By electronic submission

Docket ID: USTR-2016-0026
Chair of the Special 301 Committee
Office of the United States Trade Representative
Washington, D.C.

BIOTECHNOLOGY INNOVATION ORGANIZATION

2017 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 2017 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. patent system, has generated hundreds of drug products, medical diagnostic tests, genetically engineered crops, and other 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]

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:

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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.*

- 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 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]

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[4] *Id. 2-3.*
[5] *Id. 6-7.*
[6] *Building the Bioeconomy 2016*. http://www.pugatch-consilium.com/reports/BIO%202016%20report_US%20size_SP.pdf. See page 17.

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, etc. 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 industries 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 protection.[9] Like in other trade areas, increased standards in IP provide a win-win situation for

[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.
[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

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 around the world. These acts, policies or practices deny or would deny adequate and effective intellectual property protection and/or fair and equitable market access for innovative medicines. 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.

A. Practices that undermine biotechnology innovation

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.

The intellectual property challenges described below are having the most serious 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 (compulsory licensing, and weak patent enforcement) 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.

Compulsory Licensing

Biotechnology innovators support strong national health systems and timely access to quality, safe and effective medicines for patients who need them. Patents 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; particularly when governments and the private sector partner to improve health outcomes.

Some governments, have issued or threatened to issue compulsory licenses (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 only in exceptional circumstances and as a last resort. Decisions should be made on public health grounds through fair and transparent processes that involve participation by all stakeholders and consider all the facts and options.

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 2017 Special 301 Report and to use all available tools to address and resolve them.

PRIORITY WATCH LIST

Algeria

BIO requests that the USTR add Algeria to the **Priority Watch List** for the following reasons:

Regulatory Data Protection

Algeria does not provide regulatory data protection for innovative pharmaceutical products that receive marketing approval. That leaves innovators subject to unfair use of their data that can result in unfair early entry of follow-on products.

National Treatment

Algeria also prohibits imports of virtually all pharmaceutical products that compete with similar products that are manufactured domestically. Pharmaceutical products and active pharmaceutical ingredients (API) that are not locally manufactured are subject to annual import quotas. Such discriminatory prohibitions undermine the ability of companies to compete with imported innovative products. In addition, pricing and reimbursement processes are cumbersome, and

linked to the marketing authorization process, which results in significant delays in product launch.

Recommendation

With continued issues surrounding regulatory data protection and national treatment, BIO recommends USTR add Algeria to the **Priority Watch List**.

Argentina

BIO requests that 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, lack of regulatory data protection and the controversial proposal to undermine the value-capture system and patents in agricultural biotechnology. 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. Argentina has expressed interests in encouraging the development of an innovated bioeconomy and BIO welcomes the opportunity to partner with the Government of Argentina.

Restrictive Patentability Criteria and Patent Prosecution Practices

Argentina has one of the most restrictive IP regimes for obtaining a biopharmaceutical patent in the world. Argentine Patent Examination Guidelines (Join Regulations 118, 546, 107 of 2012) restrict as patentable eligible subject matter innovations that are essential for the biotech sector. In addition, Resolution 283/2015 restricts the patentability of biotechnological inventions, such as plants, plant parts and plant components as well as animals, animal parts and animal components. 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 introduction of biotech innovation into Argentina and could contribute to increased 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 also has a significant patent backlog, with no patent term extension or provisional protection, which creates an environment in which patent applicants have very limited legal recourse against infringers. Thus BIO's members suffer a substantial loss of patent term due to delays in examination. 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 are persistent.

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

Seed Law

An amendment to the Argentina Seeds Law 20,247 (the "Bill") is being discussed at the Argentina National Congress that introduces limitations to the scope of IP rights for agricultural biotechnology inventions contained in a seed. The Bill introduces significant limitations to the scope of the plant variety protection rights regulated in the Argentina Seeds Law 20,247 and the patent rights regulated in the Argentina Patent Law 24,481.

The Bill contradicts fundamental principles provided for in the Argentina Constitution, and International Treaties (i.e. TRIPS and UPOV78) to which Argentina is member. Some of the key limitations are:

(i) Limiting the plant variety protection term and the patent term by eliminating enforceability and royalty collection from a user of the patented invention after three (3) multiplications (yearly uses) from the first authorized use of the patented invention contained in a seed;

(ii) Limiting both plant variety protection rights and patent rights on agricultural biotechnology inventions contained in a seed by prohibiting enforcement against and royalty collection from farmers (a) with annual incomes in excess of three times the higher "*monotributo*" tax category (i.e. USD 200,000), (b) family farmers and (c) farmers that belong to native communities;

(iii) Allowing third party commercial experimentation of agricultural biotechnology inventions contained in a seed and allowing third parties to acquire IP rights on the plant variety containing the patented invention—which is the result of said commercial experimentation—without any remedy available for the patent owner;

(iv) Limiting the right to conclude licensing agreements and negotiate the price based on the value of the agricultural biotechnology inventions contained in the seeds;

(v) Declaring these limits to the plant variety protection rights and patent rights to be issues of Public Order, not allowing the owner of the IP rights any rights to negotiate and not providing any remedy for the unauthorized use of the protected plant variety and the patented agricultural biotechnology invention.

