



By electronic submission

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BIOTECHNOLOGY INDUSTRY ORGANIZATION

2015 SPECIAL 301 SUBMISSION

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Executive Summary:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to participate in the Special 301 process and is hopeful that our contribution will assist the United States Trade Representative's (USTR) efforts in preserving strong intellectual property protections for United States' companies internationally. BIO appreciates the opportunity to comment on *2015 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing*.

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 of the 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, supports more than 7.5 million jobs in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech 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 investment to take their technologies to commercialization. More and more, BIO's members are looking abroad as they expand their markets and R&D and commercialization efforts.

While IP reforms in foreign countries would greatly improve export of biotech products from the United States, improvements in IP would benefit foreign countries as well. Studies show that even developing countries obtain economic benefits from increasing their IP protection.¹ Like in other trade areas, increased standards in IP provide a win-win situation for the United States and other nations around the world.

To help in assessing the IP challenges abroad that may hinder our companies' activities, 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. BIO has chosen to aggregate the issues to help identify

¹ 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 Compliments to the Strengthening of IPRS in Developing Countries – China's Intellectual Property Environment: A Firm-Level Perspective*, 14 Sep 2010, accessed at http://www.oecd-ilibrary.org/trade/policy-complements-to-the-strengthening-of-iprs-in-developing-countries-china-s-intellectual-propertyenvironment_5km7fmtw4qmv-en;jsessionid=1p4jzo8xww6ep.delta; Lee Branstetter and Kamal Saggi, *Intellectual Property Rights, Foreign Direct Investment, and Industrial Development*, Oct. 2009, accessed at <http://repository.cmu.edu/sds/52/> on January 25, 2011; Lee Branstetter, Raymond Fisman, C. Fritz Foley, and Kamal Saggi, *Intellectual Property Rights, Imitation, and Foreign Direct Investment: Theory and Evidence*, April 2007, accessed at <http://repository.cmu.edu/heinzworks/126/> on January 25, 2011.

roadblocks affecting U.S. biotechnology companies and to maintain the confidentiality of our member's responses.

To this end, BIO has identified the following countries of interest and recommends the following for our 2013 Special 301 submission.

Priority Watch List: BIO requests USTR to place Argentina, Brazil, Canada, Chile, China, Ecuador, India, Indonesia, South Korea, Thailand, Turkey, and Venezuela on the Priority Watch List.

Watch List: BIO requests USTR to place Australia, Colombia, Egypt, the European Union, Mexico, Paraguay, Peru, Philippines, Russia, and Vietnam on the Watch List.

Section 306 Monitoring: BIO requests USTR to continue monitoring Paraguay under Section 306.

For each of the countries identified in this submission, BIO has identified numerous issues as important to our members. While the biotechnology industry faces international IPR challenges that are common across industries, it also faces challenges that are unique to the biotechnology sector. Those issues common across industry sectors include **counterfeiting, large backlogs and patent office inefficiency, differing administrative, legal, and judicial standards for patentability, compulsory licensing, inadequate protection of regulatory and test data,** and a need for **harmonization** of substantive standards and processes across patent offices around the world. Issues unique to biotechnology include **patentability of biotechnology inventions, double patent review systems, genetic resource access and benefit regimes, and technology transfer issues** that involve intellectual property. This submission will address these issues as they apply in each country.

BIO hopes this submission informs U.S. Government officials and the public about the IPR challenges U.S. biotechnology companies face around the world. Finally, we hope our submission helps the U.S. government identify IPR roadblocks and potential solutions that will help increase U.S. exports and create jobs in the United States.

Background

Biotechnology companies provide unique benefits to the United States and the world. In the health care sector alone, the industry has developed and commercialized more than 300 biotechnology drugs and diagnostics and there are over 400 products in the pipeline. In the agricultural field, biotechnology innovations are simultaneously increasing food supplies, reducing damage to the environment, conserving natural resources of land, water and nutrients, and increasing farm income in economies worldwide. In the energy and environmental sector, biotech innovation is cleaning our environment and fighting global climate change by reducing our dependence on petroleum and fossil fuels. Biotechnology innovation, if supported by appropriate public policies, has the potential to provide treatments for some of the world's most

intractable diseases and address some of the most pressing agricultural, energy, and environmental challenges facing our society today.

The biotechnology industry relies heavily on patents. The development of a single biotechnology product often takes more than a decade to be commercialized, and hundreds of millions (if not 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 products 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 have 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. Venture capital firms invest in capital-intensive, long-term, and high-risk research and development endeavors only if they believe there will be a return on their investment. Patents help provide this assurance.² 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 societal value biotechnology can offer.

Recent BIO IP Publications

Taking Stock: How Global Biotechnology Benefits from Intellectual Property Rights provides a survey of current economic academic literature regarding IP. The key findings include;

- a) A “growing body of evidence suggesting a positive link between economic development and growth, technology transfer, increased rates of innovation and the strengthening of IPRs. This is particularly true in knowledge-intensive sectors such as biopharmaceuticals.
- b) “Much of the international debate on biopharmaceutical innovation focuses on downstream issues: whether IPRs stand in the way of commercialization and whether they enable or delay access to medicines in developing countries. This discussion is usually placed in the context of the "North-South" divide (i.e. developed vs. developing world) and the extent to which the use of IPRs benefits or damages developing countries.”
- c) “The discussion on the use of IPRs in upstream innovation (or the relationship of IPRs and biotechnology innovation in the context of biotech SMEs and universities) is often theoretical in nature and only at times based on data and collected evidence. Some international debates on IPRs relating to the upstream R&D process also examine the

² According to a patent survey conducted by researchers at the University of California Berkeley, 73% of the biotechnology entrepreneurs surveyed reported that potential funders, such as venture capitalists, angel investors, and commercial banks, etc. indicated patents were an important factor in their investment decisions. See 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>

issue of ownership of genetic innovations and biologic materials and so-called research exemptions.”

d) “Recent empirical studies and surveys seem to significantly ease ongoing concerns about the extent to which the patent system may be used in a manner that slows or hinders access to biotechnological research and innovation. Still, there is a relative paucity of direct evidence and data on the roles that IPRs play in stimulating biotech research and innovation.”

Specifically regarding biotechnology the report finds:

a) “IPRs, especially patents, are actively facilitating and contributing to upstream and downstream biotechnology activities in both developed and developing countries.”

b) “Today, not only mature economies but also major emerging economies are making growing use of the patent system to facilitate biotechnology research and commercialization.”

c) “Accordingly, biotechnology alliances for research and technology transfer have increased markedly since the early 1990s.”

d) “Case study analysis suggests that strengthening IPRs and introducing technology transfer frameworks based on IPRs in combination with other reforms can have a positive and sustained impact on innovation, economic development and growth, pharmaceutical R&D and access to biotech products in emerging economies.”³

BIO also commissioned research to review the economic effects of university and nonprofit licensing of inventions in the United States. For the years 1996-2010 the study finds:

a) Academic licensing contributed up to \$836 billion in gross industry output,

b) Contributed up to \$388 billion to the GDP,

c) And provided up to 3 million “person years of employment.”⁴

Finally, BIO participated in two reports reviewing innovative models and approaches for providing health care in the developing and least developed world. *Bringing Innovation to Neglected Disease Research and Development* reviews the barriers to neglected disease research and product development.⁵ The second report, *Case Studies for Global Health* provides access to a database of innovative approaches to solve a global health challenge.⁶

³ The full report is available at <http://www.bio.org/articles/taking-stock-how-global-biotechnology-benefits-intellectual-property-rights>

⁴ The full report may be found at <http://www.bio.org/articles/economic-contribution-universitynonprofit-inventions-united-states-1996-2010>

⁵ Full report found at <http://www.bio.org/articles/bringing-innovation-neglected-disease-research-and-development-joint-report-bio-and-bio-ven>

⁶ <http://www.casestudiesforglobalhealth.org/>

PRIORITY WATCH LIST

Argentina

Argentina continues to have deficiencies within its patent and regulatory data protection regimes. BIO requests that Argentina remain on the **Priority Watch List**.

On May 8, 2012 the Ministries of Health and Industry and the National Institute of Industrial Property issued Joint Regulation No 118/2012, 546/2012 and 107/2012 setting Guidelines for Patentability Examination of Patent Applications on Chemical and Pharmaceutical Inventions. The Guidelines apply exclusively to the pharmaceutical area and apply to all future and pending applications. The new Guidelines reject patents with claims for compositions, dosages, salts, esters and ethers, polymorphs, analogous procedures, active metabolites and pro-drugs, enantiomers, selection patents and Markush-type claims. In addition, processes for the manufacture of active compounds disclosed in a specification must be reproducible and applicable on an industrial scale to be patentable. The Guidelines refer to biotechnological inventions (biologics) and requires that they be analyzed using these principles. The Guidelines represent a clear 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.”

