encouraged at prospects of US-EU FTA as an opportunity to address IP and market access concerns, the erosion of SPCs in Europe, coupled with proposals that appear to reconsider the value of orphan and pediatric exclusivities, along with other foundational IP rights in Europe, which generally has been an innovation leader with a strong IP system, raises significant concern. Accordingly, BIO recommends USTR place the European Union on the **Watch List** in light of these challenges.

### **Exemption to SPC Rights**

The adopted exemption to SPC rights<sup>18</sup> frustrates the fundamental purpose of these rights, i.e., to compensate innovators for lost standard patent term that results from costly and lengthy 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.”<sup>19</sup>

While BIO acknowledges that certain safeguards, e.g., to provide notice to SPC holders of intended acts, that the new exemption will not apply to any SPCs in effect at the time of entry-

<sup>18</sup> 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>

<sup>19</sup> 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).

into-force, etc., may mitigate the damage to a certain degree, the fact remains that the exemption undermines innovation incentives in Europe and marks an unprecedented step backwards in the European IP landscape for the life sciences industry.

According to a recent study, implementation of an EU-wide SPC manufacturing exemption could potentially result in annual losses ranging between USD 1.34 billion to USD 2.27 billion to the European innovative biopharmaceutical industry. These losses translate to estimated direct job loss of between 4,500-7,700 (with an additional 19,000-32,000 indirect job losses) and a decrease of between EUR 215 million to EUR 364 million in R&D investment.<sup>20</sup> These numbers were based solely on an export exception, but are likely to be exacerbated by the fact that final changes to the amendments actually expanded the exception to apply to stockpiling (limited to 6 months) for the European market as well.

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. Thus, BIO urges the USG to work with the EU to reconsider the implementation of the SPC waiver and to eliminate it as soon as possible.

### **Incentives Review Associated with Orphan and Pediatric Medicinal Products**

In addition to changes to the SPC regime, BIO remains concerned about potential changes to IP 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. 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 in the healthcare system. The EU Orphan Regulations have already been proven successful since their 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, such as in the areas of anti-microbial resistance and pediatric rare diseases.

### **Compulsory Licensing Threats**

Finally, BIO is monitoring developments regarding potential plans to implement policies to expand compulsory licensing of biopharmaceuticals. Recognizing the plans in the Netherlands and the Dutch role to address market access policies within the Commission, we highlight our concerns that policies such as what is being proposed in Holland present unnecessary risks to human health and run counter to the pro-innovation and investment climate needed in the EU.

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<sup>20</sup> Pugatch, "Unintended Consequences" 2017 at 3, accessed at: [http://www.pugatch-consilium.com/reports/Unintended\\_Consequences\\_October\\_%202017.pdf](http://www.pugatch-consilium.com/reports/Unintended_Consequences_October_%202017.pdf).

## **Mexico**

BIO recommends that Mexico be placed on the **Watch List** and that USTR conduct an **Out of Cycle Review** to monitor the changing IP, market access and drug procurement developments.

### **Regulatory Data Protection**

Mexico continues to inadequately implement its obligations relating to test data required by regulatory agencies to obtain marketing approval for pharmaceuticals. Mexico has obligations under TRIPS Article 39.3 to provide protection for pharmaceutical test data against “unfair commercial use,” and under the North American Free Trade Agreement (NAFTA) Article 1711 section 6 to provide at least a five-year protection period after marketing approval against reliance by subsequent applicants on the data supplied by the originator. Nevertheless, Mexico still 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.

Officials in the Mexican government have stated that they do not intend to extend data protection to biological medicines. Such actions are contrary to Mexico’s obligations under NAFTA, the newly negotiated USMCA and TRIPS.

Again, the United States had an opportunity to significantly improve support for biotechnology innovation internationally by including at least ten years of regulatory data protection in the USMCA. That provision of the negotiated text was deleted at the last minute. Nevertheless, BIO would like to stress the importance of Mexico implementing the minimum USMCA obligations that include a patent linkage system, patent term restoration and 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.