All of these limitations to the plant variety protection rights of the protected plant variety and to the patent rights of the patent owner of the biotechnology invention are provided without any kind of compensation, or right to sue for the same, imply a denial of recognition of the intellectual property rights contained in a seed, and discriminate against the property rights conferred by a patent if they are related to agricultural biotechnology inventions.

BIO is concerned that if this Bill is approved, as written, it will have an undue adverse impact on the scope of the legal and economic rights enjoyed by the holders of plant variety protection rights and patent rights for agricultural biotechnology inventions contained in a seed in Argentina.

Recommendations

A lack of significant progress in the patent regime, data protection, and patent claim scope areas has convinced BIO to request the USTR to maintain Argentina on the **Priority Watch List**. BIO further requests that the USTR utilizes all bilateral and multilateral opportunities, including appropriate WTO committees, to raise concerns regarding agricultural biotechnology patent rights with the Argentine government. Additionally, BIO requests that the USTR creates an IPR action plan that encompasses agricultural biotechnology challenges, including (i) amendments to the Ag-Biotech patentability criteria for the examination of patent applications; (ii) amendments to the Argentina Seeds Law; (iii) limitations to the scope of patent rights; and, (iv) enforcement of patent rights.

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 agenda across technology sectors, particularly with respect to the biotechnology sector.[10] 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 introduced below. For example, 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 regulatory authority ANVISA from the patent review process, and having strong patent enforcement measures in place for patent holders to benefit from their granted patent could send a positive signal to investors and innovators that Brazil is a country that is serious about attracting investment in this sector.

Biotechnology companies would also greatly benefit from any possibility of Brazil joining with the U.S. or other countries in harmonization efforts and strongly encourages 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

[10] 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).

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 other internationally adopted standards from 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 to 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 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, although not a specific patent prosecution matter, it is worth noting that 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. BIO applauds these moves and encourages that additional support is granted. Approximately more than 200,000 patent applications are pending for roughly 270 examiners and, therefore, BIO hopes that further improvements are made in order to address these significant resource gaps.

The problems of the backlog may be exacerbated if Bill 139/1999 (5402/2013) before the Brazilian legislature is passed. The bill seeks to reduce patent term by not allowing for patent term adjustment, essentially removing the guarantee that a patent will have at least 10 years of patent term. If patent applicants are left with only 20 years of patent term from filing date, they 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. The PPH is currently restricted to oil and gas sectors and BIO members are hopeful that if PPH 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, nonobviousness, 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.[11]

Interministerial guidance has opined on this issue and have attempted to iron out procedural process for the exchange of files between ANVISA and INPI. For example, pharmaceutical patent applications are now, oddly, sent first to ANVISA for an assessment and only if the patent application refers to a "strategic" drug will ANVISA carry out a patentability assessment. The list of "strategic" drugs can be updated on an ad hoc basis at any moment without any public consultation. 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.

In the agricultural biotech space, unclear provisions in the Plant Variety Protection (PVP) Law presents challenges for innovators to receive royalty payments on the use of GMO seeds based on a supposed conflict between the IP Law and the PVP law regarding the protection of plants and plant-relate

Recommendations

For all of these reasons, BIO requests that Brazil be placed on the **Priority Watch List,** until more meaningful improvements are made to their IP legal and regulatory framework**.**

[11] 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

Canada

Canada continues to present challenges to the intellectual property rights of BIO's members, namely the Patent Utility Doctrine, patent term restoration, injunction relief and the right of appeal in PM(NOC) proceedings. 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. Should the U.S. government engage Canada on the renegotiation of the North American Free Trade Agreement (NAFTA), addressing these long standing barriers and intellectual property protection is essential to BIO and its members.

Canadian Utility Requirements

One of the most significant threats to biopharmaceutical innovation in Canada emanates from the burdensome Canadian standard for patentable utility. Canada's approach to patent utility discriminates against the biopharmaceutical industry, creates significant uncertainty in the patenting process, and is inconsistent with Canada's international obligations.

The Canadian requirement that a patent demonstrate or disclose the basis of a sound prediction for the subjectively-construed "promise" of utility in the application at the time of filing is out of step with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the North America Free Trade Agreement (NAFTA) and the Patent Cooperation Treaty (PCT). Canada's utility requirements also stand in sharp contrast to practice in the United States, which merely requires a specific and practical utility; for pharmaceutical inventions, in practice this standard is met by disclosing a specific disease against which the claimed invention is useful.

Since 2005, these onerous utility requirements, which are unique to Canada, have caused approximately 25 patents for plainly useful pharmaceuticals to be invalidated for inutility.[12] Utility *in fact* is all that is required by the TRIPS Agreement and NAFTA. Under Canada's burdensome utility test, however, there is substantial uncertainty as to how much work must be performed and disclosed when a patent application is filed. Further, it is nearly impossible to predict how a court will interpret the "promise" of the patent in litigation that occurs many years after the filing of an application and the grant of the initial patent.

The so-called "promise" of the patent is construed by the court on an entirely subjective basis and with reference to extrinsic factors beyond the claims of the patent.[13] This subjective construction of the patent is then used to justify entirely unrealistic and impractical evidentiary demands. For example, Canadian courts have required evidence of long-term clinical studies in patients in order to find utility simply because a drug can be used to treat a chronic condition.[14]

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[12] http://www.canadianpatentutility.org/sites/default/files/uploads/canadian_federal_court_decisions_revoking_pharmaceutical_patents_based_on_inutility_5.2.16.pdf.)