In 2012, Argentina also had a judicial interpretation stating that the Argentine Patents Act does not protect a patent while it is pending. The Court held that the patent only grants protection from the date of grant (rather than the date of filing). This results in a term of less than 20 years.⁷

Argentina’s patent examination system continues to suffer from a backlog of patent applications that delays the grant of patent protection for valuable inventions and thereby denies the adequate and effective protection of intellectual property rights for BIO’s members. We understand that Argentina has taken steps in recent years to reduce its backlog, but excessive delays are persistent. Currently, the National Institute of Industrial Property (INPI) performs substantive examinations according to the chronological order of the filing date of the corresponding request of examination. Typically in Argentina, substantive examination begins five to six years after the filing date. Consequently, a patent application requires around eight to 10 years to be granted. Argentina’s patent law neither provides for sufficient patent term extensions to fully compensate for unwarranted delays by INPI in the examination of patent applications, nor provides provisional protection rights to applicants of such pending patent applications. Thus BIO’s members suffer a substantial loss of patent term due to delays in examination.

⁷ Novartis AG vs. Laboratorios LKM SA re cease of use of patent, 3rd Chamber of the Federal Civil and Commercial Appellate Court of Argentina. News article summarizing decision at <http://www.ip-watch.org/2012/11/14/analysis-argentine-court-clarifies-what-patent-holders-can-and-cannot-prohibit/>

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. Further, the highly restrictive patent examination guidelines issued by the INPI in Argentina exclude protection for a wide range of biotechnological inventions. The criteria adopted by INPI, which denies patent claims directed to transgenic plants and animals, their parts and components, also appear to be inconsistent with the Argentine patent law. The patent law provides an exception to patentability only for living material and substances that are "pre-existing in nature." Transgenic plants and animals, their parts and components are not pre-existing in nature. BIO's members also continue to experience difficulties enforcing patent and plant variety protections in Argentina. Finally, INPI does not grant patents for polymorphs or salt forms of known pharmaceutical compounds.

Argentina also does not provide adequate protection for the data that must be generated in support of marketing authorization to prove that biotechnology products applicable to the pharmaceutical and agricultural chemical industries are safe and effective. Specifically, law 24,766 permits Argentine officials to rely on innovator data to approve generic products. Generic companies may also rely on marketing approval of an innovative product in other countries. This protection is critical to the ability of biotechnology companies to develop and commercialize such biotechnology products in a particular market. Moreover, TRIPS Article 39.3 obligates Argentina to protect such data against "unfair commercial use." 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.

Our companies have expressed concern over the unpatentability of the use of a drug in a method of treatment. Many other nations permit claims to the "use of compound X in preparation of a medicament for treating disease Y" or "compound X for use in treating disease Y." The Patent Office Patent Bulletin from 2002 (Circular A.N.P. No. 008/02) demonstrates the restrictiveness of its provision. The provision states that no patent protection will be awarded to second medical uses as a main object in the following cases:

- a) claims directed to the use of a known compound for the treatment of a certain disease, because they will be considered as included in the prohibition to patent methods of treatment contained in the Argentine Patent Law.
- b) claims worded as Swiss-type claims, since the Patent Office will assume that the invention does not comply with the novelty requirement.
- c) claims directed to the process for the manufacture of a medicament when the novelty of the process is based on a new use of a known compound, because the Patent Office will consider that the invention does not comply with the novelty requirement.

These restrictions on patentability fail to recognize possible flexibilities allowed in other countries that represent a compromise between both government and U.S. business needs.

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**.

Brazil

Although Brazil has made some improvements to its protection of intellectual property over the years, there are still several problematic issues that hinder Brazil from fully achieving a positive IP agenda across technology sectors, particularly with respect to the biotechnology sector. Past reforms have reaffirmed the fact that changes in the patent law have encouraged Brazilian biotech innovation; however, lack of significant progress on new reforms and lack of coordination at the Congressional and Federal government level present short- and long-term obstacles to achieving an optimum IP environment in one of Latin America's most important and influential economies⁸. In light of these reasons, BIO recommends that USTR place Brazil on the **Priority Watch List**.

Brazilian Patent Office (INPI)

In September 2013, INPI issued a binding opinion “clarifying” that the patent term for applications filed between January 1, 1995, and May 14, 1997, is limited to 20 years from the filing date. The opinion distinguishes “mailbox” patents from subsequent patents, which are guaranteed a patent life of 20 years from filing with a minimum term of 10 years from patent grant, under Article 40 of Brazil's patent law. More than 250 of these “mailbox” patents were filed as part of Brazil's obligations created by its WTO ascension. Prior to this time, Brazil did not issue patents for pharmaceutical or agricultural products.

As INPI's opinion is not self-executing, INPI then filed more than 30 lawsuits against at least 120 companies and institutions, seeking to alter the patent terms on these patents or have them declared invalid. This raises significant process and fairness issues as INPI previously approved these patents and the corresponding patent term and now seeks to change these terms retroactively. Many of our members in the biopharmaceutical and agricultural sectors are named defendants in the suits. INPI has requested a preliminary injunction to nullify these patents pending resolution of the case. Thus far, the courts are split and the majority of 48 lawsuits initially filed are still pending decisions. These lawsuits based on the lack of consensus between judges and Federal Courts as well as delays in the judicial system have not helped to improve and stabilize the local IP environment and has impacted industry's relationship, to some degree, with the INPI.

⁸ 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).

INPI has released proposed rules which would result in new Biotechnology Patent Examination Guidelines.⁹ BIO requests the U.S. Government ensures that innovative biotechnology companies are adequately protected in the new Guidelines. Despite the proposed rules having been released well over a year ago, there are no developments or official word from the INPI on when these new rules will be published. This uncertainty and inefficiency presents additional obstacles to obtaining a positive IP environment.

We understand that the Brazilian Patent Office has plans to hire new patent examiners, including new biotechnology patent examiners, in order to address the Office's lack of an adequately sized staff of properly trained patent examiners. Nonetheless, again inefficiencies in the hiring process and administrative problems and bureaucratic issues have delayed the hiring of new examiners in 2014, despite this being the new INPI President's major priority in 2014.

The INPI President also established that a major goal of 2014 was to reduce the patent backlog. However, despite a successful green technology fast-track patent campaign which was limited to only 500 applications, there has been no noticeable improvement in the backlog, particularly in the biotechnology sector. Companies routinely wait for eight to ten years before examination occurs, with any potential issuance of a patent occurring several years later. One biotech company reported that they filed 335 cases over 30 years with only 5 being granted. Only 2 patents have not expired with about 80 cases being abandoned by the company. Another company reports filing 200 patent applications with only 2 patents issued in the past dozen years. While conditions are improving, biotechnology companies are still hesitant to seek market authorization for their products in Brazil due to this backlog at the Patent Office.

Another problem involves the INPI practice of not allowing amendments or added claims to patent applications after the examination has been requested. In addition, the INPI has also been denying divisional applications with different claim scope than that of the parent patent application for divisional applications filed after examination has been requested. In other words, INPI prohibits amending claims to include classes or categories of claims not included in the original claim set. The applicant cannot broaden the claims after the examination request. This prevents the applicant from adding claims to preferred embodiments that, for example, cover actual drugs sold in Brazil that were present in the application initially filed.

Some Brazilian lawyers claim that the patent examiners often fail to follow their own INPI guidance when examining patent applications. Our companies have to navigate difficult administrative hurdles. One company reported that they had to file multiple appeals to the President of INPI before allowance. These particular administrative hurdles are not found in other developed patent systems like Brazil. Some members of BIO also report that examiners abuse the obviousness standard. Some members state that in their experience, examiners often rely heavily on hindsight reasoning to make obviousness arguments in biotech cases.

Members also have inadequate access to INPI patent prosecution records. One company reported receiving notice of rejection of claims in a pending application but not receiving the substantive action until after the deadline for responding. Electronic access to INPI prosecution

⁹ For BIO's Comments see, <http://www.bio.org/advocacy/letters/bio-comments-inpi-guidelines-examination-patent-applications>

records is possible; however, the system often presents problems and is not completely reliable making it necessary to continue to obtain access to patents and file wrappers by physically visiting the INPI and waiting to receive copies of requested documents.

