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BIOTECHNOLOGY INNOVATION ORGANIZATION

2018 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 2018 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 intellectual property (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.

A. BIOSIENCE 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 1.66 million people in 2014 across more than 77,000 U.S. business establishments. The broader employment impact of U.S. bioscience jobs is an additional 7.53 million jobs throughout the rest of the economy. Taken together, these direct, indirect, and induced bioscience jobs account for a total employment impact of 9.2 million jobs.[1]

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 $95,000 per year, or 85% greater than the private sector average. Since 2001, bioscience wages have grown substantially faster than overall private sector wages.[2] The bioscience industry is also well distributed geographically in the United States: 32 states and Puerto Rico have an employment specialization in at least one bioscience subsector. For U.S. metropolitan areas, 222 of 381 have employment in at least one biotechnology sector.[3]

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[1] "**The Value of Bioscience Innovation in Growing Jobs and Improving Quality of Life 2016", https://www.bio.org/sites/default/files/BIO%202016_Report_FINAL_DIGITAL.pdf at 2.**

[2] *Id.*

[3] *Id.*

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 20% since its peak in 1991, due in large part to medicines;

- Among children born during the last 20 years, it is estimated that vaccination and advances in vaccines will prevent more than 730,000 early deaths in the U.S.[4]

C. BIOSCIENCE INNOVATION IMPROVES AGRIGULTURE AND OTHER INDUSTRIES

In addition to health outcome improvements, bioscience advances are found in agriculture and food and industrial biotechnology. For instance:

- In agriculture, genetically engineered crops have been on the market for twenty years. During this time advances in bioscience have enabled farmers to more effectively manage harmful pests and disease thereby increasing crop yields, reducing environmental impacts 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.

- In industrial biotechnology, 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.[5]

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

[4] *Id. 2-3.*
[5] *Id. 6-7.*

innovation environment for biotechnology: human capital, infrastructure for R&D, intellectual property protection, regulatory environment, technology transfer, market and commercial incentives, and legal certainty.[6]

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

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 RDP 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.[7]

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 to society.

While the IP environment in the United States has contributed to 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 products from the United States. In addition improvements in IP would benefit those countries. An OECD study by Cavazos et al, 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.[8]
Studies show that even developing countries obtain economic benefits from increasing their IP

[6] *Building the Bioeconomy 2017*. http://www.pugatch-consilium.com/reports/BIO_2017_report_US.pdf See page 19-39

[7] 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

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

protection.[9] Like in other trade areas, increased standards in IP provide a win-win situation for the United States and other nations around the world.

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.[10] These acts, policies or practices deny or would deny adequate and effective intellectual

[9] See Cepeda, Lippoldt, and Senft, Policy Compliments to the Strengthening of IPRS in Developing Countries, 14, September 2010, accessed at http://www.oecdilibrary.org/fr/trade/policy-complements-to-the-strengthening-of-iprs-in-developing-countries_5km7fmwz85d4-en on January 24, 2011 (Working Paper); Minyuan Zhao, Policy Complements to the Strengthening of IPRS in Developing Countries – China's Intellectual Property Environment: A Firm-Level Perspective, 14 Sep 2010, accessed at http://www.oecd-ilibrary.org/trade/policy-complements-to-the-strengthening-of-iprs-in-developing-countries-china-s-intellectual-propertyenvironment_5km7fmtw4qmv-en;jsessionid=1p4jzo8xww6ep.delta; Lee Branstetter and Kamal Saggi, Intellectual Property Rights, Foreign Direct Investment, and Industrial Development, Oct. 2009, accessed at http://repository.cmu.edu/sds/52/ on January 25, 2011; Lee Branstetter, Raymond Fisman, C. Fritz Foley, and Kamal Saggi, Intellectual Property Rights, Imitation, and Foreign Direct Investment: Theory and Evidence, April 2007, accessed at http://repository.cmu.edu/heinzworks/126/ on January 25, 2011.

[10] Pugatch, Localization Barriers, **http://www.pugatch-consilium.com/reports/Localization%20Paper_US_FINAL.pdf**.

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 the IP and pricing related to new drugs and biologics have long been a source of debate, multilateral institutions are increasingly providing fora to pursue biased work streams that cast innovators and the systems that incentivize innovation as 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. BIO describes below some of these flawed approached that should be prioritized by the U.S. government in its trade-related negotiations with foreign countries and in its dealings with multilateral organizations.

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.

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. In many foreign countries, where the government is responsible for health care costs, industry is under attack to lower prices. 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. In particular, BIO is concerned about such practices by developed economies such as Canada, Japan and 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 to support innovators working to improve health outcomes globally. We provide below brief summaries of negative market-access policies in these countries that have been identified by BIO members. Additional detail can be found in the specific country sections in this submission or in the Special 301 submission of PhRMA.

BIO encourages the United States to place Canada, Japan and Korea on the Priority Watch List to prioritize addressing these practices in the context of ongoing trade negotiations.

Canada

In 2017, Canada proposed regulatory changes to the Patented Medicine Prices Review Board (PMPRB) with a stated goal of ensuring "non-excessive" prices. Key proposals would amend the basket of reference countries used to calculate reimbursement prices by deleting the United States and Switzerland. They also would introduce various new factors to determine whether a price is "excessive," and require manufacturers to report all indirect price reductions. These proposed changes could have a serious negative impact on the value of innovative products and their associated intellectual property rights developed and introduced by U.S. biopharmaceutical companies operating in Canada. BIO understands these changes will be implemented in January 2019.

Japan

In December 2017, the Japanese government approved a drug pricing reform package that contains a number of new pricing efforts that significantly undermine Japan's pro-innovation environment and its efforts to carry its fair share of the costs of global R&D efforts. The eligibility criteria for the new Price Maintenance Premium (PMP) program means that some of American's most innovative pharmaceutical products will now be significantly undervalued. In addition, specific elements of the PMP call into question Japan's commitment to non-discriminatory policies, including "national treatment" principles.

Korea

Korea restricts the prices of innovative medicines by valuing them according to the prices of older medicines or prices in poorer countries. Through these valuation techniques, Korea seeks to benefit from research and development generated to a large degree in the United States without paying its fair share. This approach harms not just the U.S. industry, but also patients around the world by reducing the revenues available to further expand R&D efforts. It is also inconsistent with Korea's commitments under KORUS to value U.S. innovation appropriately to ensure that patent owners can secure reasonable economic rewards free from price distortions. In addition, Korea's pricing policies overtly favor its domestic pharmaceutical industry.

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 (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 and prevent timely patient access to valuable new treatments and cures. 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: Argentina, Brazil, Canada, Chile, China, Peru, India, Indonesia, Thailand, Turkey, Egypt and Peru.

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: Algeria, Argentina, Brazil, China, India, Indonesia, Russia, Thailand, Turkey, Ecuador, Egypt and Mexico.

BIO members urge USTR and other federal agencies to highlight these countries and challenges in the 2018 Special 301 Report and to use all available tools to address and resolve them.