[13] See *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197, 85 CPR (4th) 413 [*Zyprexa FCA*] at paragraph 93, leave to appeal to SCC refused [2010] SCCA No 377.

[14] See *Strattera FCA*, (at paragraph 19, quoting the trial judge: "In the case of the '735 Patent, the inventors claimed a new use for atomoxetine to effectively treat humans with ADHD. What is implicit in this promise is that atomoxetine will work in the longer term."). See also *Olanzapine*, (at paragraph 232: "The chronic nature of the

As discussed below, BIO member companies typically must file their patent applications early in the development process, and in many cases before clinically conclusive data exists. As such, in many cases the practical effect of Canada's "promise doctrine" may be a bar to patentability for any drug capable of use in the treatment of a chronic condition.

These judicial decisions on a patent's "promise" and the Canadian policies that require the "promised" utility to be demonstrated or "soundly predicted" at the time of filing have had a discriminatory impact on the biopharmaceutical sector, particularly given the unique lifecycle development for pharmaceutical products. NAFTA and TRIPS require that patents be "available and patent rights enjoyable without discrimination as to the field of technology," but Canada's doctrine has had disproportionate effects on pharmaceuticals.

Since 2005, there has not been a single non-pharmaceutical patent revoked for lack of utility in Canada.[15] Ironically, every pharmaceutical patent revoked on this basis was capable of industrial application since it was, in fact, subsequently industrially applied, and the patented pharmaceuticals were approved by Health Canada as safe and effective, used by hundreds of thousands of patients, and, ultimately, continued to be marketed by those who successfully challenged the patents as "not useful."

Canada's unique and burdensome utility test has also been incorporated into Canada's Manual of Patent Office Practice (MOPOP). Thus the Canadian Intellectual Property Office (CIPO) requirements for establishing utility for a patentable invention are also contrary to the practice of other countries. For example, MOPOP Chapter 9.04, the chapter on utility, requires that the patent description *as filed* provide whatever explanation is necessary to supplement the common general knowledge of the person skilled in the art so as to permit a person skilled in the art to *soundly predict* that an invention will have the proposed utility. It also violates the requirements of NAFTA, TRIPS and the PCT, all of which are in force and binding upon Canada.

Similarly, under the PCT applicants may seek patent protection in some or all member countries by filing a single international application. While the sufficiency requirements of the PCT require that the applicant disclose the invention in a manner sufficiently clear and complete for the utility of the invention to be carried out by a person of ordinary skill in the art, the PCT does not require that proof of utility be contained within the application as filed.[16]

Nor is such evidence typically required post-filing. In Europe, if an invention is alleged to have a "credible or plausible" utility, so long as the invention does not operate in a manner contrary to well-established physical laws the invention will be patentable as possessing industrial

condition treated by a patented compound must be taken into account when determining whether a patent's promise has been demonstrated or can be soundly predicted"); and *Latanoprost FCA*, (at paragraph 30: "In our case utility would be demonstrated if the patent disclosed studies showing latanoprost when administered on a chronic basis reduced intraocular pressure without causing substantial side effects.").

[15] In only one case outside the pharmaceutical sector have any challenged claims been found to lack utility; a distinct claim under the same patent was upheld as useful, such that the patent remained valid. *See Bell Helicopter Textron Canada Limitée v. Eurocopter*, 2013 FCA 219.

[16] Patent Cooperation Treaty, Article 5.

applicability (the European equivalent to the utility requirement).[17] Similarly, in the United States, supporting submissions are required only in circumstances where the USPTO provides evidence that the stated specific and substantial utility is incredible.[18] Canada's heightened evidentiary requirement is an outlier.

The standard for assessing utility remains improper even in light of recent Canadian case law. While the court has found some pharmaceutical patents to have utility, Canada continues to apply its arbitrary promise utility doctrine and unique approach to patentable utility (demonstration versus sound prediction) to the detriment of biopharmaceutical innovators.[19] The Canadian standard remains subjective and unpredictable, as a patentee cannot reliably know the construction of a patent's promised utility. Thus the standard remains inconsistent with international norms.

Canada's utility requirements place biopharmaceutical innovators in a difficult Catch 22 dilemma in view of the other substantive requirements for patentability.[20] If an innovator seeks to comply with the enhanced obligations for proof of utility and waits to file an application, then it increases the risk of invalidity on the basis of lack of novelty or obviousness. In other words, a biopharmaceutical innovator who might seek to establish utility for a drug that treats a chronic condition by conducting longer term clinical studies before filing its patent application would potentially be exposed to an allegation of invalidity based on anticipation.[21] Awaiting longer term study results may effectively deprive a biopharmaceutical innovator of its patent rights in Canada. BIO members urge the U.S. Government to engage with the Government of Canada toward finding a solution to these problems and bringing Canadian patent practice in line with international norms and Canada's treaty obligations.