It is also important to note that there is some political uncertainty with respect to the future direction and leadership of the Patent Office. In December 2013, a new President of the Patent Office was named. In addition, in February 2014, a new Minister of the Ministry of Development, Industry and Trade was named. After a challenging Presidential re-election campaign and increased political pressure in the capitol Brasilia, the President named in December 2014 yet a new Minister. The Patent Office falls under this Ministry and due to the number of transitions over the last year, there is some degree of uncertainty as to the leadership and direction of the Patent Office in 2015.

Finally, biotechnology companies would greatly benefit from any possibility of Brazil joining with the U.S. or other countries in harmonization efforts.

Patent Law

Brazil lacks meaningful patent protection for secondary claims covering novel uses. In fact, two proposed bills seek to exclude second medical uses altogether.¹⁰ This deters product development by innovator companies as it disincentivizes biotech companies from further developing their products to find new applications or to adjust the products to serve unique and underserved customers. Lack of secondary claims covering novel uses impedes biotechnology companies' progress in Brazil.

Exemptions for patent infringement are excessive in Brazil which unfairly curtails patent holder's enforcement rights. Private non-commercial use that does not "result in prejudice to owner's economic interests" is exempted. Experimental use related to technological research is exempted. Use of inventions placed into the domestic market by the patent owner under owner's consent is exempted. Use of the subject matter of patents related to living matter as a source to obtain new products is exempted. Use or distribution of patented biological material that has been legally introduced into the market by owners, except for commercial propagation is exempted. Finally, the use of patented medicines by pharmacies for 'individual cases' are exempted. These exemptions go beyond the global norm.

In 2007, Brazil granted a compulsory license for efavirenz. This act raises significant concerns about whether intellectual property rights can be adequately and effectively protected in Brazil. Brazilian law also requires a patentee to "make use of" a patent or allow others to do so within three years of issuance. Failure to comply results in INPI issuing a compulsory license to a third party with technical and economical capacity and legitimate interest in using the technology of the patent (in other words, the noninnovative competitor). In addition, according to Decree N^o 4.820 of September 4, 2003, the patent holder may also be obligated to supply technical know-how to perform the invention or potentially have the patent declared invalid.

While BIO understands the challenges that countries face in providing affordable healthcare systems, BIO continues to believe that the most effective solutions will result from

¹⁰ 2.511/07 and 3.995/08

policies that respect and encourage innovation. The granting of compulsory licenses in this manner will undermine incentives needed to develop new medicines.

Brazil has a plant variety protection (PVP) law in force, but excludes patent protection for plants in generic terms (i.e. beyond plant varieties). As consequence, the Brazilian government has created a significant gap in intellectual property protection for inventions in the field of agriculture. Innovators of plant-based inventions that are applicable to many plants or to many plant varieties cannot obtain adequate protection for their inventions either with patents ("plants" broadly excluded) or from PVP (only applicable to plant varieties). Amending Article 18.III of the Brazilian IP Law by limiting the exclusion to "plant varieties" instead of "plants" (and "animal races" instead of "animals") should positively remove this gap of protection for agriculture innovations.

In addition, certain innovations in the agriculture sector may qualify as "all or part of natural living beings and biological materials found in nature ", which are excluded from protection under Article 10.IX of the Brazilian IP Law. However, such innovations require much investigations and investments to be identified as useful for agriculture, and removal of such exclusion would be as much necessary to maintain the investments in the development of such innovations addressing the challenges of agriculture.

Courts

ABIFINA, a Brazilian association representing national companies with chemical interests including many generics companies, filed a legal action in the Brazilian courts this November challenging the constitutionality of Brazil's guarantee of a minimum patent term of 10 years for all patents. A 10-year minimum has been crucial for biotech innovators to protect against INPI's notorious patent review delays. Companies routinely wait 8-10 years before patent examination even begins. Revoking the 10-year minimum patent term could significantly shorten patent life for many biotechnology inventions.

On November 6, 2013, the judge assigned to the ABIFINA case, Justice Fux, denied ABIFINA's request for a preliminary injunction, which would have immediately suspended the minimum 10-year term. However, Justice Fux placed the case on accelerated track status. As part of the proceedings, the National Congress and the President of the Republic have been asked to provide their opinion of the constitutional challenge. Both have responded rejecting ABIFINA's claim of unconstitutionality and support the 10-year patent minimum.

The case is still pending and on November 26, 2014 Justice Fux allowed Interfarma, a local R&D based pharmaceutical industry organization, and Andef, a local R&D based agricultural industry organization, to be admitted as *amicus curiae*.

ANVISA Review of Patentability

Brazilian law dictates that the regulatory authority (ANVISA) must provide prior consent on the grant of a pharmaceutical patent. Traditionally, ANVISA has interpreted this requirement as an obligation to review patentability criteria in a patent application. Innovators have always

maintained that such actions are inconsistent with TRIPS Articles 27 and 62.2, as ANVISA required applicants to reargue their claims already deemed allowable by INPI.

On January 25, 2010 the Brazilian Attorney General of the Union (AGU) provided a legal opinion to resolve this issue and determined that ANVISA's review should be restricted to an analysis of the sanitary risks of the patented drug to health.¹¹ The Attorney General found that any other analysis would entail an invasion of INPI's competence and be contrary to Brazilian law.

BIO understands that an Inter-Ministerial Working Group formed to resolve this issue. The Working Group issued a statement reaffirming the involvement of each Agency in the patent review process and indicating that ANVISA and INPI would propose rules for public comment on how each agency would proceed. On October 16, 2012, ANVISA issued Public Consultation No. 66 detailing how they would approach their mandate to provide prior consent for pharmaceutical patent grants and on April 15, 2013 Resolution 21/2013 was published.

BIO remains concerned about how Resolution 21/2013 defines when ANVISA should deny prior consent of pharmaceutical patent applications. According to the regulation, prior consent should be denied when the application is "contrary to public health". ANVISA defines "contrary to public health" as:

- I "The pharmaceutical product or process contained in the patent presents a health risk
- II. The patent application of the pharmaceutical product or process is of interest to the policies regulating the universal access to medicine and pharmaceutical assistance as provided for under SUS – Universal Public Health System – and that do not meet the patentability requirements and other criteria as established in the IP Law 9.279/1996."

First, according to ANVISA a patent application presents a health risk when any narcotic or prohibited substance in Brazil is part of the invention.

According to the regulation, ANVISA may assess patentability requirements if the application refers to a strategic drug of SUS and if ANVISA determines that the application does not meet the patentability requirements, prior consent will be denied and the patent application will be forwarded to the INPI where the INPI should publish a notice of rejection.

BIO is concerned as to what ANVISA may refer to when stating that it may assess patentability requirements of applications that are "of interest to the policies regulating the universal access to medicine and pharmaceutical assistance as provided for under SUS."

The Brazilian Health Ministry recently published a new Ordinance 2888/2014 which creates a new list of strategically important drugs for the SUS. This new list is significantly smaller than the former list of strategic drugs contained in the recently revoked Ordinance

¹¹ Accessed on February 10, 2011 and found at:
http://translate.google.com/translate?sl=auto&tl=en&u=http://www.agu.gov.br/sistemas/site/TemplateImagemT extoThumb.aspx?idConteudo%3D153676%26id_site%3D3

3089/2013. ANVISA has in practice restricted its prior consent review and patentability assessment to applications that refer to drugs and drug categories listed in these Ordinances.

Nonetheless, there is still uncertainty as to whether ANVISA will restrict its prior consent to drugs listed in Ordinance 2888/2014 or will broadly apply prior consent to drugs that were contained in previous lists of strategic drugs to the SUS. In addition, there is uncertainty whether ANVISA will restrict its review to those drugs specifically listed in the Ordinance or whether ANVISA will broaden its review to all drugs that fall under the strategic medical treatment categories listed in the previous Ordinances.

The rules in place and practices of ANVISA in reviewing patent applications for patentability requirements raise serious concerns as to whether this conduct goes beyond the Agency's competencies and goes against the previous Attorney General's opinion.

BIO Members from the pharmaceutical industry have also reported delays with respect to the INPI examination of patent applications that have undergone a substantive patentability examination by the food and health regulatory agency ANVISA. BIO Members have stated that there is increasing political tension between the INPI and ANVISA with respect to ANVISA's role in reviewing patentability criteria and until the matter is resolved politically or judicially Members expect the review of patent applications affected by this 'prior consent' analysis by ANVISA to be postponed.