PRIORITY FOREIGN COUNTRY

Malaysia

BIO and its member companies are alarmed by recent 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 on a patented therapeutic product, despite the patent owner's agreement to address related public health concerns through voluntary licenses. The government-use license, effectively a compulsory 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 is expected to have far reaching ramifications for the biopharmaceutical industry.

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 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. The government moved forward on the decision despite a voluntary license offer made by the patent owner, which would address the stated public health concerns while providing patients with quality-assured products in a timely manner.

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.

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. 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 the urgent 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.

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.

PRIORITY WATCH LIST

Argentina

Argentina has expressed interests in encouraging the development of an innovative bio-economy and BIO welcomes the opportunity to partner with the Government of Argentina. However BIO members continue to face a challenging IP environment in Argentina. As such, BIO recommends Argentina remain on the **Priority Watch List**.

Argentina continues to present a significant challenge to the biotechnology industry, particularly with respect to its patent and regulatory data protection regime. Most concerning are persistent patent backlogs, lack of patent term extension, narrow patentability requirements and lack of regulatory data protection. BIO encourages USTR to engage the Macri administration through

the negotiations of the Trade and Investment Framework Agreement (TIFA) and other bilateral means to address these challenges.

Restrictive Patentability Criteria and Patent Prosecution Practices

Argentina has one of the most restrictive IP regimes for obtaining biopharmaceutical and agribiotechnology patents in the world. Argentine Patent Examination Guidelines Disposition No. 73/2013; Joint Resolutions No. 118, 546, 107 of 2012 for biopharmaceutical inventions; and Resolution No. 283/2015 for biotechnology inventions applied to plants or animals introduced higher standards for the examination of patent applications, and restrict as patent eligible subject matter innovations that are essential for the biotech sector. For example, pharmaceutical patents are not available for compositions, dosages, salts, esters and ethers, polymorphs, analogous processes, active metabolites and pro-drugs, enantiomers and selection patents. In addition, the ability to describe and claim an invention using Markush-type claims is severely limited. While TRIPS permits countries to exclude plants and animals from the scope of patentable inventions, Argentina would benefit from allowing such patents as they provide incentives for the introduction of more biotech innovations into Argentina and could incentivize local innovation in these areas.

In addition, Argentina has yet to implement the Patent Cooperation Treaty (PCT), which facilitates the filing and examination of patent applications in more than a hundred member countries. Implementing this widely accepted agreement would be a positive step toward reducing unnecessary expenses and facilitating the procurement of patent protection in Argentina for BIO's members.

Patent Backlog, Patent Term Extension, Regulatory Data Protection

Argentina has over the last 12 months made efforts to reduce its patent backlog. However, the backlog remains a significant problem with no compensating patent term extension or provisional protection. This creates a situation in which inventions remain unprotected from infringers. By the time patents have been granted, the effective term has been severely curtailed due to the resulting delays in the examination process. We understand that the current administration of the National Institute of Industrial Property (INPI) is focused on taking steps to reduce its backlog, but excessive delays persist.

In 2017 the INPI held discussion with the USPTO on the participation of the two offices in the Patent Prosecution Highway (PPH) program. Effective implementation of the PPH program in Argentina would be a very concrete step to resolve the existing backlog while leveraging resources of other PPH partner patent offices. So far, no further steps have been taken by INPI to benefit from the PPH. We look forward to INPI taking further steps in PPH implementation including issuing applicable regulations in order to address the patent backlog.

In addition, Argentina does not provide adequate protection for data submitted in support of marketing authorizations to establish that either agricultural, chemical, pharmaceutical products and/or biotechnology products are safe and effective. Specifically, law 24,766 permits Argentine officials to rely on innovator data to approve generic products as soon as the innovator product is

itself approved. Generic companies in Argentina may also rely on marketing approval of an innovative product in other countries to support their Argentine filing.

Persistent deficiencies in the patent and data protection regime in Argentina deny adequate and effective protection for the intellectual property rights of BIO's members.

Brazil

Although Brazil has made some improvements to its protection of intellectual property over the years, there are still several persistent problems that hinder Brazil from fully achieving a positive IP environment across technology sectors, particularly with respect to the biotechnology sector.[11] In light of the ongoing problems, BIO recommends that USTR place Brazil on the **Priority Watch List.**

Brazil could improve its IP environment by addressing some of the key issues briefly summarized here. Broadening the scope of patent eligible subject matter for biotech inventions would be a welcome improvement. In addition, reducing its major patent backlog, removing the health regulatory agency, ANVISA, from the patent review process, and having strong patent enforcement measures in place Brazil would send a positive signal to investors and innovators that it is serious about attracting investment in this sector.

Biotechnology companies would also greatly benefit from Brazil joining with the U.S. or other countries in harmonization efforts and strongly encourage the expansion of the Patent Prosecution Highway partnership between the Brazilian Patent Office (INPI) and USPTO, so that it is not restricted to the oil and gas sector and, therefore, available to all patent applicants.

Restrictive Patentability Criteria and Patent Prosecution Practices

The INPI has developed patent examination guidelines for biotech inventions across the health, agriculture, energy, and industrial biotech sectors. Although offering some improvements and clarity on INPI positions on patentable subject matter, the guidelines continue to reflect a restrictive approach to defining patent eligible subject matter and have a narrower interpretation of these issues than standards adopted in other innovative countries.

Other INPI resolutions and guidelines that govern the patent prosecution practice present further 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. A restrictive approach to adopting more flexible patent prosecution standards presents challenges to innovative companies that seek patent protection in Brazil. In addition to restrictive patentability criteria and challenging patent prosecution rules that are at odds with global best practices, there are a

[11] For example, this study provides five post-patent law reform bio-medical technology and innovation projects in the state of Sao Paulo that all show how patents incentivized Brazilian entrepreneurs to bring Brazilian biotech innovation to the market. *See* Ryan, Michael P., *Patent Incentives, Technology Markets, and Public-Private Bio-Medical Innovation Networks in Brazil*, World Development Journal 38 (2010).

number of bills before the Brazilian legislature that may negatively affect the IP environment. For example, Bill 139/1999 (5402/2013) seeks to reduce patent term by not allowing for patent term adjustment and Bill 827/2015 and 5557/2016 may significant impact innovative agriculture sector and ability to obtain patent protection for these agriculture innovations.

Finally, in addition to the patent-specific concerns our industry faces, BIO members also do not have any regulatory data protection for pharmaceutical products. This lack of data protection continues to present significant challenges to our sector and signals Brazil's unwillingness to support IP assets.

Patent Backlog

The Brazilian Federal Government has recently supported the INPI in its request to hire more qualified patent examiners in an effort to reduce the enormous patent backlog and in 2017 announced the hiring of dozens of examiners. With more than 200,000 patent applications pending for roughly 270 examiners, this additional support is essential. Furthermore, the Ministry of Development, Industry, and Trade (MDIC) announced in December 2017 that they will be investing R$40 million Brazilian real to modernize the INPI over the course of three years. BIO applauds these moves and encourages that this additional support is used to address the backlog for biotech patent applications.