The consequences of Canada's burdensome utility standards for U.S. companies are substantial: unpredictability in the patenting process, forfeiture of intellectual property rights granted in other developed countries around the world, and billions of dollars in lost sales when patent rights are prematurely terminated by Canadian courts or denied by the Canadian Intellectual Property Office (CIPO). To date, based on court actions alone, U.S. companies have suffered damages of more than $736 million from the premature loss of patent protection based solely on Canada's outlier patent utility standard based on IMS sales data.

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

[17] Patent Cooperation Treaty International Search and Preliminary Examination Guidelines, Chapter 14; See also *Human Genome Sciences Inc v Eli Lilly & Co*., [2011] UKSC 51, reversing [2010] EWCA Civ 33, affirming [2008] EWHC 1903 (Pat).
[18] See *Eli Lilly and Co. v. Actavis Elizabeth LLC*, No. 10-01500, 2011 BL 197400 (Fed. Cir. July 29, 2011).
[19] *Eli Lilly Canada Inc v. Hospira*, 2016 FC 47; *Allergan Inc. v. Apotex Inc.*, 2016 FC 344.

[20] All the patent laws of major countries require an invention to be new and non-obvious in addition to possessing utility.
[21] See *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915, 87 CPR (4th) 301 at paragraphs 46 through 48, affirmed *Strattera FCA, supra* note 3, where Novopharm argued that two oral conversations that fell outside the one-year grace period rendered the invention anticipated.

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. The recent acceptance of the Canada-European Union Comprehensive Economic and Trade Agreement (CETA) may resolve this issue by including a provision that ensures a general commitment by the Canadian government to "ensure litigants are afforded effective rights of appeal, which gives scope for Canada to end the practice of dual litigation."[22] However, the USTR will need to monitor implementation to ensure that innovators are adequately protected by this provision.

Injunctive Relief

Canadian jurisprudence takes the view that monetary damages are sufficient compensation in patent infringement cases – making injunctive relief rarely if ever available. Interlocutory injunctions to prevent market entry are rarely granted. Even if the biopharmaceutical patentee prevails, there is a significant loss of reasonable opportunities to enjoy the full benefits of the patent. Justice Moore of the U.S. Court of Appeals for the Federal Circuit has commented that the loss of market to a generic is likely irreparable harm in this industry (*Sanofi Aventis et al., vs. Sandoz et al.*, US Court of Appeals for the Federal Circuit, 2009, 1427-1444). BIO urges Canada to revisit the remedies available to innovators and make injunctive relief pending the outcome of litigation more readily available.

Patent Term Restoration

Canada lacks patent term restoration which restores the loss to patent term caused by lengthy clinical trials and the regulatory approval process. The recent acceptance of the Canada-European Union Comprehensive Economic and Trade Agreement (CETA) may resolve this issue by including a provision that ensures a general commitment by the Canadian government to ensure Patent Term restoration of up to two years. However, the USTR will need to monitor implementation to ensure that innovators are adequately protected by this provision. Any implementation of PTR that does not confer full patent rights, e.g., that would provide an exception for "manufacturing for export" or other infringing activities, would not be consistent with the fundamental purpose of restoring patent term lost due to marketing approval delays and should be avoided. Likewise, there exists in Canada no meaningful ability to mitigate the effects of wrongful generic entry on the basis of a court's application of incorrect principles of law. Damages or profits are often poor compensation for the loss of the innovator's market position following generic entry. As more steps toward implementation are released, the USTR should monitor to ensure that patent rights are adequately protected.

CETA Implementation

USTR should monitor Canada's implementation of the Comprehensive Economic and Trade Agreement (CETA) with the Europe Union. The Canadian government has indicated that generic manufacturers will be allowed, in accordance with the agreement, to manufacture

[22] Technical Summary of Final Negotiated Outcomes, Canada-European Union Comprehensive Economic and Trade Agreement. Accessed at http://www.actionplan.gc.ca/sites/default/files/pdfs/ceta-technicalsummary.pdf

infringing generics for export while the patent term restoration period remains in effect. As noted previously, an implementation of PTR that does not confer full patent rights would not be consistent with the fundamental purpose of restoring patent term lost due to marketing approval delays and should be avoided.

Internet Pharmacies

The Canadian government continues to refuse to correct certain practices by Canadian internet pharmacies. These practices include marketing directly to U.S. consumers unauthorized and counterfeit drug products violating the rights of patent holders and posing significant public health risks to U.S. patients. Canadian border officials have no authority to act *ex officio* with respect to unauthorized and counterfeit products and this authority must be corrected to meet its existing obligations.

Orphan Drug Market Access Issues

In 2013, the Canadian Agency for Drugs and Technologies in Health (CADTH) indicated a willingness to consider a unique process for Ultra Rare Diseases (URD). However, CADTH decided to use the same process for URDs as they use for traditional drugs including a cost effectiveness analysis. Orphan Drugs and URDs are different from traditional drugs as they are indicated for rare conditions with limited data available to conduct a traditional drug assessment for approval or a cost effectiveness analysis. Due to smaller patient populations, traditional review and cost assessment analysis is inherently limited due to smaller amounts of data. As a result of these concerns, BIO members that produce medicines for orphan diseases are unfairly disadvantaged in their access to the Canadian market.