Recently, a local pharmaceutical industry organization representing members engaged in R&D and developing novel drugs, Interfarma, brought a class action lawsuit against ANVISA on this matter of prior consent. The action seeks to establish that Resolution 21/2013 cannot be considered a valid/legal instrument to legitimate ANVISA's role in examining patentability requirements in order to determine whether a patent application presents a health issue. ANVISA has not filed a response to this lawsuit but developments from this lawsuit will significantly impact the pharmaceutical IP environment in Brazil.

Regulatory Issues

Biotechnology companies find operating in the current regulatory environment difficult; especially when unauthorized copies of products receive registrations on undisclosed tests and other confidential data. Brazil's lack of data protection for biopharmaceuticals is inconsistent with TRIPS Article 39. Article 39.3 requires that members, requiring approval for pharmaceutical or agricultural chemical products, "protect data against unfair commercial use." While Brazil implemented 10 years of data exclusivity for agrochemical and veterinary products, it has yet to provide similar protections for biopharmaceutical products. Providing an appropriate period of data protection, e.g. 5 years of protection for small molecules and 12 years for biologics reflecting U.S. law with some form of patent linkage would help biotechnology companies enter and succeed in the Brazilian market. Moreover, this type of protection could be strengthened by also implementing a patent enforcement mechanism that would permit innovators to initiate and resolve patent disputes prior to launch of a generic product on the Brazilian market.

Proposed New Regulatory Pathway for “Low-Complexity” Biologics

Besides not providing for any data protection for biopharmaceuticals, there are additional regulatory questions with respect to a proposed regulatory pathway in Brazil for approving biosimilars. ANVISA has discussed placing on its 2015 regulatory agenda a new regulation for registering “low-complexity” biosimilars. This simplified regulatory pathway for “low-complexity” biologics is problematic in that it may compromise patient safety by allowing for biosimilars to be approved and commercialized that have not been appropriately tested and compared to reference biologics in order to assess their quality, efficacy and safety profiles. Besides the obvious public health concerns that this may raise, this pathway may result in biologic drugs being approved that may infringe on BIO Member’s IP rights in Brazil and that are approved based upon, in part, the use of non-disclosed regulatory data that should be protected by ANVISA.

BIO understands that the current ANVISA regulations on registering biosimilars established in RDC 55/2010, namely the Comparability Development Pathway and the Individual Development Pathway, are adequate and sufficiently clear for registering the full spectrum of biologic drugs, independent of their complexities. The level of “complexity” of a potential biosimilar or biological product should not provide the sole justification for developing a distinct regulatory pathway.

Regardless of ANVISA’s assessment of a biologic drug’s “complexity”, biosimilars require a thorough and directly comparative analytical characterization and quality studies followed by pre-clinical and clinical development program to show high similarity to the reference biologic in terms of safety, quality and efficacy. Ideally, biosimilar regulations should not present IP challenges, particularly with respect to regulatory data protection, and should be designed in order to ensure that patients are receiving biosimilars of proven safety, quality, and efficacy in comparison to reference biologic drugs.

Enforcement

Licensing and IP enforcement laws remain difficult to navigate and weighted against the interests of the IP owner. For example, INPI requires registration of license agreements before they can be enforced, before royalty revenues can be exported, or before companies can utilize favorable tax rates. Further, INPI can dictate terms prohibiting parties from freely contracting and restricting the owner from fully exploiting their IP. For example, INPI can stipulate that royalty rates not exceed 5% of gross income per unit. In addition, Federal law prohibits royalty payments to be sent abroad to foreign patent holders when the royalty payments refer to a pending patent application. In other words, only upon granting of a patent, which may take over ten years from filing, will a patent holder be able to receive royalty payments. Finally, confidentiality provisions extending beyond the term of the agreement are limited to five to ten years. These issues may discourage innovative companies to enter into licensing agreements in Brazil.

Genetic Resources

In 2001, a Provisional Act for the implementation of access and benefit sharing regime in Brazil was issued. The Provisional Act represents the current law in Brazil but the Act also requires the legislature and regulatory agencies to better define and create an access and benefit sharing regime. However, although the regulatory agencies have issued internal norms and regulations, the legislature has not acted to clarify the Provisional Act for the past 10 years. This has created significant uncertainty for the protection of inventions that rely on genetic materials.

The Act prohibits access of Brazilian genetic resources without authorization by Brazil's Council for the Management of Genetic Patrimony (CGEN), a regulatory agency under the management of the Ministry of Environment. Authorization by CGEN has taken 2 to 3 years although there are reports that this delay is diminishing somewhat. Under the Act, researchers may not, in theory, start their research on the genetic resource while they are waiting for authorization. It is not possible to obtain a patent without such Authorization.

On April 30, 2009, the INPI implemented the Act by stating that any applicant should inform the patent office of authorization in the patent application. Failure to provide such an authorization will lead to an immediate administrative office action requesting a copy of the authorization which may ultimately result in the patent being cancelled or suspended. The Act then requires that once authorization and the patent have been granted, the patent owner must share benefits through the payment of royalties. However, the Act does not delineate, and regulations have not yet been promulgated to address, whom or what entity should receive these royalties. In short, the access and benefit regime in Brazil is fragmented and uncertain. The definition of a Brazilian genetic resource remains unclear. The timing of acquiring authorization from the government to access a genetic resource remains unclear. The Act contains penalties to those who do not comply and companies such as Natura have been fined U.S. \$12.6 million.¹² This uncertainty is detrimental to U.S. business and university researchers trying to perform biotechnology research that results from the access to Brazilian genetic resources and trying to commercialize that research for future use.

BIO has heard that a federal court in the State of Acre issued a decision restricting the definition of "access" of a genetic resource. The court held that simply exploring features/properties of a genetic resource that was disclosed beforehand in the scientific literature is not "accessing" a genetic resource triggering requirements under Brazilian law. We have been told that this may affect the above mentioned litigation against companies that were merely utilizing products with properties that were previously disclosed a long time ago.

Recently, a new Bill 7735/2014 has been proposed before the Legislature by the Executive Branch concerning access to genetic resources. This Bill would replace the Provisional Act that currently regulates the area. The Bill has been prioritized for review; however, over 100 amendments have been presented and due to other issues before the Legislature the Bill has not yet gained traction.

¹² See <http://www.cosmeticsdesign.com/Market-Trends/Natura-accused-of-not-respecting-Brazil-s-biodiversity-laws>

Curiously the Bill does not refer to access to genetic resources for agricultural or food products. A second proposed bill drafted by the former Minister of Agriculture has been circulating in Brasilia. In December 2014, a new Minister of Agriculture was named and it is unclear whether this second proposed bill regarding access to genetic resources specifically for the agricultural and food products industries will progress under the new leadership at the Ministry of Agriculture. If not, access to genetic resources for the development of food or agricultural products would be regulated by the Provisional Act and not by the Bill currently before the Legislature.

Bill 7735/2014 does make access to genetic resources a less bureaucratic process; however, the proposed rules are different for foreign and domestic companies. As this is a Bill and as there are over 100 amendments, its potential effects on the industry are still uncertain – although, in general, there is some improvement over the original Provisional Act.

For all of these reasons, BIO requests that Brazil be placed on the **Priority Watch List**.

Canada

Canada continues to present challenges to the intellectual property rights of BIO's members. Canada has joined the Trans-Pacific Partnership (TPP) negotiations, and it is important that the U.S. Government understands the IP challenges in Canada and holds the Canadian government accountable during TPP negotiations. Canada's burdensome standard for establishing patent utility, restrictive listing requirements, lack of an equitable right of appeal, injunctive relief and patent term restoration, de-listing patents, threats of disclosure of commercially confidential information, issues with internet pharmacies, and other issues lead BIO to request that Canada be placed on the **Priority Watch List** with an **Out of Cycle Review**.

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 20 patents for plainly useful pharmaceuticals to be invalidated for inutility in

infringement or revocation cases or subjected to a finding that allegations of inutility are justified in hearings under the *Patented Medicines (Notice of Compliance) Regulations (PMNOC Regulations)*.¹³ 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.¹⁴ 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.¹⁵ 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.