The backlog problems may be exacerbated however 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.

One potential solution to the patent backlog is through collaboration and harmonization with other foreign IP offices, through programs such as the Patent Prosecution Highway (PPH) that the INPI currently has with the USPTO and with other global patent offices, such as the Japanese Patent Office (JPO). The PPH with USPTO is currently restricted to oil and gas sectors and the PPH with JPO is also restricted to specific sectors that do not include biotechnology. BIO members are hopeful that if PPH with USPTO is revisited that the program be extended to additional sectors, including biotech.

Another potential solution to improve the backlog is by creating an accelerated pathway for obtaining green patents. Although this pathway exists in theory, in practice is still has not yet reached its full potential. BIO members are hopeful that they will be able to file more patents through this accelerated pathway as we continue to innovate in this space.

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 has interpreted this requirement as an obligation to review patentability criteria (novelty, non-obviousness, and utility).

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 that determined that ANVISA's review should be restricted to an analysis of the sanitary risks of the patented product to health.[12]

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, 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 new 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. Therefore, the issue continues to present significant problems to our members, creating delays in the patent examination, and providing unnecessary insecurity with respect to a patent applicant's pending patent application.

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 INPI 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.

[12] Accessed on February 1, 2017 and found at: http://translate.google.com/translate?sl=auto&tl=en&u=http://www.agu.gov.br/sistemas/site/TemplateImagemTextoThumb.aspx?idConteudo%3D153676%26id_site%3D3

In the agricultural biotech space, unclear provisions in the Plant Variety Protection (PVP) Law present challenges for innovators to collect royalty payments on the use of GMO seeds. The issue is based on a supposed conflict between how the Intellectual Property Law and the PVP law afford protections for plant varieties and other plant-related innovations.

Canada

Canada continues to present a number of challenges to BIO's members. Specifically, new pricing policies for patented medicines, the right of appeal in PM(NOC) proceedings, patent term restoration, injunction relief and are highly concerning to BIO's membership. As such, BIO requests that Canada be elevated from the Watch List to the placed on the **Priority Watch List** with an **Out of Cycle Review** to assess the IP environment in Canada. The on-going renegotiation of the North American Free Trade Agreement (NAFTA) presents the opportunity to address these long-standing concerns.

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, on December 2, 2017, Canada's draft Patented Medicines Pricing Regulations were published. The new regulations are expected to cost the innovative biopharmaceutical industry over $3 billion annually. Proposed amendments include removing the United States and Switzerland from the basket of reference countries and to target OECD median prices.

In addition, the regulation would require patentees to report price and revenues, net of all price adjustments (e.g., confidential rebates). Specifically, the proposal would require 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 proposal includes 3 new 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 a publicly funded Canadian organization and there would be an obligation on patentees to submit most recent cost-utility analyses, but that there would be no obligation on the patentee to prepare a cost-utility analysis if one does not exist. However, no 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 that 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 that 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.

Right of Appeal in PM(NOC) Proceedings

The PM(NOC) regulations create a process and a forum to resolve patent infringement issues and validity between generic and brand companies as part of the early working regulatory exception to patent infringement in the Patent Act (Section 55.2). However, practically, the regulations provide unequal appeal rights in favor of the generic company. A generic company can appeal the decision in a Notice of Compliance proceeding, but an innovator cannot. Any changes to rules surrounding PM(NOC) proceedings must acknowledge that even with a patent infringement action under the current procedure, complete redress remains illusory.

Changes to the PM(NOC) regulations proposed as part of CETA implementations (discussed below) also go beyond the terms of that agreement and unnecessarily introduce greater legal uncertainty into the patent litigation regime in Canada. Changes to the regulations have been far beyond what would be necessary to implement the CETA obligation to provide both innovators and generics with "equivalent and effective" rights of appeal. Instead, the new regulations introduce significantly more procedural complexity, while retaining the same 24-month statutory stay, raising significant questions about the ability to obtain effective enforcement – including effective use of the appeal rights introduced – under this system.

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 effectiveness of the reforms will be determined in regulations that are still being formulated.

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.

In particular, contrary to existing practices, the proposed CSPs are subject to a "manufacture for export" exception and therefore do not convey the same rights as the underlying patent – therefore not fulfilling the underlying purpose of restoring patent term lost due to marketing approval delays in the Canadian system. Moreover, the proposed rules for CSPs appear to restrict availability in ways that could make them of little value. 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.

Promise Doctrine

In June 2017, the Supreme Court of Canada issued its highly anticipated decision ruling that the "promise doctrine" is not the correct method to determine whether the utility requirement in the Patent Act. Rather, the correct approach is to first identify the subject-matter of the invention

as claimed in the patent, and then ask whether that subject-matter is useful. [13] BIO and its members welcome this decision and will follow its application in future cases.

Chile

Due to unresolved IP issues in Chile 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, and other general patentability problems BIO encourages that Chile remain on the **Priority Watch List**.

Restrictive Patentability Criteria and Patent Prosecution Practices

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.

In addition, 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.

Some members have encountered difficulty obtaining claims addressing dosage regimens (i.e., where drugs are administered at a specific dose or in combination with other drugs). Patentability of claims should be analyzed based on all of the elements. In this sense, there is no

[13] *AstraZeneca v Apotex*, 2017 SCC 36 (June 30, 2017)

legal grounds to objecting to the dosage element; there should not be an assumption of non-patentability as there currently appears to be.

Enforcement

Additionally, 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

For reasons provided in the following paragraphs, BIO requests that China be placed on the **Priority Watch List**.

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 Food and Drug Administration (CFDA), 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 State Intellectual Property Office (SIPO) 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 CFDA's proposal to provide six, ten, and ten 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.

Onerous regulatory requirements or standards that effectively act as localization barriers to trade can compromise the global biopharmaceutical innovation ecosystem, and create economic inefficiencies as well as unnecessary burdens for enterprises. In this regard, BIO welcomes the announcement by CFDA in 2017 to accept overseas clinical trial data to support drug registration in China. Such policies, effectively implemented, would streamline and accelerate the drug evaluation and approval process in China and improve patient access. However, localized testing requirements in China, such as the biologics testing requirement and quality testing of imported commercial products, continue to add unnecessary burden and delay time-to-market of innovative therapies. Furthermore, China's clinical research requirements involving bio-samples and sampling materials, under the management of the Ministry of Science and Technology, restrict cross-border transport of materials and data for clinical studies and limit their

applicability for future research. Finally, BIO continues to support harmonization of China's Pharmacopeia (ChP) requirements with international standards accepted by other regulators. In some instances, the ChP requirements, as applied, create conditions that favor domestic manufacturers and can result in unnecessary risks in the global drug supply chain.

Restrictive Patentability Criteria

Our companies have reported that SIPO 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. 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 urges USTR and other US Agencies to work with China to ensure effective implementation of rules related to consideration of supplemental data.