Pricing for Patented Medicines

Canada's Patented Medicines Review Board (PMPRB) has jurisdiction over ex-factory pricing of patented drugs and routinely imposes significant price controls. This forces innovators to choose between maintaining their patent rights and obtaining a fair price for their products. In addition, the PMPRB asserts jurisdiction not only when a patent actually covers an approved product but in any circumstance where there is even the slightest tenuous relation (a "mere slender thread", as the courts have put it) between the patent and the product, e.g. a patented container technology that is not used-- but could someday be used-- for a patented medicine. The result is that price controls are imposed on unpatented medicines because patents exist that "pertain to" them but do not cover them. Companies are at risk of having to surrender not only the patent rights that protect their innovative products but also rights that have little or no meaningful relationship to those products.

Recommendations

Patent requirements related to utility, eligibility for listing, an inequitable right of appeal in PM(NOC) decisions, lack of both injunctive relief and patent term restoration, de-listing patents, threats of disclosure of commercially confidential information, and issues with internet pharmacies have led BIO to request that Canada be elevated to the **Priority Watch List** with an **Out of Cycle Review.** While some of these issues may be resolved by CETA, BIO requests that USTR continues to monitor these issues until full and fair implementation occurs.

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 essential for marketing of biopharmaceuticals in key markets. Chile does currently provide data protection for new *chemical* entities for 5 years. This is according to articles 89 and following the Industrial Property Law. 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 broad 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 further these provisions are not consistent with Chile's obligations under either the FTA or Article 39.3 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 a request is put forth to the Industrial Property Court to compensate for unwarranted administrative delays in marketing approval process. The request must be filed within six months of the approval being granted, the pharmaceutical product must have a patent and the prosecution of the marketing approval process must have lasted longer 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.

The patent law in Chile also excludes transgenic plants and animals from patent protection, thereby further 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.

Our member companies have also noted that the Patent Office has very short deadlines. Some members have been asked to respond to Office Actions in one month or less, which are among the shortest in the world and appear to be arbitrary. Other countries typically allow six months to respond to their office actions.

Other 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). Claims in Chile should be analyzed including all of the elements. In this sense, there is no legal grounds to objecting to the dosage element. However, in the Expert Report, INAPI tends to consider claims

that include dosage to be medical treatment claims and objects to their patentability. Additionally, some Experts are very strict regarding whether the dosage gives the claim novelty and inventive step. Increasing the types of patent protection available to cover approved uses of drugs would help biotechnology companies in Chile. Countries that restrict the patentability of human treatment typically allow coverage for the use of the drug for treatment so that there is patent coverage of commercial sales of the drugs (rather than the treatment method per se).

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 of BIO member patents. The lack of protection is particularly troubling in light of Chile's clear obligations under the FTA.

Recommendation

Chile's intellectual property regime falls short of its obligations in a number of ways that deny protection for biotechnological inventions. In light of these and other deficiencies of the intellectual property regime in Chile, lack of compliance with the U.S.-Chile FTA provisions, and particularly in light of the recent developments in the Chilean legislature with respect to Resolution 798, BIO requests that Chile remain on the **Priority Watch List**.

China

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 United States International Trade Commission, in a 2011 study, estimated that U.S. exports and affiliate sales to China could increase by an estimated $107 billion if IPR protection in China was strengthened to a level comparable to those in the United States.[23] The same study also argues that a substantial improvement in IPR protection in China could have positive effects on employment in the United States.

In addition to IPR protection and enforcement, market access challenges, including indigenous innovation policies that discriminate against foreign companies, lack of transparency and meaningful industry engagement in the rules-making process, regulatory requirements that are more trade restrictive than necessary, as well as restrictive pharmaceutical pricing policies have the effect of blunting innovation in the global biopharmaceutical industry and undermining patient access in China.

For reasons provided in the following paragraphs BIO requests that China be placed on the **Priority Watch List** for the 2017 Special 301 Report.

[23] United States International Trade Commission, *China: Effects of Intellectual Property Infringement and Indigenous Innovation Policies on the U.S. Economy*, USITC Publication 4226, May 2011.

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 October 2016, China released draft revisions to its Patent Examination Guidelines for public notice and comment. The draft appears to move in the right direction by including a proposed article clarifying that examiners must consider in their examination process certain post-filing supplemental data.

While the proposed Guidelines could be an important step forward if fully implemented, 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.

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

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.

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 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[24], 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 measures 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 2016, CFDA implemented a new 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 considers sales outside of China. When combined with the inability to get preliminary injunctions, low damages means that infringement is encouraged by China's system.

Regulatory Data Protection

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

China's Regulation for the Implementation of the Drug Administration Law provides a six-year data exclusivity term for pharmaceutical and agricultural chemical products containing new chemical entity. However, in practice, this term is not applied to foreign originators of pharmaceutical products in an effective manner. BIO welcomes China's commitment made at the 2012 JCCT to define "new chemical entity" in a manner consistent with international R&D practice. In 2015, China proposed to interpret "new drug", in the chemical drug registration categories, as "new" anywhere in the world rather than new in China. BIO is concerned with the proposed revisions to the regulatory categories, furthermore, it is unclear if said policy indicates data protection would only apply when a pharmaceutical product's first global launch is in China. That would be different than the rules of other countries with data protection and with the manner in which data protection is applied in China to agricultural products. BIO urges China to provide regulatory data protection for undisclosed test or other data against unfair commercial use in a way consistent with the practices of other countries and its own agricultural authorities.