¹³ Decisions invalidating pharmaceutical patents for a lack of utility in infringement or revocation proceedings include the following: *Eli Lilly & Co. v. Teva Canada Ltd.*, 2011 FCA 220 [*Strattera FCA*]; *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2011 FCA 300, leave to appeal to SCC refused [2012] SCCA No 19 (QL); *Ratiopharm Inc. v. Pfizer Ltd.*, 2009 FC 711, 76 CPR (4th) 241, affirmed 2010 FCA 204, 87 CPR (4th) 185 (FCA does not comment on utility); and *Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288 [*Olanzapine*], affirmed 2012 FCA 232. Decisions where allegations of inutility were found to be justified in PMNOC hearings include the following: *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, 95 CPR (4th) 193 [*Latanoprost FCA*], leave to appeal to SCC refused [2011] SCCA No 458 (QL); *Evista*, *supra* note 3; *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 235, 73 CPR (4th) 253; *Pfizer Canada Inc. v. Ratiopharm Inc.*, 2010 FC 612; *AstraZeneca Canada Inc. v. Apotex Inc.*, 2010 FC 714, 88 CPR (4th) 28; *GlaxoSmithKline Inc. v. Pharmascience Inc.*, 2008 FC 593, 72 CPR (4th) 295; and *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 26, 59 CPR (4th) 183, affirmed 2007 FCA 195, 60 CPR (4th) 177, leave to appeal to SCC refused [2007] SCCA No 371 (QL); *Sanofi-Aventis v. Ratiopharm Inc.*, 2010 FC 230, 82 CPR (4th) 414; *Shire Biochem Inc. v. Canada (Health)*, 2008 FC 538, 67 CPR (4th) 94.

¹⁴ 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.

¹⁵ 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 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.").

Since 2005, there has not been a single non-pharmaceutical patent revoked for lack of utility in Canada.¹⁶ 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.¹⁷

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 applicability (the European equivalent to the utility requirement).¹⁸ 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.¹⁹ Canada’s heightened evidentiary requirement is an outlier.

The standard for assessing utility remains improper even in light of recent Canadian case law. While there have been a number of individual cases that found particular pharmaceutical patents to have utility, Canada has maintained its promise utility doctrine and unique approach to patentable utility (demonstration versus sound prediction).²⁰ 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.

¹⁶ 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.

¹⁷ Patent Cooperation Treaty, Article 5.

¹⁸ 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).

¹⁹ See *Eli Lilly and Co. v. Actavis Elizabeth LLC*, No. 10-01500, 2011 BL 197400 (Fed. Cir. July 29, 2011).

²⁰ *Sanofi-Aventis v. Apotex Inc*, 2013 FCA 186; *Bell Helicopter Textron Canada Limited v. Eurocopter*, 2013 FCA 219; *Teva Canada Limited v. Novartis AG*, 2013 FC 141.

Canada's utility requirements place biopharmaceutical innovators in a difficult Catch 22 dilemma in view of the other substantive requirements for patentability.²¹ 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.²² 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.

Losses

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 \$750 million from the premature loss of patent protection based solely on Canada's outlier patent utility standard based on IMS sales data.

De-Listing of Patents from the Patent Register

Recent jurisprudence has made listing patents on the Patent Register more difficult for innovators. The Patent Register (the equivalent of the Orange and Green Books) is the gateway to enforcement of patents under the Patent Medicines (Notice of Compliance) or PM(NOC) regulations. This is the sole means of enforcement that permits innovators to have patent infringement and validity allegations assessed while the generic or subsequent entry biologic manufacturer (SEBM) are permitted to submit their regulatory dossier for approval to Health Canada. If relevant patents are not listed on the Patent Register, then early working of the patent rights are permitted without even a preliminary assessment of infringement of the patents covering the innovative product. Recent jurisprudence has required exact specificity between the ingredients in the approved combination product and the listable patents. The impact is that innovative drug companies may not be able to list single ingredient patents for combination products or such patents could be delisted. In fact, it is our understanding that OMPL has recently requested delisting of single-ingredient patents listed for FDC products, which enhances our concern. The only remedy for impacted/delisted single agent patents will be to seek damages after an at risk launch. This judicial interpretation of listing requirements is inconsistent with global best practices to ensure adequate and effective enforcement of patents.

²¹ All the patent laws of major countries require an invention to be new and non-obvious in addition to possessing utility.

²² 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.

Lack of Right of Appeal in PM(NOC) Proceedings

Also in PM(NOC) proceedings, where a generic or a SEBM wins an initial decision as to whether allegations of non-infringement or invalidity are sufficient to justify launch of a competing equivalent product, the Health authority can issue market approval. When this occurs, the PM(NOC) procedure becomes moot and any appeal is dismissed for mootness. The lack of an equitable right of appeal therefore remains an enforcement challenge in Canada. The PM(NOC) regulations create a process and a forum to resolve patent infringement issues and validity between generic and brand companies as part of the early working regulatory exception to patent infringement in the Patent Act (Section 55.2). However, practically, the regulations provide unequal appeal rights in favor of the generic company. A generic company can appeal the decision in a Notice of Compliance proceeding, but an innovator cannot. Any changes to rules surrounding PM(NOC) proceedings must acknowledge that even with a patent infringement action under the current procedure, complete redress remains illusory. 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.”²³ However, the USTR will need to monitor implementation to ensure that innovators are adequately protected by this provision.

Lack of Appropriate Injunctive Relief

A related issue is that Canadian jurisprudence takes the view that monetary damages are sufficient. 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).

Lack of 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. 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.

²³ 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>

Bill C-17

Canada recently passed Bill C-17, *An Act to Amend the Food and Drug Act* which makes revisions to the Food and Drug Act. Some of the provisions in this bill conflict with Canada's international obligations under the TRIPS Agreement. Certain amendments allow the Minister of Health to disclose confidential business information (CBI) to members of the public, foreign governments, and competitors, without confidentiality obligations or other protections against 'unfair commercial use' required by TRIPS Article 39.3.²⁴ This directly places the billions of dollars invested in this data at risk and has repercussions across the globe, as competitors in other markets outside Canada could rely on this data. The USTR should monitor implementation to ensure innovators confidential business information is adequately protected from disclosure and should ensure this issue is resolved satisfactorily prior to entry into force of the TPP vis a vis Canada.

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 infringing generics for export while the patent term restoration period remains in effect.

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.

²⁴ See Bill C-17, Clause 3, amendments after section 21; Clause 6, amendments to section 30 after subsection 1.1 and AdvaMed, BIO and PhRMA's full comments at <https://www.bio.org/advocacy/letters/bio-phrma-and-advamed-submit-comments-response-canadas-wto-notification>

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.

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

No data protection for biologics, U.S.-Chile Free Trade Agreement (FTA) noncompliance, lack of patent term adjustment or patent term restoration, and other patentability issues, has convinced BIO to request that Chile remain on the **Priority Watch List**.

The patent examination process suffers from excessive delays. Additionally, it remains difficult to enforce patents in the courts due to a lack of technical expertise on IP matters and a perceived lack of independence of the judicial branch on IP sensitive matters.

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. 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. These provisions are not consistent with Chile's obligations under either the FTA or Article 39.3 of the TRIPS Agreement.

Further, 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.

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. 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). 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).

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, and particularly in light of its apparent lack of compliance with the U.S.-Chile FTA provisions, BIO requests that Chile remain on the **Priority Watch List**.

China

China's large consumer market presents unique opportunities for U.S. biotechnology companies to increase exports and create jobs in the United States. However, failure to adequately protect U.S. IPR greatly affects BIO's members. In fact, the United States International Trade Commission reported that in 2009 U.S. businesses that operated in China lost approximately \$48.2 billion in sales, royalties, or license fees due to IPR infringement.²⁵ For the reasons stated below, BIO requests that China be placed on the **Priority Watch List**.

Patent Office (SIPO)

Our companies have reported that obtaining patent claims of reasonable scope is difficult in China. The examiners use the data requirements to restrict value. Variation from examiner to

²⁵ 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.

examiner is high and the appeal process is difficult. Finally, SIPO should consider accelerated examination processes to help compensate for the examination backlog.

SIPO has also invalidated important biotechnology patents protected elsewhere around the world due to lack of novelty and other patentability concerns. BIO hopes that USTR monitors these developments closely to ensure that the Chinese government is not creating arbitrary standards out of harmony with those standards of other developed markets around the world.

Biotechnology companies appreciate the 2009 amendments to the patent examination guidelines that protect medicinal inventions based on new properties. The guidelines recognize the non-obvious inventions based on drug optimization. However, SIPO applies a strict requirement for the inclusion in the patent application of experimental support for the new claimed usage. In other words, a company cannot subsequently show experimental support during prosecution. The requirement results in a delay that allows the competition to file first in China, even when they are not the original innovator.