In biotechnology applications, it appears that SIPO 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.

Patent Term Extensions

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 SIPO and regulatory review delays at the China Food and Drug Administration (CFDA) 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.

BIO is encourage by the joint announcement by the General Office of the Communist Party of China and the State Council in October, 2017, proposing a pilot patent term extension for

selective pharmaceutical products. However, details of the proposal, as well as implementation timeline, remains unclear.

Genetic Resource Disclosure Requirements

China enacted the Third Patent Law Amendments in December 2008. The amendments entered into force in October 2009. BIO's members are concerned that Article 5 of the Chinese 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." 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.

Further, amendments to Article 26 of the patent law require 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 amendments 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.

In February 2016, China's Ministry of Science and Technology released the proposed Regulation on Human Genetic Resources for public comment. BIO is concerned that the draft regulation defines "genetic resource" to include "data and other information" resulting from human genetic resources. Further clarification is also needed on certain provisions in the proposed regulation, including ownership requirements, potential restrictions on procurement, and collection activities that would exclude foreign funded legal entities.

Compulsory Licensing

The amendments to Articles 48 to 52 of China's patent law provide changes with respect to compulsory licensing of inventions. BIO urges SIPO to clarify what constitutes inadequate working in China and should state that clinical and/or preclinical works related to getting CFDA approval should be considered adequate working in China. In addition clarification of the events

that would trigger compulsory licensing, as well as the scope and duration of the licenses granted, could be helpful.

Effective Patent Enforcement

In comments provided at the request of the United States Patent and Trademark Office BIO's identified[14], several issues that make it difficult to enforce a patent in China mainly involving the Courts. Patent enforcement could be improved if BIO's suggestions, summarized below, are addressed.

Chinese law 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). BIO believes 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.

CFDA, in the current Provision for Drug Registration Administration, does provide a basic mechanism that require patent notification by patentees and the submission to CFDA of "statement of non-infringement" in cases where another party holds a valid patent and allows generic applicants to submit their application no earlier than 2 years before the expiry of the patent. However, CFDA has not made the statements publicly available. BIO considers the current system fairly ineffective in preventing the regulatory approval and sale of infringing drugs in China. More concerning is the revised draft Provision for Drug Registration Administration have proposed to remove significant portions of the basic mechanism and may further erode patent enforcement.

In 2017, CFDA 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 CFDA in cases where another party holds a valid patent.

Even when our innovator company wins an infringement suit, damages are insufficient to cover the true nature of the loss. China provides statutory compensation for infringement, which is minimal and does not consider sales outside of China. When combined with the inability to get preliminary injunctions, low damages means that infringement is encouraged by China's system.

Price Undertaking as Regulatory Requirement

China's State Council Opinion 2015 No. 44 includes a provision stating that companies seeking new drug registration should pledge that its product's sale price in China's market is no higher than prices in the manufacturing country or in China's surrounding markets. In April, 2016, CFDA began drafting a measure to implement the State Council Opinion that would effectively

[14] See http://www.bio.org/advocacy/amicus-brief/china-patent-enforcement-comments-uspto

require drug manufacturers to commit to a drug price ceiling in order to receive regulatory approval in China. The implementing measure has not been finalized nor released in draft form for public notice-and-comment at time of writing. BIO has significant concerns with regard to CFDA's proposal, as it would create serious market access barriers for U.S. companies and potentially delay the introduction of critically-needed drugs to China. BIO firmly supports distinct processes to: (1) asses the clinical safety and efficacy of drugs and biologics; and (2) establish pricing and/or reimbursement requirements for these products. Maintaining regulatory assessments that are independent of pricing considerations is crucial to ensuring that drugs and biologics reaching the market are evaluated objectively against evidence-based clinical and scientific standards for safety and efficacy. This is in contrast with the type of information that forms the basis for pricing decision. Furthermore, linking regulatory approval with pricing decisions would be inconsistent with international, science-based regulatory standards. China's drug pricing authorities consist of the National Development and Reform Commission (NDRC), the Ministry of Human Resources and Social Security (MOHRSS), and the National Health and Family Planning Commission (NHFPC), and their role in the implementation of this State Council Opinion remains unclear.

At the 2016 U.S.-China JCCT in Washington, DC, China agreed that as it implemented the State Council Opinion, it would: (1) not link the pricing pledge to drug regulatory evaluation and approval; and (2) not require specific pricing information. BIO applauds this outcome and requests USTR to ensure the full implementation of the JCCT outcome to so that the drug evaluation and approval process would be effectively and administratively delinked from drug pricing decisions and policies. If CFDA's proposal is put in place, the policy could have serious distorting effects on the market, which may adversely impact innovation in the global biopharmaceutical industry.

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 manufacturers 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. At the 2014 U.S-China Strategic and Economic Dialogue, China agreed, during the process of revising the Drug Administration Law, to consider amendments requiring regulatory control of the manufacturers of bulk chemicals that can be used as APIs, including "export only" producers and distributors. BIO requests USTR to continue to promote more effective policy framework and enforcement directed to combat the manufacturing and distribution of precursor chemicals and counterfeit medicines in China.

Proposed 2017 IP Reforms

As noted above, China proposed a series of reforms in 2017, including 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. If effectively implemented, these reforms could introduce significant improvements to the Chinese IP system. The proposed policies would, among other things: (i) Require submission of a declaration that lists any relevant patents at the time of an application for drug registration; (ii) Notify patentees regarding non-infringement within 20 days of drug registration application; (iii) Create a 24-month stay period for approving generic/biosimilar application; (iv) Establish a list of drugs approved in China (i.e., "China Orange Book"; and (v) Provide data exclusivity for the following: 6 years for innovative drugs, 10 years for innovative orphan/pediatric drugs, 3 years for improved orphan/pediatric drugs, and 10 years for innovative biologics.

As noted, these draft provisions are yet to be implemented, and numerous questions remain, including the details regarding the patent listing process (e.g., types of patents for listing, availability to the public, etc.), certification statement (e.g., would it be similar to the Paragraphs I-IV Certification in the U.S.),the stay mechanism (e.g., what triggers the "stay" process), and how the regulatory data protection will be calculated if a product is filed in China after the one-year window, as required by the CFDA proposal.

On October 8, 2017, the General Office of the Central Committee of the Communist Party of China and the State Council issued the "Opinion on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices" (the "Opinion"). The Opinion provides guidance on various regulatory policies with the intent to continue reform of the drug evaluation and approval system and to encourage innovation – including expedited regulatory pathways for innovative drugs, clinical trial requirements, and the

marketing authorization holder (MAH) system. However, BIO is concerned that the Opinion appears to take a more ambiguous position with regard to patent linkage and RDP. For example, while Circular 55 proposes to establish a patent linkage system, the Opinion instructs the ministries to "explore" the establishment of a patent linkage system. In addition, the Opinion leaves out certain critical details, such as the number of years of RDP for new biologics, orphans and pediatric medicines.