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 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 China implements the State Council Opinion, to: (1) not link the pricing pledge to drug regulatory evaluation and approval; and (2) to 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 market distorting effects 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 to, 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.

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

First, an update with respect to the increasingly intolerant landscape for IP rights for biotherapeutics. In 2015, Colombia passed laws based on the National Development Plan 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 recommends that the National Pricing Commission use the declaration as the basis for 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." The Ministry of Health has publicly stated that this will not be the last "Declaration of Public Interest" and that the Ministry of Health will follow this precedent in order to weaken IP rights in the pharmaceutical and biotech sector in an effort to drive down prices and stimulate generic/biosimilar competition.

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 routinely 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.

Recommendations

BIO recommends that USTR focus on ensuring that Colombia implements its obligations under the Free Trade Agreement with the U.S.

BIO requests that Colombia remain on the **Priority Watch List with an Out-of-Cycle Review**.

Ecuador

As of 2014, the Ecuadorian Institute of Intellectual Property (IEPI) has issued nine compulsory licenses, six in 2014. This represents a dramatic shift in policy that materially damages intellectual property rights. Although some improvements have been made there are still unresolved issues that put into question the IP protection in Ecuador. For these reasons, BIO recommends that USTR place Ecuador on the **Priority Watch List.**

Compulsory Licenses

BIO appreciates the government's need to expand access however, the decision to maintain policies relying on frequent resort to compulsory licenses ignore other more effective options for increasing access, undermines the ability to adequately protect intellectual property, and provides a powerful disincentive for our members to do business in Ecuador. BIO continues to believe that the most effective global solutions for increasing access to medicines will result from policies that respect and encourage innovation.

Regulatory Data Protection

In addition to frequently imposing compulsory licenses Ecuador does not offer effective data protection of data submitted for marketing approval of pharmaceutical and agricultural products. This further undermines the incentives for introducing innovative products into Ecuador to the detriment of patients. Ecuador also has yet to establish specialized IPR courts that were required under Ecuador's 1998 IPR law.

Trademark Rights

Trademark rights have also been undermined by Executive Decree No. 522 or at least made them less certain. That Decree appears to limit an innovator's ability to use their trademarks once a patent expires. The decree seems to state that once a patent expires for the reference medicine the innovator may no longer use its trademark by stating, "It is forbidden to sell generic medicines exclusively with a given trademark." BIO understands that the government is currently seeking to clarify this Decree and requests USTR to monitor developments to ensure U.S. trademarks are protected.

Patent Application Fees

Ecuador has also implemented procedural changes that increase the burdens and of securing and maintaining IP rights. Since October 2012, fees for patents have drastically increased in Ecuador. The impact of this increase is mainly seen in the maintenance and examination fees. As of 2014 maintenance fees have increased between 800% and 3529% (e.g. up to USD 4,514 and USD 20,760 for the 10^{th} and 20^{th} year respectively). The cumulated annuities amount results in USD 24,964 for 10 years and USD 139,767 for 20 years. At the time of the increase, the amounts were respectively 12 and 24 times higher than Colombia, 7 and 12 times higher than Brazil, 7 and 11 times higher than the U.S. As of 2014 examination fees were raised from USD

196 to USD 964 to USD 1,510.40 depending on the number of pages or claims. While international applications have page fees of USD 16 for more than 30 pages, Ecuador charges USD 151.04 per page for more than 19 pages.

Recommendations

BIO members encourage the United States government to place Ecuador on the **Priority Watch List** and to monitor the IP and compulsory license developments in Ecuador.

India

In May 2016, India announced a new National Intellectual Property Rights (IPR).[25] 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.

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, **BIO requests that USTR place India on the Priority Watch List with an Out-of-Cycle Review (OCR).** 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.

Intellectual Property Protection

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

[25] 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).

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"[26], with steps such as by reviewing existing Indian IP laws to update/improve them or to remove anomalies and inconsistencies, in consultation with stakeholders.[27] 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 that BIO members suggest India review in evaluating the Guidelines and their application are provided in the footnote accompanying this text.[28]

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

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

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

[28] 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.

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 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.

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",[29] 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.

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 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.

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.[30] If the company does not comply, the

[29] Bayer Corp. vs Union of India, OA/35/2012/PT/MUM (para 46)
[30] http://www.ipindia.nic.in/iponew/publicNotice_21January2015.pdf

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 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

The protection of intellectual property rights in Indonesia has deteriorated for BIO's membership. In 2016 Indonesia amended its patent law in ways that raise significant concern among BIO members. The problematic changes, added to an already difficult environment, include restrictive patentability criteria and an expansive, non-transparent approach to compulsory licensing. 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.

Recommendations

For these reasons, we request that Indonesia be placed on the **Priority Watch List**.

Thailand

In light of continued policies relating to compulsory licensing of patents, and the lack of any significant progress, BIO requests USTR to place Thailand 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 a 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.

Recommendations

We request USTR place Thailand on the **Priority Watch List**.

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.

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. This raises serious concerns about the ability of innovators to meaningfully enforce patents in Russia and will discourage investors and innovators from being 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.