### **Patent Infringement Adjudication**

In addition, extensive periods of time pass before patent infringement cases are decided. 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 is particularly acute as the possibility to recover damages is delayed until after all appeals are exhausted.

Even then, innovators are not allowed to receive damages in court and must 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.

## **Patent Linkage**

As aforementioned, BIO would like to stress the importance of Mexico implementing the USMCA obligations that include a patent linkage system. Recent concerning statements by COFEPRIS (Mexican Sanitary Regulatory Agency) 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 patent office refuses to publish these patents without litigation and the regulatory agency has shown reluctance to observe these patents. Normally, patents are only included in the linkage gazette when the patentee requests it. The linkage system provides a process in which COFEPRIS consults the Mexican Patent Office on whether a specific generic infringes on an existing patent.

## **Market Access Barriers**

BIO companies are concerned about extensive market access delays due to the regulatory approval process at COFEPRIS due to the inability of the regulatory agency to act and lack of transparency around its operation, notably the New Molecules Committee. COFEPRIS had previously made important improvements in the approval process despite limited resources and cost-containment pressures; however, since the beginning of the current administration, further progress by COFEPRIS in this area has been suspended. The agency has cut off communication with the agricultural and pharmaceutical industries and has put on hold the work and processes of its New Molecules Committee. This exacerbates the already long delays that Mexican patients face to access new medicines and creates unnecessary challenges for agricultural market access as well.

## **Procurement Process Inconsistencies with International and Domestic Law**

In 2019, Mexico conducted tenders for pharmaceutical drugs under a new government procurement system, centralizing procurement under the Ministry of Finance. BIO would like to highlight certain procedural matters that may be inconsistent under existing obligations under NAFTA and the USMCA. For example, BIO members have expressed concern over the timing and speed at which the tender proceeded, potential discrimination in favor of national suppliers over foreign entities, pricing, transparency, and rights to appeal tender decisions.

The Ministry of Finance requested bids during a tender process, for example, in 13 days rather than the 40 days required under NAFTA and USMCA. The Ministry of Finance then granted its awards only 6 days after receiving bids, which raises concerns about the review process, transparency, and whether bids were adequately evaluated based on technical criteria. This, among other things, suggests potential discrimination in favor of national suppliers, particularly when there is a lack of transparency over how preferences would function and how they may be extended to treaty partners. Furthermore, there is concern that the Ministry of Finance set maximum reference prices unreasonably low for a number of products, effectively pricing U.S. innovative products out of the tender and restricting market access. Finally, the new tender system does not appear to establish clear procedures through which companies may challenge a procurement decision and thus consider complaints and determine potential damages. This also

seems to run counter to NAFTA and USMCA obligations, creating challenges for U.S. BIO members to enter the Mexican market.

### **Bill in Support of Compulsory Licensing**

In November 2019, a bill was proposed in the Senate that could greatly increase the risk of compulsory licensing for patents directed to treatments for non-communicable diseases. This is a development BIO is watching with concern.

## **United Arab Emirates**

The United Arab Emirates (UAE) has made great progress in recent years to provide an increasingly competitive environment for investment in the biotechnology sector, exemplified by a growing local innovative industry. Nevertheless, an issue of growing concern has emerged related to the protection of patents of innovative pharmaceutical products based on the country of origin and the reciprocal patent recognition within the Gulf Cooperation Council (GCC). BIO and its member companies are encouraged by a recent series of IP workshops held in the UAE in an attempt to resolve the issues, but as of this date the UAE has not confirmed a concrete resolution of the challenges outlined below that would reassure investors and companies operating in the innovative biopharmaceutical sector.

For these reasons, BIO recommends placing the UAE on the **Watch List**.

### **GCC Patent Recognition**

While the UAE is required to recognize GCC patents as of the date they are filed, BIO member companies are concerned by recent generic approvals in the UAE for patented products within their GCC patent term. BIO requests written affirmation from the Ministry of Health and Ministry of Economy that GCC patented products will be granted protection in the UAE.