BIO's companies have also faced a few issues with SIPO's requirements involving confidentiality or secrecy examination. The level of detail about the invention required in the submission for secrecy examination is high and therefore requires a substantial amount of time to draft the document for submission for secrecy examination. Thus, meeting this high level of detail would significantly delay the filing in a foreign jurisdiction. It is BIO's hope that as long as the submission document provides sufficient information for the reviewing examiner to determine that the subject matter is of a nature that is not restricted or prohibited, permission should be granted for foreign filing.

Biotech companies also find it difficult to determine how to define an invention "made in China" and thus whether first filing or secrecy examination in China is required. In pharmaceutical and biotechnological companies, many inventions are conceived by scientists in R&D centers outside China, but some data were collected in China. In such circumstances, no inventors are from China. It would be very cumbersome if such inventions need to be first filed in China since SIPO is not competent to be the Receiving Office for the PCT.

Adding new matter to an existing application in secrecy examination has proven difficult. While the new matter does not change the general nature of the invention, the rules remain unclear on whether a second secrecy examination is required for the new matter. BIO members believe a second examination should not be required as the general nature of the invention remains unchanged. Obtaining the secrecy clearance takes about one month leading to at least one month loss of priority year, especially for foreign filings in non-PCT countries.

A recent SIPO interpretation of the invention enablement requirements also presents challenges for U.S. companies in China. The new requirements limit the interpretation of the invention enablement to the disclosure in the examples of a patent application, or in other words, the examiner looks no further than the working examples of the case. In biotech applications, it appears that SIPO does not consider the use of percent identity or hybridization conditions as clear unless these are specifically used in the working examples to define breadth. As a result, bio-informatic methods of defining sequence scope acceptable in many countries are not

recognized as clear within China. These requirements are problematic as biotech research is expensive and developing the number of working examples necessary to cover all embodiments may not be possible. The nature of industrial microbiology often requires a generic claim scope due to the redundancy found in nature (i.e., enzymes from different sources). Slight variations in structures are essentially impossible to protect.

BIO understands that current practice in China only allows applicants to supplement data of the reference compound or biologic to overcome the lack of inventiveness rejection. The data for the invention compound cannot be submitted. However, submission data after the date of filing should be allowed during prosecution because the applicant cannot know which prior art will be regarded as the closest prior art at the time of filing.

In addition, U.S. companies seeking to bring innovative therapies to market in China face additional hurdles posed by China's improperly retroactive application of new guidelines related to Article 26.3 of its patent laws.

Today's life-saving drugs are primarily protected by patents issued from patent applications filed well before 2006. Biopharmaceutical companies followed SIPO's examination guidelines effective before 2006 in describing their new drugs and methods of preparation and medical uses of the new drugs. Chinese patent examiners, in a manner consistent with pre-2006 guidelines, allowed applicants to submit post-filing pre-clinical and clinical data to support patentability of the new drugs.

In 2006, however, SIPO amended its Examination Guidelines for chemical inventions and disallowed examiners from considering post-filing data in support of the patentability of the new drug inventions, even with respect to patent applications filed well before 2006. SIPO made the data sufficiency guidelines by interpreting Article 26.3 of the Chinese Patent Law. Key to note is that Article 26.3 itself has not materially changed since China enacted patent laws in 1984.

Further complications are created by the fact that SIPO's Patent Reexamination Board (PRB) has allowed parties to use the 2006 version of the guidelines related to Article 26.3 to invalidate chemical patents issued from applications filed before 2006. Such retroactive application of the guidelines renders numerous new drug patents issued from applications filed before 2006 vulnerable to invalidation. Innovators could not possibly have been aware, pre-2006, of the high standards imposed by the 2006 guidelines and could not comply, post-2006, with the rule by submitting post-filing data. The pernicious nature of the retroactive application of 26.3 rule has been exemplified, e.g., in cases in which individuals demanded that biopharmaceutical patent owners pay them in exchange for dropping invalidation requests based on the new 2006 guidance related to Article 26.3.

We understand that, at the 2013 U.S.-China Joint Commission on Commerce and Trade plenary meeting, China agreed to cease retroactive application of the 2006 guidelines related to Article 26.3. Feedback BIO has received has indicated that very few cases are currently being rejected under Article 26.3. However, BIO urges USTR both to continue to maintain a close watch on this issue and specifically to address this issue in its Special 301 Report.

China has a plant variety protection (PVP) law in force, and its patent law excludes patent protection for plant varieties, which, on paper, fits very well with TRIPS obligations and would provide a workable IP landscape for innovator companies in the field of agriculture. However, the SIPO has introduced certain deviations from the wording of the patent law in its Guidelines for Patent Examination, 2010. From an exclusion limited to animal and plant varieties in the Patent law, the SIPO Guidelines have broadened the exclusion to any animal and any plant claimed in generic terms (i.e. beyond plant varieties). As consequence, the SIPO has created a significant gap in intellectual property protection for inventions in the field of agriculture. Innovators of plant-based inventions that are applicable to many plants or to many plant varieties 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 exclusion to "plant varieties" instead of "plants" (and "animal races" instead of "animals") should positively remove this gap of protection for agriculture innovations, and would at the same time align the SIPO practice with the Chinese patent law.

Finally, SIPO should include more information on its electronic system where the public can access information including prosecution histories before patent grant and for granted patents. These resources should also be available by paper. BIO also hopes that for any given case the complete file history is made available in complete form so that all parts of the file history are accessible by the public.

Patent Law

Chinese patent law limits the ability to secure intellectual property on methods of surgery, therapy, and diagnosis. China permits Swiss-type claims, but not method of treatment claims. While this is allowable under TRIPS, Chinese law limits the types of IPR most biotech companies seek to protect as they want to protect, both their drug compounds and how they are used. Many companies also rely heavily on formulation patents to protect the pharmaceutical development.

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 CFDA significantly curtail the rights of IP owners. 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 countries, having so-called Bolar provisions, which allow the development of generic products during the term of the patent. China has adopted a Bolar provision without a system of patent term restoration. A Bolar provision without the ability to recoup the time lost for regulatory delay represents an unbalanced system and is detrimental to innovator companies.

Chinese law also makes it difficult to establish claim priority from earlier-filed applications. Chinese law allows priority for a provisional or other application only through providing evidence that the inventors listed have assigned their rights to the applicant. This evidence may not be available as inventorship often is not fully determined in a provisional application. Under U.S. law, a provisional application need not recite any claims that precisely define what the inventor believes his invention to be. As a result, it is common practice for

inventorship to differ between a provisional application and subsequent non-provisional (or international) application. If an applicant cannot produce an agreement from the inventor which expressly assigns his rights to the applicant, then Chinese law will not permit the applicant to claim priority from the application.

China enacted the Third Patent Law Amendments in December 2008. The amendments entered into force in October 2009. BIO's members are concerned about some of the changes made in these amendments. In particular, 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 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, the amendments to Article 26 for the first time 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 appear to be intended to promote compliance with provisions of the Convention on Biological Diversity (CBD) relating to access to genetic resources and equitable sharing of benefits from utilization of these resources. However, such provisions will not further these goals, which can be accomplished most effectively by improved transparency in national access and benefit-sharing regimes. The failure to identify the "direct source" of a biological material used in the invention is apparently also a basis for denying a patent to an otherwise deserving invention. In the case of the "original source," failure to disclose may also result in denial of a patent unless the inventor can "state the reasons" that the original source "could not be explained." These special disclosure requirements 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 and, consequently, the scope of requirements is additionally complicated.

These amendments also do not appear to be consistent with China's obligations under the TRIPS Agreement to make patents available for "any inventions" that are new, have an inventive step, and are capable of industrial applicability. Further, the additional requirement for inventions in a particular field of technology (i.e., inventions involving genetic resources) is not consistent with China's obligation to make such patents available, and patent rights enjoyable, "without discrimination ... as to field of technology." 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 inconsistent with these provisions. Thus, these requirements should be deleted. To the extent that rules remain in force, however, we suggest that, at a minimum, the initial burden shift to the examiner to first identify which material the applicant must show "source." Without such identification, the requirement should not apply. It would also be suggested that at best any disclosure requirement is limited to the disclosure of the direct source from which biological material - that is directly claimed in the patent application - is obtained. Also, there should be no obligation to disclose the source of any biological material if such material was already the subject of a public disclosure prior to the filing of the patent application. In the latter case the citation to such publications should be sufficient to comply with the disclosure requirement.