At time of writing, China is finalizing the Fourth Amendment to the Patent Law, and, in order to effectively implement the patent linkage system proposed by CFDA in Circular 55, the appropriate revisions would need to be added to the Patent Law to allow a patent-holder to file an infringement suit and to ensure that patent disputes may be resolved prior to market entry by follow-on biopharmaceutical products. However, the Opinion did not provide guidance on amending the Patent Law, which could raise issues about the ease with which innovators would be able to file cases to initiate the stay.

Regarding RDP, BIO is concerned with the proposal under CFDA's Circular 55 to require companies to initiate a marketing approval application process in China within one year of approval in the U.S., EU, or Japan in order to benefit from the full proposed RDP terms. 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 a punitive mechanism. Moreover, 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 window requirement.

BIO is closely monitoring the revisions to the Drug Administration Law (DAL), the Provisions for Drug Registration (DRR), and, as appropriate, the Regulation for the Implementation of the DAL, to ensure the proposed policy revisions are transparently and expeditiously implemented in a manner that provides for robust and effective IP protection for U.S. biopharmaceutical companies. It is important to ensure the revisions take into account industry recommendations for best practices and do not discriminate against foreign biopharmaceutical companies, including SMEs.

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 and government initiatives that put IP rights at risk raise a number of concerns for BIO's members. In light of these concerns, BIO requests that Colombia 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 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 were recently the subject of significant price reductions in Colombia 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.

The continued threat faced by BIO membership of compulsory licenses in Colombia has concerned BIO's membership considerably. Colombia will compromise the integrity of its intellectual property regime if it proceeds with these measures, thereby undermining the introduction of future scientific innovations.

Patentability

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 deny 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 of biosimilar marketing approvals are pending.

India

In May 2016, India announced a new National Intellectual Property Rights (IPR).[15] That policy document recognizes the economic and socio-cultural benefits that a strong IP regime could bring to India through economic growth, employment, and a vibrant R&D environment. BIO will welcome India's plans to implement the National IPR Policy that would improve the incentives for innovators and innovation in India through improved intellectual property protections. BIO also appreciates the opportunities it has been afforded to engage with the Government of India as it considers its innovation policy environment. BIO supports the Modi Administration's efforts to create a world-class IP environment for innovation in India, and urges India to use the new IPR Policy as a basis for taking steps that address attributes of its IPR regime that continue to hinder the IPR environment for BIO members. BIO also notes the strong and independent court system for enforcement of IP in India and the improvements that are being made in this area. While it is a valiant effort, however, the text does not address the fundamental weaknesses in India's IP framework, notably for biopharmaceuticals.

Although long-standing problems with India's IPR regime for BIO members persist (and are summarized in the following paragraphs) in recognition of India's improved willingness to engage with the U.S. Government and BIO on issues associated with its IPR environment and some progress in terms of expediting patent approval processes to reduce pendency rates and

[15] Department of Industrial Policy and Promotion, "National Intellectual Property Rights Policy," May 12, 2016, available at http://dipp.gov.in/English/Schemes/Intellectual_Property_Rights/National_IPR_Policy_08.08.2016.pdf (last visited Oct. 27, 2016).

implementing training programs to enhance enforcement, **BIO requests that USTR place India on the Priority Watch List.** Given the list of outstanding concerns with regards to IPR in India, as outlined below, we believe that an OCR will give the USTR an appropriate opportunity for dialogue with the Government of India. It is our hope that through such dialogue, the two governments can discuss differences in an amicable manner and bring India into conformance with international standards for IPR.

Restrictive Patentability Criteria

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.

The National IPR Policy mentions attaining "strong and effective IPR laws"[16], with steps such as by reviewing existing Indian IP laws to update/improve them or to remove anomalies and inconsistencies, in consultation with stakeholders.[17] Section 3(d) of India's IP laws would directly benefit from such a review to remove the existing "anomalies and inconsistencies" in the examination of pharmaceutical patents.

India excludes from patentable subject matter method of treatment claims. While TRIPS Article 27.3 allows member states to exclude method of treatment claims, pursuing that course may not be in India's best interests. Other patent offices that prohibit method claims (such as the European Patent Office and the State Intellectual Property Office (SIPO) in China) allow claims for the "use of compound X in preparation of a medicament for treating disease Y" or "compound X for use in treating disease Y." BIO urges India to consider adopting a similar, more flexible approach to such method innovations.

The Indian patent office has denied or revoked patents on a number of innovations that most other countries have granted patents on. BIO members believe these anomalous outcomes result from inconsistent application of conventional patentability criteria. BIO representatives have 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. Specific cases

[16] Objective 3, National IPR Policy, May 2016.

[17] See Objective 3, Step 3.1, National IPR Policy, May 2016.

that BIO members suggest India review in evaluating the Guidelines and their application are provided in the footnote accompanying this text.[18]

The lack of consistent adherence to patent rules and procedures between the four regional patent offices creates problems. U.S. companies in India have reported filing in separate regional patent offices and getting opposite results. Increased training on patentability criteria would help alleviate some of the disparities that our companies face on a regular basis. The revised guidelines on search and examination of patent applications should assist in this matter. In addition, improved transparency would help guide future prosecution.

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 has not implemented any meaningful protection for the data that must be generated to prove that pharmaceutical and agricultural chemical products are safe and effective. 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

[18] The Indian Intellectual Property Appellate Board (IPAB) has revoked several pharmaceutical patents in post-grant opposition proceedings in the last few years including patents protecting Sutent, Pegasys, Ganfort, Combigan, and Renadyl. In addition, IPAB denied an application for a method patent protecting Glyphosate that increases climate resilience in plants. In March 2015, Boehringer Ingelheim's patent for Spiriva (Tiotropium Bromide Monohydrate) was revoked by the Patent Office (PO) as a result of a post-grant opposition filed by Cipla Limited. In May 2016, the PO reversed its earlier decision to reject Gilead's patent application for Sofosbuvir (Sovaldi) after remand from the Delhi High Court to review the matter afresh. Again in November 2016, the PO rejected a patent application by The Regents of the University of California relating to Enzalutamide (Xtandi) opposed in pre-grant oppositions filed by Fresenius Kabi Oncology Limited; BDR Pharmaceutical International Pvt. Ltd.; and the Indian Pharmaceutical Alliance.

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.

Effective Patent Enforcement

The early reliance of generic companies on innovator's data is compounded by the absence of any mechanisms for resolving patent disputes prior to market entry of a generic product. BIO members urge India to provide mechanisms that would facilitate initiation and possible resolution of patent disputes before follow-on products enter the market. In addition, the marketing approval authority should be made aware of any existing patents on a product that is being considered for approval. Currently, marketing approval does not require disclosure of the patent status of a New Drug.

Compulsory Licensing

Provisions of The Indian Patents Act (Act) provide broad authority for the grant of compulsory licenses, including authority on the basis that the patented products are not "worked" (manufactured) in India. That authority was relied upon in 2012 when a compulsory license was granted to Natco Pharma on Bayer's Sorafenib (Nexavar) a product that treats liver and kidney cancer.