Recommendation

BIO requests that USTR designate Russia to the **Priority Watch List.**

Turkey

BIO strongly supports the progress Turkey has made on improving the legal framework particularly on the protection of intellectual and on PIC/S membership. However, the government's delisting efforts to enforce local production of pharmaceuticals is concerning and deteriorates the market conditions for members. BIO recommends that USTR place Turkey on the **Priority Watch List,** all things considered.

Patentability

The Industrial Property Law numbered 6769 has been accepted by Turkish Parliament and 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 EPC. However, certain areas, such as defining and ruling biotechnological inventions explicitly, second/further medical use claims, have not been addressed by the law. It is clear that there is no obstacle to having patents granted on such inventions in Turkey as Turkey is a member of EPC. However there are some concerns if biotechnological inventions or second or further medical use inventions will be enforced and protected against third parties smoothly despite a lack of clear provisions in the law.

Compulsory Licenses

Another critical concern in the law is related to its compulsory license provisions. Article 130(2) of the IP 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 for 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 Paris Convention as a ground for this provision in law. However; Article 5A paragraph 4 of 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 Good Manufacturing Practice

standards being implemented in Turkey. Accordingly, the effective amount of data protection an innovator receives may only be limited one to two years. Data protection for combination products is also inadequate. As a summary, current Registration Regulation of Medicinal Products for Human Use does conflict with EU standards in data protection.

Non-Trade Barrier: Forced Localization

Another major non-trade barrier does concern "forced localization" practices in the pharmaceutical sector. The Health Servicing Pricing Committee has taken a number of decisions on 'localization' pursuant to Action 46 of the 64th Government Action Plan-2016. This action is a 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"

Localization decisions are being brought into agenda by Turkish Medical Devices and Medicine Agency and Social Security Institution. In the first phase, those imported products, which have at least 3 locally manufactured equivalents with a +50% market share, are targeted to be delisted unless they are too 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 imported medicines from reimbursement scheme on the grounds that the importer company chooses not to produce it locally, is discrimination against imported products and considered as 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, requirement still occurs for the most of the products before product registration application in Turkey and has caused significant registration delays among our companies. The Ministry of Health does allow for GMP certificates from other competent authorities but that acceptance is conditioned on other countries recognizing Turkish GMP certification. However, this is hard to accomplish as Turkey has not joined the PIC/S (Pharmaceutical Inspection Convention and Cooperation Scheme) that dictates international GMP standards. Nevertheless, Turkey's long-lasting accession to PIC/S membership is expected to be concluded in 2017.

Pricing and reimbursement processes remain a challenge for our members. Non execution of the mandate of the pricing regulation since 2011 caused several ongoing lawsuits filed by the pharmaceutical sector, which all were eventually ruled in favor of the sector yet the court orders were also disregarded and consequently drastic budget cuts directly targeting innovative medicines have occurred in the last few years. Still, pricing of the innovative products is significantly lower than European level as a mainly result of taking euro value into calculation with almost half of its real value. Also, the reimbursement decision criteria are not clearly

defined, the process is not transparent, and involves a large amount of time to conclude the process (on average 36 weeks).[31] Newly implemented, yet poorly defined alternative reimbursement process increases the uncertainty on the top of existing challenges.

Orphan Drugs

Orphan drugs have not been thoroughly addressed by Turkish legislation. Turkey's implementation of a comprehensive Orphan Drug Guideline is necessary to facilitate the development and commercialization of drugs to treat rare diseases and maintain an attractive market for foreign direct investment as well as R&D. BIO members are encouraged that the Ministry of Health has been working on a new legislation, the Orphan Drug Guidelines. Turkish Medicines Agency (TITCK) recently opened the draft regulation to debate. Following the contributions of AIFD, TITCK shared the draft "Orphan Drug Guidelines". The major progress within the draft guideline is the prevalence criteria. The criteria for prevalence is accepted as 5/10,000 as per EU directives. 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 access to best medicines and Turkey to emerge as a globally-competitive economy in medical innovation.

Recommendation

For these reasons, BIO recommends that USTR place Turkey on the **Priority Watch List.**

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 Violations

Australia's government embarked on an unprecedented attack on innovative biopharmaceutical companies in 2012 and 2013 that has put Australia out of step with the rest of the developed world regarding its treatment of intellectual property rights. The government has intervened in the suits and requested damages from the innovator for alleged losses the government says it suffered by the delay in listing a generic's drug in the country's pharmaceutical benefits scheme ("PBS") when the innovator lost a patent infringement suit due to a court finding of patent invalidity despite the fact that the company had won a preliminary injunction earlier in the suit. The allegation made by the government was that the delay was caused by the patent enforcement. In the first case where the government has intervened under this policy, the

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

government claims that the innovator owes more than $400 million in damages to the government.

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).

This 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 policy threatens the ability of innovative biopharmaceutical companies to utilize their legal right to enforce their patents. This approach is a major and inappropriate shift in policy and practice by the Australian government.