The amendments to Articles 48 to 52 of China's patent law provide changes with respect to compulsory licensing of inventions. BIO supports a number of changes in this area. For example, SIPO should 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. However, significant clarification regarding the events that would trigger compulsory licensing, as well as the scope and duration of the licenses granted, is needed.

China did issue *Draft Measures for the Compulsory Licensing of Patents* in October of 2011 to try to clarify the compulsory license process and seek comment. BIO commented on the Draft Measures requesting clarification on key terms, recommending that importation of the patented product constitutes exploitation of the patent in China, calling for a prohibition on the export of compulsory license product to developed countries, as well as some procedural recommendations.²⁶

Finally, in 2012 China released a draft regulation on service inventions regulating the contractual liberty between the employer and employee. The draft regulation proposes unnecessary restrictions on enterprises and their contractual relationships with inventors and would likely lead to disputes and litigation on inventor remuneration. There is much uncertainty about how the regulations are to be interpreted and applied. For example, although the proposed regulations allow companies to enter into agreements with employees or have rules on service invention award and remuneration, an agreement or rule can be determined to be invalid if judged as eliminating or limiting the rights that the inventor is entitled to according to the regulations. Another example is it seems inventors have the first right of refusal to acquire the company's patent right if the company wants to assign it and there is uncertainty whether this first right of refusal can be waived by agreement. (Although the provision on this first right of refusal is no longer present in a recent draft, it is not certain whether this provision will reappear later in the regulations; furthermore, the Chinese Contract Laws have a similar provision.) Such regulations will likely disincentivize companies from conducting research and development in China.

Enforcement

Some biotechnology companies have commented that China's processes and remedies for patent infringement and trade secret misappropriation are ineffective. China requires U.S. companies to pursue enforcement actions 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.

Chinese law also requires proof that violations in counterfeit activity exceed threshold values before any action is taken by authorities. While this provision does seem to recognize the

²⁶ For a full list of recommendations please see *China Compulsory License Proposed Provisions Draw Reaction from BIO* accessed at <http://www.bio.org/advocacy/letters/china-compulsory-license-proposed-provisions-draw-reaction-bio>

limited resources and prioritization of Chinese enforcement, violators have adjusted by operating in diffuse networks to make enforcement more challenging. Overall, criminal penalties are insufficient and law enforcement is slow to act.

Chinese manufacturers that only export their products are not subject to regulatory oversight or review. As a result, infringing products manufactured in China are often of low quality. Some companies have suggested that evidence exists that competing pharmaceutical products are of such inferior quality that they would not meet FDA approval. Company representatives were able to purchase counterfeit goods in China and in jurisdictions outside of China indicating inadequate export controls. Internet pharmacies and other illicit distribution routes allow the counterfeits to enter foreign markets with intellectual property protection for those products. Chinese counterfeits are entering the U.S. market as evidenced by Attorney General Holder's announcement on November 29, 2010, that the United States seized 82 websites offering counterfeit Chinese goods. The notorious counterfeit markets in China are Shandong, Guandong, and Fujian provinces.

Finally, Chinese law does not allow preliminary injunctions to stop the export of infringing products. Since the courts need to decide preliminary injunction requests within 48 hours, courts simply do not accept them. Many have suggested that the courts be given enough time to decide the injunction requests. However, in the biopharmaceutical area, it is critical that patent issues are resolved before product launch. Thus, China should either have an effective process for preliminary relief, or there should be a patent linkage process, allowing the regulatory body to withhold approval of a generic product until the patent issues are resolved in the courts.

BIO requests USTR to continue to promote more effective enforcement directed to combat the distribution of counterfeit biopharmaceuticals in China.

Courts

BIO responded to requests from the United States Patent and Trademark Office for more information on patent enforcement in China. In BIO's submission²⁷, our companies identified several issues that make it difficult to enforce a patent in China mainly involving the Courts.

Chinese law requires that the product is actually sold in China before a patent holder can bring an infringement action. It is not enough to produce the infringing product, or seek regulatory approval of the infringing product. Additionally, the Supreme Peoples' Court has cautioned lower courts from issuing preliminary injunctions for 'complicated' technologies (like biotechnology). The rules also require a decision on a preliminary injunction within 48 hours. Given these restrictions, it is unlikely that any Chinese judge would issue a preliminary injunction. Biotechnology companies are left to try to obtain an injunction after conclusion of the litigation which will still not restrict the CFDA from approving other generic applications.

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 considers sales in China and not outside the country. When combined with the

²⁷ See <http://www.bio.org/advocacy/amicus-brief/china-patent-enforcement-comments-uspto>

inability to get preliminary injunctions, low damages does not serve as a deterrent for infringers. Further, cumbersome notarization requirements, problems with discovery procedures, and lack of compliance with court orders (because they are not enforced upon the infringing party) greatly hinders the innovator's ability to prevail in an infringement suit. Finally, China restricts expert testimony to government or court-sanctioned experts who are not familiar with the technology and cannot adequately testify in an infringement action.

Finally, wide spread abuse of utility model patents occurs and injunctions based on utility model patents should not be granted until the utility model has been examined and deemed valid by SIPO.

Regulatory Bodies

Under Chinese regulatory approval laws regarding generic drugs, if the innovator drug is approved and being marketed in another major market, then a generic company can receive approval in China. This loophole allows generic companies to file and gain regulatory approval in China before the U.S. innovator company. In addition, if the generic company has filed an IND and received approval in China before the U.S. innovator company, then the generic receives five years of exclusivity. This blocks the innovator from receiving approval for those five years. Some companies have successfully sued these generic companies under process patents, but the problem remains. Innovator companies often chose to file an IND in China before they know whether or not they are going to bring their product to market in China to preserve their right to enter the market and to protect themselves from generics gaining exclusivity for the innovator's drug.

The Third Patent Law amendments also add a "Bolar exemption" to patent infringement for pharmaceutical products in Article 69(5). However, unlike the law of many countries that provide this exemption, the exemption codified in the patent law amendments is not balanced by extensions of patent term to compensate patent owners for delays encountered in the regulatory approval process. Without such a balancing provision, the amendment, standing alone, does not provide equitable treatment to owners of intellectual property rights relating to pharmaceutical inventions.

China has implemented a six-year data exclusivity term for pharmaceutical and agricultural chemical products. However, this term is not applied in practice in a manner consistent with adequate and effective protection of regulatory approval data. The law, as currently implemented, does not provide the level of protection that is necessary for biopharmaceutical entities to bring products to market, and permits unfair commercial use of pharmaceutical test data developed by innovators. The definition of "new drug" is interpreted as "new" anywhere in the world rather than new in China allowing much earlier generic entry. Thus, generic products are approved before the 6 year period has expired, and in some cases generic products have been approved before the innovator product has been approved. Finally, no patent linkage exists to help ensure that innovators know when generics have violated their intellectual property rights, as described above. The regulatory body should be allowed to withhold approval of a generic product pending resolution of the patent issues in the courts.

Data exclusivity enforcement also arise when generic companies apply for registration as a category 3 drug. China classifies new drugs into 5 categories with Category 1 relating to new drugs which have not been launched anywhere in the world. Category 3 drugs have already been launched in a country outside China but not in China. For Category 3 drugs, only require innovators to provide a pk study and a 100 pairs of randomize clinical trial data because the other data has been provided to other markets during registration. Generic companies have been trying to use the Category 3 designation to get approval in China without providing phase 1-3 clinical studies during the data protection period undermining the innovator's IP rights in China.

A final issue involves government sponsorship of the manufacture of infringing products. The National Program for the Development of Major Drugs is a government sponsored program which funds the manufacture of generic versions of U.S. patented pharmaceuticals. The Ministry of Health and the CFDA are both stakeholders in this program. This creates a conflict of interest and a specific challenge for U.S. biotech innovators as often their competition is the Chinese government itself.

Other Laws Affecting U.S. Intellectual Property Rights

The Corporate Income Tax Law revision in 2007 requires China registered legal entities to "own IP" as one of the essential prerequisites to qualify for "high-tech status" and enjoy a lower tax rate of 15% compared with the average 25%. As China's IP atmosphere is risky for foreign firms, many multinationals and U.S. companies tend to license, instead of letting the local entity "own," the IP. The tax requirement makes it difficult for U.S. companies to partner with Chinese companies and retain the "high-tech" status, regardless of the high technology content of their activities in China.