The Controller interpreted the working requirement to require local manufacturing in India. While the subsequent IPAB decision left it unclear whether local manufacture was required by finding that Bayer had not "worked" invention on a commercial scale "even if 'import' alone would satisfy the working condition",[19] the Controller's interpretation of the final ground is a clear violation of TRIPS Article 27.1 requiring nondiscrimination based on "the place of invention, the field of technology and whether products are imported or locally produced." In July 2014, the Bombay High Court denied Bayer's appeal from the IPAB leaving this area of the law unclear for innovators. Several attempts to secure CLs were made after the Sorafenib decision but no additional CLs have yet been granted. However, the broad and ambiguous contours of India's laws pertaining to this topic remain a concern.

In the National Pharma Policy 2017, reference is made of usage of Compulsory licensing or Paragraph 19 to control prices for patented products. BIO is concerned that draft NPP 2017 proposes to use CL's as a mechanism for price control of patented drugs. This is against the principles of the patent laws as well as against India's WTO TRIPS obligations. Further, same paragraph of the draft policy mentions that Para 19 of DPCO 2013 is one of the suggested methods of price control of patented drugs. This too is a matter of concern as this would be a regressive step as well as not in consonance with Government of India's stated direction.

BIO members are also concerned about the non-transparent manner in which the Ministry of Agriculture (MoA) issued Gazette Notification No. 1236 dated May 18, 2016, prescribing licensing guidelines and formats for GM Technology Agreements. The notification prohibited the licensor of an approved GM technology to refuse grant of a license to any eligible seed company wanting to incorporate it into its own hybrids or varieties that have the practical effect

[19] Bayer Corp. vs Union of India, OA/35/2012/PT/MUM (para 46)

of a compulsory license. We hope that the MoA involves all stakeholders before finalizing the Guidelines.

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 of approximately 5 years.

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 abolished or severely curtailed to better reflect international practice. The ability of third parties to submit references prior to patent grant provides sufficient opportunity to weed out applications that do not meet novelty and inventive step requirements; and should be the preferred method of challenge pre-grant. All of these make the whole process unnecessarily expensive and time consuming.

The Patent Office requires all patentees must submit a yearly "statement of working" that proves that the patentee is exploiting its invention in India.[20] 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 a USFDA "clinical hold"). Additionally, the biotechnology industry requires long-term development and investment, which results in biotech products being commercialized much more than three years after patent grant. This requirement of Indian law should be reviewed and adjusted to account for the realities of biotechnology R&D realities.

A final issue involves the administrative burden of first filing in India for inventions made by Indian residents or seek permission to first file application abroad. This process poses hurdles in efficient patent application filing, especially when the patent applicant is a non-Indian entity that has joint inventions with Indian residents and institutions. India should consider accepting first

[20] http://www.ipindia.nic.in/iponew/publicNotice_21January2015.pdf

filing in the country where research or product development is conducted for joint inventions or in the country where the patent applicant is located.

Indonesia

In 2016 Indonesia amended its patent law in ways that could raise significant concern among BIO members if implementation is not structured carefully. BIO appreciates the government's decision to delay implementation to allow for further consideration of the best pathway forward. We look forward to further dialogue with the government as it develops its implementing regulations. BIO's concerns for specific provisions of the new patent law are summarized below.

For reasons provided below, BIO urges USTR to place Indonesia on the **Priority Watch List**.

Restrictive Patentability Criteria

The recently revised Patent Law precludes patents on new uses and establishes an additional patentability criteria 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 particular 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 revised 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.

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 recently amended 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.

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.

Japan

BIO recognizes Japan's continued efforts to reward innovation in its regulatory framework and to improve efficiency in its drug evaluation and approval system. However, BIO member companies are concerned that the new drug pricing reform package, approved by the Central Social Insurance Medical Council (Chuikyo) of the Ministry of Health, Labour and Welfare (MHLW) in December 2017, will undermine the tremendous progress made by relevant authorities to exalt Japan as a leading market in the global biotech ecosystem. Notably, the revisions to the Price Maintenance Premium (PMP) program, as well as other changes to the pricing rules, may 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.

BIO recommend USTR place Japan on the **Priority Watch List**

Technology Localization and Impact on Small and Medium Sized Enterprises

Under the new 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 70% of the global clinical pipeline and 84% of all Orphan-designated products in development[21]. As the eligible SMEs lack the necessary resources and pipeline to satisfy the localization requirements, exclusion from the full pricing premium may encourage American 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.

Additional Issues of Concern

In addition to localization requirements that effectively exclude SMEs from the full pricing premium, BIO member companies are concerned with the narrowing cope of the PMP program, which is expected to reduce the number of total innovative products that would be eligible for the program. Furthermore, BIO member companies were concerned with the lack of transparency, due process, and stakeholder engagement as the Japanese government finalized its changes to the pricing rules, including "annual repricing" and "optimal use guidelines." BIO urges 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.

Russia

BIO members continue to experience challenging problems in Russia that lead BIO to request that USTR place Russia on the **Priority Watch List**.

Preliminary Injunctions

In Russia, 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 at the end of successful litigation.

Procurement Processes

On December 5, 2016, the Ministry of Health put forward draft regulations to restrict identifying criteria for medicines in the state procurement process; dosage form, treatment method or other characteristics would no longer determine eligibility, only an International Nonproprietary Name

[21] Emerging Therapeutic Company Investment and Deal Trends, David Thomas and Chad Wessel. BIO Industry Analysis. 2016.

(INN) would be required. This would further undermine incentives to innovate and the quality, safety and efficacy of treatments available to patients.

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 allow 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 (4+2 and 3+3). Without adequate enforcement mechanisms (noted above), 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 FL 61 will further weaken RDP in Russia.

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.

Compulsory Licenses

More recently, senior Russian government officials have indicated a desire to more systematically use compulsory licensing to address access and pricing. Currently compulsory licensing is technically permitted under article 1362 of the Civil Code, but this can only be done in the interest of national defense. Despite this, the FAS is seeking expanded compulsory licensing provisions, which would mean pharmaceutical companies could lose their exclusive rights to certain products. A test case was filed by Russian firm Nativ, for the local production of generic versions of an innovator multiple myeloma drug. This raises 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, particularly since FAS has not put forward clear criteria or process for determining suitable use. We urge the USG to monitor this situation closely and to encourage their Russian counterparts to avoid misuse of this tool, which should be used only in extraordinary circumstances as a last resort to address health-related needs.

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 16th 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.

Counterfeit Medicines

With respect to counterfeit medicines, the Russian Parliament adopted new legislation aimed at criminalizing (1) counterfeiting and (2) distribution of counterfeited and falsified medicines, falsified biologically active supplements, unregistered medicines, and medical devices. The law became effective in January 2015, and reflects the serious public health concerns associated with the distribution of fake and potentially dangerous medicines to patients. BIO's member companies are encouraged by this legislation, but close monitoring will be necessary to ensure enforcement, as well as active participation in discussions around developing an effective tracking system for medicines in the EAEU.