The impact of the approach described above is illustrated by Australia's suit against Sanofi and BMS. In this case, Sanofi owned a patent covering a drug (Plavix) that it marketed in Australia itself and under an arrangement with Bristol Myers Squibb ("BMS"). In 2007, Apotex, a generic drug company, applied to register a generic version of Plavix on the Australian Register of Therapeutic Goods ("ARTG"), intending to list the generic drug on the PBS and launch it on the Australian market. Sanofi sought the usual form of preliminary injunction against Apotex to prevent Apotex from infringing Sanofi's patent. Sanofi was required to give the usual form of undertaking to the court as to damages to compensate persons affected by the injunction.

At the time, Sanofi made its decision to seek injunctive relief, the government did not notify anyone of any intent to seek compensation if Sanofi and BMS lost the lawsuit.

Sanofi had successfully enforced its patent in many jurisdictions around the world where it had been challenged. Similarly, in 2008 the Australian trial court upheld the validity of the key claims in the patent. That position prevailed until the appeals court reversed the trial judge and invalidated the key claims in the patent in late 2009. Finally, the High Court (Australia's Supreme Court) declined Sanofi's appeal in March 2010, ending the "merits" portion of the lawsuit. One month later, the government listed Apotex's drug on the PBS.

The government first notified Sanofi of its claim for compensation in February 2012 – more than two years after the patent was invalidated, and almost five years after Sanofi and BMS gave the undertaking as to damages that the government relied on as its basis for recovering money. The government did not actually intervene until 2013.

When the government first notified Sanofi and BMS of its claim in February 2012, the government stated that it had suffered money damages of AUD 65 million. The government subsequently revised its damages claim to approximately AUD 400 million. The commercial impact of such figures is obvious. The context in which a decision is made to seek an injunction

and defend a patent when faced with the risk of a $400 million claim if you lose the lawsuit – even though the decision is bona fide and reasonable – is quite different from the decision-making process absent knowledge of that risk or where the defense is not undertaken on a bona fide basis.

Finally, the Australian government has issued reports that recommend the reduction of IP rights and will likely lead to the deterioration of the innovative climate in Australia. Suggestions include reducing patent term extensions, removing patent linkage, making manufacturing for export a non-infringing act, and not increasing the term of data protection.

BIO requests the placement of Australia on the **Watch List.**

Egypt

During 2016, 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. BIO notes that as part of Egypt's drive to strengthen its competitiveness in the sector, government officials have demonstrated a willingness to analyze challenges and engage in meaningful dialogue.

In recent years, Egypt has taken some steps to enhance the environment for life science/biopharmaceutical companies. 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 foreign exchange adjustments and replacing the old pricing decree, have not been resolved. Significant problems persist in the area of intellectual property against the backdrop of the broader trend in a region that has continued to advance during the past decade. 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 2016, 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.

Mexico

BIO recommends that Mexico be placed on the **Watch List** due to continued difficulty in protecting and enforcing intellectual property rights. Should the U.S. government engage Mexico on the renegotiation of the North American Free Trade Agreement (NAFTA), addressing these long standing barriers and intellectual property protection is essential to BIO and its members.

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. Further, the U.S. Government should take such statements seriously during the upcoming Trans Pacific Partnership negotiations and ensure Mexico will meet their existing obligations before extending additional trade preferences to Mexico in the TPP agreement.

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.

In light of these concerns, BIO requests that USTR continue to monitor events and that Mexico be placed on the **Watch List**.

South Korea

BIO requests that USTR place South Korea on the **Watch List** for new deficiencies in their intellectual property system and failure to adequately implement their free trade obligations.

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.[32] 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.[33] If an invention 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 unpatentable 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 12 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.

[32] 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)).

[33] 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 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.

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 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).

Recommendation

We urge the USG to engage their Korean counterparts to secure passage of an appropriate patent enforcement mechanism consistent with KORUS provisions.

Vietnam

BIO members continue to face burdensome examination guidelines and counterfeit issues in Vietnam. Thus, BIO requests that USTR place Vietnam on the **Watch List.**

Patent Examination Guidelines

Vietnam has implemented new examination guidelines similar to those in Argentina. Discriminating against pharmaceutical inventions in this manner is a violation of TRIPS Article 27.1 which requires "patent rights to be enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

Counterfeits

Additionally, BIO members report increasing instances of cross-border counterfeit and parallel importation in Vietnam. As part of a regional trend in counterfeiting, the issue emanates from a lack of resources and expertise amongst judicial and law enforcement officials.

For these reasons, we urge the United States Trade Representative to maintain Vietnam on the **Watch List**.

Jurisdictions to Monitor

South East Asia

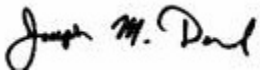
BIO members report a worrisome trend across South East Asia regarding cross-border counterfeiting and parallel importation of innovative biotech seeds. This regional proliferation in the trade of counterfeits, which started in Indonesia, Malaysia and the Philippines, is currently moving towards the territory corridor of South East Asia, including Cambodia, Laos, Malaysia, Myanmar and Thailand. This raises a number of significant concerns and constitutes a serious risk to the valuable intellectual property rights of BIO's members. This issue continues to spread across the region due to a lack of expertise and resources in the courts and law enforcement agencies to confront this issue directly. Furthermore, corruption at the local police levels continues to create hurdles for BIO members.

BIO members encourage the USTR to monitor and address these regional issues.

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.

Sincerely,



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