### **Protection of Biopharmaceutical Patents Based on Country of Origin**

The UAE made tremendous gains in IP since the issuance of Decree No. 404 on 30 April, 2000. However, a recent issue seeks to reverse some of the developments from Decree No. 404. BIO interprets Decree 404 as to provide marketing exclusivity to innovative products based on the protection of regulatory data in the country of origin up until the expiration of the patent in the country of origin. We appreciate that the UAE government itself in a letter to the US Embassy in 2002 specifically said that Decree 404 provided IP rights through the end of a product's patent.

Nonetheless, in 2017, the UAE registered two generics of an innovative pharmaceutical product still under patent protection in the UAE. In the case of BIO's member company, the clear violation of Decree 404 is a worrisome precedent which creates uncertainty for our member companies.

## **United Kingdom**

BIO recommends placing the United Kingdom on the **Watch List** given unresolved market access and pricing concerns for biotherapeutics and concerns over IP rights in the context of the UK's exit from the European Union. BIO would encourage the U.S. Government to continue to support implementation of policies by the UK Government that support biopharmaceutical innovation and market access. Trade negotiations between the U.S. and U.K. would present an opportunity to strengthen important IP standards, including regulatory data protection.

### **IP Protection and Brexit**

Maintaining as much predictability and stability in the IP system in the aftermath of Brexit is of significant import to BIO membership. BIO members expect continuity of IP rights obtained in the UK under EU law and that the UK Government take measures to bring their IP framework, which is already one of the strongest in the world, further in line with global practices and those of their European neighbors. One scenario that presents concern to BIO members is in the event a new relationship between the UK and EU is not agreed upon by the end of 2020, there may be implications on determining the start of data or market exclusivity for biotherapeutics from date of authorization in the EU or UK, whichever is earlier. The biopharmaceutical sector believes that in such a scenario regulatory data protection should run from the date of UK marketing authorization. Similarly, Supplementary Protection Certificates (SPCs), which convey the identical rights as those conveyed in the underlying patent, should run from the date of UK marketing authorization.

### **Market Access**

Patient access to novel biotherapeutics continue to present challenges to the innovative biopharmaceutical sector. National Health Technology Assessment (HTA) processes as well as sub-national assessments aim to contain costs but create an environment where UK patients are less likely to have speedy access to innovative drugs than patients living in other countries with similar healthcare systems. The UK's National Institute for Health and Care Excellence (NICE) has a high rate of rejections based on rigid and outdated cost effectiveness measures.

Current NICE methodologies hinder the introduction of transformative therapies including advanced therapy medicinal products (ATMPs). NICE's static analytic approach cannot manage the uncertainty around the long-term benefit of breakthrough therapies and treatments for rare diseases with small populations and does not fully take into account the future benefit of curative treatments. This is at odds with regulators who have adjusted their approaches to accelerate the most important innovations. Indeed, best practices from other assessment groups, including Norway and Sweden, reward innovation and thus incentivize research in areas where patients would benefit most. Moreover, with certainty on branded medicines expenditure through the new Voluntary Pricing and Access Scheme (VPAS), there is more reason to bring requirements in line with global best practices. Of note, BIO recognizes that although VPAS has been signed, fulfillment to date has been slow, and therefore key access challenges remain and its implementation will continue to be monitored.

BIO would welcome meaningful stakeholder engagement to reform NICE methodologies so as to enable the prioritization of transformative technologies that address the severest conditions. Further, when deciding whether or not a therapy is innovative, NICE should consider a technology's role in the future global standard of care, as well as the broader benefits gained by individual patients.

To this effect, the Life Science Industrial Strategy (LSIS) provides a policy framework that would enable a thriving biopharmaceutical sector. BIO strongly encourages the Government to implement the LSIS recommendations, recognizing the importance of reforms to improve access to innovative products.

## **CONCLUSION**

BIO appreciates the opportunity to comment on the intellectual property rights issues affecting U.S. biotechnology companies abroad. We hope that our submission helps the efforts of the U.S. Government in monitoring intellectual property rights and related market access barriers internationally.