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 in Saudi Arabia and recommends USTR place Saudi Arabia on the **Priority Watch List.**

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 deal with the situation.

This follows the 2016 violation of regulatory data protection involving an innovative hepatitis C medicine. The Saudi Food and Drug Authority (SFDA) granted marketing authorization and set prices for two unauthorized generic copies of the medicine to two local companies, apparently relying on test data submitted by the innovator. Compounding the problem of infringement, the Ministry of Health proceeded with procurement of one of the infringing products despite

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

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." [22]

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—deflecting from the substance of the complaint.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), however, imposes more than a non-disclosure obligation. Rather, 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.

Issues of patent infringement and the lack of regulatory data protection enforcement are greatly concerning in this G-20 economy, as was the Saudi Governments refusal to engage the industry or affected companies for many months as the crisis deepened. This negative development for

[22] 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.

Saudi Arabia and runs counter to the goals and general principles of both the Vision 2030 and National Transformation Program 2020.

South Korea

BIO requests that USTR place South Korea on the **Priority Watch List** for pricing and reimbursement policies that undervalue innovative biopharmaceutical products, deficiencies in their intellectual property system, and failure to adequately implement their free trade obligations. As USTR engages South Korea in the context of KORUS, we request the following issues be prioritized.

Pricing and Reimbursement Policies

BIO member companies are concerned with the lack of robust enforcement 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".

Burdensome Data Requirements for Patent Applications

South Korea's data requirement for patent applications raises concerns similar to those noted in respect to China. South Korea should 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.

South Korean patent law requires that for a medicinal use invention, the original specification (i.e., the international application in most cases) must contain quantitative pharmacological data for at least one specific active ingredient, unless the pharmacological mechanism was established prior to the filing date of the patent application.[23] If such pharmacological data is not included in the original specification, the application will be rejected (or the granted patent subsequently invalidated). Moreover, South Korea does not permit the applicant or patent owner to submit such data in response to an office action or post-issue invalidation proceeding.[24] If an invention

[23] This requirement has been strictly interpreted by the courts and the Korean Patent Office: Disclosing the IC50 range for a group of compounds without specifying which compound provides which value is not sufficient to satisfy the data requirement (see voluminous case law on this subject, including *In re Allergan* (Supreme Court Case 99 Hu 2143; November 27, 2001)).

[24] Later addition of such data to the specification constitutes adding new matter and is not allowed [see, e.g., In re Pfizer (Supreme Court Case 2000 Hu 2965; November 30, 2001)]. However, if the original specification contains

is based on a finding of little or no side effects or toxicity, South Korean patent law still requires that data supporting such effects be contained in the original specification.

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 requirements 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 have reported problems with 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 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 9 month 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. These practices add uncertainty to IP protections for both innovators and generic manufacturers and are inconsistent with Korea's obligations under the FTA.

In July 2014, the MFDS announced its revised, proposed draft legislation for the Korean patent-regulatory approval linkage system. Notably, favorable changes regarding several issues are contained in the proposal. In particular, the phrase "need to prevent significant damage" has been deleted from the provisions regarding the stay mechanism, and it now appears the MFDS is very likely to grant stays on the basis of the actual patent claims in view of the MFDS's position. Further, the stay mechanism appears to be more or less "automatic"; although a patentee's request still would be required, it appears a stay will be granted as long as certain formalities such as the requisite time period or the filing of an enforcement action are met. Overall, the revised draft provides the requirements and procedures for ensuring that market

pharmacological data for at least one compound, it may then be possible to submit data for other compounds in response to an office action that states that the claims are not adequately supported by data.

approval of a generic drug would not necessarily facilitate patent infringement would provide a first generic applicant's exclusivity, and reporting of a settlement agreement between the holder of the market approval for the brand drug or the patentee and the applicant for generic approval. However, the revised proposal is not yet approved. In fact, there is an opposition bill that raises significant concerns, which would exclude biopharmaceuticals from the scope of the proposed mechanism and, moreover, includes provisions that may subject innovators to significant damages in cases of good faith enforcement of patents where a patent is determined to be invalid.

Additionally, it is our understanding that the Ministry of Health and Welfare (MOHW) has rejected the proposed amendment to the National Health Insurance Act (NHIA), which would have enabled the Korean Government to recover so-called "improper profits," which occur when an innovator prevents sales of follow-on products through a court injunction (or an automatic stay of regulatory approval of a follow-on version of the innovator's drug).

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 2018, 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. BIO is aware of efforts by the Thai government to develop a biotechnology sector, and appreciates its outreach to the biotechnology industry. However, policies such as compulsory licensing will only serve to drive biotech investment away from Thailand.

The Thai Government's defense of compulsory licenses for drugs that treat non-communicable diseases (such as cancer, stroke, or myocardial infarction) is of particular 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 prove 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. This is particularly harmful in the biotech sector as biotech drug development can cost a billion dollars or more and can take more than a decade. Without assurance of recoupment of investment, and in particular in these difficult economic times, biotechnology research and development will diminish.

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 polices 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 strongly 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 is related 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. The government refers to Article 5A paragraph 4 of the Paris Convention as a ground for this provision. However, this paragraph in the Paris Convention does not refer to "satisfaction of domestic market demand," but to "insufficient use of the invention." We believe "satisfaction of national market demand" directly refers to a specific amount of provision of patented product to the market and if this amount is not met, it will be possible to deem it as a ground for compulsory license. On the other hand, the term of "insufficient use" does not refer to a pre-determined specific amount.

Regulatory Delays

A necessary step in European Union Accession involves Supplementary Protection Certificates (SPC) that compensate for regulatory delay. Turkey should pursue compliance with the European Union by providing up to five years of additional protection through SPCs for patented products and six additional months for approved pediatric studies.

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. In the first phase, imported products that have at least 3 locally manufactured equivalents with a +50% market share are due to be delisted in Q1 2018 unless they are locally produced. In the announced second phase, the threshold for market share of locally manufactured equivalents is decreased to +10%, hence those imported products that have at least 2 locally manufactured equivalents with a +10% market share are targeted to be delisted if the companies selling them do not commit to produce these locally.

Delisting of specified imported medicines from the reimbursement scheme on the grounds that the importer company chooses not to produce it locally is discrimination against imported products and considered a violation of international agreements to which Turkey is a party.

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 and is set to begin in January 2018, 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).[25] A newly implemented, yet poorly defined and nontransparent alternative reimbursement process increases the uncertainty on top of existing challenges.

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 and Turkey to emerge as a globally-competitive economy in medical innovation.

WATCH LIST

Australia

BIO's members have recently faced unique IP challenges in Australia. BIO requests that the U.S. Government monitor the situation and place Australia on the **Watch List**.

Patent Damages Policies

Australia's government has embarked on an unprecedented attack on innovative biopharmaceutical companies by seeking significant litigation damages from companies that

[25] Association of Research Based Pharmaceutical Companies (AIFD) Market Access Survey, 2015

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") caused by 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, when the innovator was ultimately unsuccessful in that litigation. In the first case where the government has intervened under this policy, 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 the Federal Court system through which the innovator s seeking to enforce its patent rights was established by the Australian government and is the means by which patent rights are enforced in Australia. Further, 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 its obligation by seeking to deter 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 unprecedented practice threatens the ability of innovative biopharmaceutical companies to utilize their legal right to enforce their patents, which were examined and granted by the very same government now claiming compensation. 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.

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. The consultation period is now closed and the government has indicated its intention to draft legislation on some of these matters in 2018. More generally, 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 environment, making it difficult for BIO's members to operate in an environment of legal certainty.

Egypt

During 2017, BIO continued regular outreach to Egyptian officials, and notes the willingness of government representatives to engage on policy issues affecting patients, the healthcare system and the innovative life sciences and biopharmaceutical sector in Egypt. In recent years, Egypt has taken some steps to enhance the environment for life science/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 policy-makers/officials have greatly improved. There has been progress in border enforcement and biosimilars regulation. BIO is also aware that a new regulatory frameworks governing clinical research has been drafted, yet another signal that Egypt intends to revitalize and strengthen the sector going forward.

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. 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-engineered plants and animals. In sum, the Egyptian law precludes patenting of a wide range of basic commercial products and processes in the biotechnology industry, discouraging both indigenous and international investment in a sector where Egypt is well-positioned to compete and succeed.

Patent Linkage, Regulatory Data Protection

Egypt also does not provide patent linkage or regulatory data protection, and despite progress in 2017, the approval of new medicines approvals continues in a not fully reformed, overly opaque system. At least one BIO member reported that this negative IP environment has deterred further investment and hiring additional employees in Egypt. BIO urges Egypt to adopt an effective patent linkage system and to extend Regulatory Data Protection for at least 5 years.

Due to these and other market access concerns, BIO requests that USTR continue to engage its Egyptian counterparts to make improvements to patent protection in Egypt and to provide for the eventual adoption of a fully TRIPS-compliant regime in that country.

European Union

BIO members are concerned with the ongoing Incentives Review process aimed at weakening Supplementary Protection Certificates (SPC). As such, BIO recommends USTR place the European Union on the **Watch List**.

SPC rights 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."[26]

SPCs currently provide right-holders the exclusive right to manufacture their approved products, including for purposes of exportation. Being the sole producer and exporter of an IP protected product from the EU market is one of the significant commercial activities through which patent owners derive economic value from their inventions. This exclusive right helps to promote investment in the research, development and production of new medicines in Europe for domestic consumption and for sale abroad.[27] The innovation-enhancing incentives of SPCs would be significantly eroded if the EU export market for high-value innovative therapeutic products were to be systematically distorted in favor of IP-infringing copycat products.

The proposed SPC manufacturing waiver is premised on contentions that it would "create thousands of high-tech jobs in the EU and many new companies." Belief that benefits will flow from eroding SPC rights is based on an academic study by Vicente and Simões, published in the

[26] 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).

[27] European Union R&D Scoreboard, *The 2016 EU Industrial R&D Investment Scoreboard*, EUROPEAN COMMISSION (2016), httpe://iri.jrc.ec.europa.edu/.

Journal of Generic Medicines in 2014.[28] In the article, the writers argue that adopting a manufacturing waiver provision would result in substantial economic gains in the EU.[29]

The magnitude of those estimated benefits and the likelihood they will materialize has been rebutted in publications that the Commission should consider.[30] In addition, the benefits, if any, are likely to be temporary and disproportionately affect the innovative biotechnology sector, as they will result in part from exploitation of a transient technological advantage enjoyed by European biosimilar producers. That advantage might for a short time allow EU biosimilar makers to capture market share from EU biologics innovators during the SPC term. But as the required technological capabilities spread globally to manufacturers in lower-cost regions the advantage held by EU biosimilar manufacturers will erode. Furthermore, the current fragmented, country-based EU enforcement regime, together with borderless nature of the EU's Single Market, would make it impossible to stop the entry onto the EU market of products made in the EU subject to the manufacturing waiver. This would make the SPC regime effectively pointless.

Structural changes to the EU's rights-based regime should not be made to exploit a potential short-term advantage at the risk of longer-term economic gains. Apart from the questionable and time-limited benefits postulated to flow from adopting the proposed manufacturing waiver, the Commission should weigh the costs in possible job loss and economic harm in the EU to the innovative biopharmaceutical sector that are predicted to result from this change. 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.[31]

The current EU intellectual property rights-based incentives framework, including SPCs, has fostered a robust ecosystem of innovation and generic competition within Europe. It protects and encourages the substantial investments made by the EU and others in this transformative technology. Adopting the proposal for a manufacturing waiver during the SPC term would undermine the rights-based framework that has and is making new healthcare solutions available. The EU should not alter its IP framework to facilitate exploitation of short-term technological advantage.

[28] Vicente, V. and Simoes, S. (2014). "Manufacturing and export provisions: Impact on the competitiveness of European pharmaceutical manufacturers and on the creation of jobs in Europe", Journal of Generic Medicines, Vol. 11, Issue 1–2, 21 pp.35–47.
[29] Id. at 35.
[30] Sussell, J. A. et al. (2017). "Reconsidering the economic impact of the EU manufacturing and export provisions", Journal of Generic Medicines, Vol. 13, Issue 2, pp. 73–89.
[31] Pugatch, "Unintended Consequences" 2017 at 3, accessed at: http://www.pugatch-consilium.com/reports/Unintended_Consequences_October_%202017.pdf.

Mexico

BIO recommends that Mexico be placed on the **Watch List** due to continued difficulty in protecting and enforcing intellectual property rights. BIO believes that renegotiation of the North American Free Trade Agreement (NAFTA) provides a good opportunity to address these long standing IPR issues in Mexico.

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 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 and TRIPS.

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

Linkage between the regulatory agency and the patent office only covers patents with 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 (Mexican Sanitary Regulatory Agency) consults IMPI on whether a specific generic infringes on an existing patent.

Singapore

BIO requests that USTR places Singapore on the **Watch List** for deficiencies with respect to patent term extension policies and lack of transparency with respect to Singapore's Health Technology Assessment (HTA) framework. Specifically, BIO recommends that Singapore updates patent term extension policies to compensate for clinical testing and marketing approval processes that are integral to the development of innovative medicines.

Clinical trials represent an integral and indispensable part of the marketing approval process in Singapore. Many developed countries' intellectual property regimes include clinical trials when calculating patent term extension periods (e.g. European Economic Area, Switzerland, Australia, Japan USA, and South Korea). It is therefore important to update patent term extension policies to compensate for clinical testing and marketing approval processes that are integral to the development of innovative medicines. In addition, Singapore effectively exempts from its patent term extension calculations most of the regulatory review process in Singapore. That should be changed and companies should be allowed to recover patent term at least for the time required for the marketing approval process in Singapore.

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 IPR internationally.