Another problematic Chinese law involves the regulation and laws of intellectual property licensing. China statutorily prohibits a Chinese party to agree to restrictions on its ability to obtain competing technology to that which is licensed from other sources. In addition, U.S. companies may not place restrictions on the export of products made using licensed technology, thereby making it difficult to license technology based on geographically defined fields. Chinese law also will not permit a Chinese entity under contract with a foreign entity to agree to terms that protect U.S. IPR interests. These terms include agreeing to not improve the technology, prohibiting reverse engineering, or granting back improvements in the technology to the licensing party unless there is separate consideration for such improvements. Absent separate agreement, and possibly approval from the government, improvements are deemed owned by the licensee. The inability to restrict the development of improvements and reverse engineering is particularly problematic for biotech inventions.

Ecuador

The Ecuadorian Institute of Intellectual Property (IEPI) has issued nine compulsory licenses, six of which occurred in 2014. This represents a dramatic shift in direction for their respect of intellectual property rights and there are reports that more compulsory license applications for medicines across multiple therapeutic areas have been filed in Ecuador.

BIO appreciates the government's need to expand access however, the decision to maintain policies relying on 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.

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. For maintenance fees, fees have increased between 800% and 3529% (e.g. up to USD 4,514 and USD 20,760 for the 10th and 20th 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.

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.

Ecuador also has yet to implement the specialized IPR courts required under Ecuador's 1998 IPR law. Finally, Ecuador does not offer effective data protection of data submitted for marketing approval of pharmaceutical and agricultural products.

Finally, Executive Decree No. 522 may result in the inability of, or at least may severely limit an innovator's ability to use their trademarks once a patent expires. While still unclear, 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." USTR should seek clarity from the Ecuadorian government to ensure U.S. trademarks are protected.

BIO's members encourage the United States government to place Ecuador on the **Priority Watch List** and to conduct an **Out of Cycle Review** to monitor the IP and compulsory license developments in Ecuador.

India

India is an important market to biotechnology companies and patents on key products result in sales of hundreds of millions of dollars. However, difficulty in obtaining and enforcing intellectual property rights in India remains a barrier to biotechnology companies. BIO is encouraged by the new willingness to engage all stakeholders by the new government but uncertainty remains.

Since the start of the new Indian government led by Prime Minister Narendra Modi, the United States and India have re-started discussions on a variety of trade and IP fronts. Most notably, the two countries have agreed to establish a new High-Level IP Working Group that will meet at least annually. In addition, the two countries met last November 2014 under the auspices of the Trade Policy Forum and the High-Technology Cooperation Group for the first time in two years. These are important milestones and the innovative biotechnology industry will be watching closely developments in these various forums.

Separately, the industry has noted some other developments in the environment for IP-intensive industry. For example, the announcement that the Department of Industrial Policy & Promotion (DIPP) would not issue a compulsory license as requested by the Ministry of Health and Family Welfare, effectively raising the standards required by the Indian government before issuance of a compulsory license. In addition, DIPP commissioned a National IPR Think Tank tasked with developing a new National IPR Policy, a draft of which was released in late December 2014. In reviewing this draft, BIO has found that while the authors express the need for respecting IPR, they do not necessarily give a strong rationale for doing so, thereby missing an opportunity to impress upon the government and the public how strong and effective enforcement of IPR is beneficial to India's economic development. Finally, in regards to this draft IPR policy, the authors do not address some of the more controversial issues being debated, such as compulsory licenses. Again this is a missed opportunity to articulate the government's position on this and other critical issues. BIO looks forward to further opportunities to share our views with the Indian Government on this draft policy.

In recognition of both the improvement in the IP environment and the willingness to engage in dialogue, therefore, BIO requests that USTR designate India to the **Priority Watch List** with an **Out of Cycle Review** to monitor IP rights in India.

Patent Law and Patentability Standards

U.S. biotechnology companies have limited capability to obtain valid patents for inventions based on formulations, dosage forms, or chemical variations of an earlier patented product. India imposes higher standards in these areas than are found in the vast majority of other countries. Patents on such inventions are crucial to incentivize biotechnology companies to continue to investigate their discoveries and improve their own products.

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, generally interpreted to mean "clinical efficacy", excludes from

patentability many significant inventions in the pharmaceuticals area, e.g., new forms of known substances with improved heat stability for tropical climates, or having safety or other benefits that may not result in “enhanced clinical efficacy” *per se* but still provide very real benefits to patients. Even if not removed, new forms of a substance that have benefits to the patient with clear support for its therapeutic improvement should be central to the concept of “improved efficacy” yet are noticeably absent in consideration for granting a patent. In addition, this provision appears to be inconsistent with India’s obligations pursuant to Article 27 of the TRIPS Agreement, which requires that patents be made available to “any inventions ... in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” Section 3(d) also 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.

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. India excludes method of treatment claims, which prevents U.S. biotechnology companies with needed treatment methods from entering the Indian market to provide life- saving products. Further, 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.” The lack of flexibility in India’s law prevents biotechnology companies from seeking protection and bringing their products to India.

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. Further, the applicant must obtain approval from the India National Biodiversity Authority even when the materials are not native to India (a requirement that seems to only apply to non-Indians). These special disclosure requirements impose unreasonable burdens on patent applicants, subjecting valuable patent rights to great uncertainty. Under the Indian law, the failure to identify the geographical source of a biological material may be a basis for opposition or revocation proceedings; however, the necessary relationship to the patented invention is not clear. These requirements pose unacceptable risks for patent applicants, seem to discriminate on the basis of national origin, and undermine the incentives of the patent system to promote innovation in biotechnological inventions. Further, such requirements are not consistent with India’s obligations under the TRIPS Agreement.

India’s plant variety protection (PVP) law has been in force since 2005, however, India excludes patent protection for plants in generic terms (i.e. beyond plant varieties). As a consequence, the Indian government has created a significant gap in intellectual property protection for inventions in the field of agriculture. Innovators of plant-based inventions that are applicable to many plants or to many plant varieties cannot obtain adequate protection for their inventions either with patents (“plants” broadly excluded) or from PVP (only applicable to plant varieties). 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 of protection for agriculture innovations.

Also, certain innovations in the agriculture sector may qualify as "living thing occurring in nature", which are excluded from protection under Section 3(c) of the Indian Patent Act. However, such innovations require much investigations and investments to be identified as useful for agriculture, and removal of such exclusion would be as much necessary to maintain the investments in the development of such innovations addressing the challenges of agriculture.

Moreover, India has failed to extend protection under PVP to all crops, thereby increasing the identified gap for such crops. Currently, there is no mechanism for appeal and the transitional provision required by the PVP law are not implemented. Finally, the Indian government must address significant inefficiencies in the PVP registration procedures.

In 2014, the Indian Intellectual Property Office (IPO) issued Draft Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, inviting comment from a wide variety of stakeholders, including public hearings as well as written comments. We commend the Indian government for its transparency and willingness to hear from interested stakeholders. BIO submitted comments to the IPO on the draft guidelines and were pleased that at least some of our comments seem to have found their way into the final version released. For example, the IPO agreed to reconsider issues pertaining to para 4 (Markush claims), para 10.2 (Section 3(c)) & para 10.3 (illustrative examples for Section 3(c)), para 10.5-10.8 (Section 3(d)), para 10.19 (Section 3(i)) among others. Furthermore, BIO raised the concerns in a public meeting that the Guidelines showed a bias against pharmaceutical patents. The Controller-General responded that the IPO would reconsider the Guidelines to ensure that they did not *prima facie* demonstrate a negative bias toward pharmaceutical patents. However, the CG categorically made it clear that the IPO would continue developing the Guidelines without succumbing to the risk that they might be challenged before the court of law. Nonetheless, BIO was pleased with the decision not to require patent applicants to list the INN name in patent applications.

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,²⁸ Pegasys, Ganfort, Combigan, and Renadyl.²⁹ In addition, IPAB denied an application for a method patent protecting Glyphosate which increases climate resilience in plants. Many of these patents were revoked on multiple grounds including obviousness and inventive step even when these patents are valid on the same standards in other patent offices around the world. If the Indian patent system is an outlier for granting patents, it makes it very difficult for biotechnology companies to continue to invest in India.

BIO member companies have also found patents invalidated for Section 8 violations (a requirement to provide information regarding corresponding foreign patent applications). The IPAB's recent judgments had put the obligation on the Patentee to provide the information to the Indian Patent Office (IPO) and non-compliance leads to revocation. This information was easily

²⁸ For Sutent, the IPAB remanded the case back to the Patent Office for a third review and reinstated the patent. However, Sutent is still at risk for losing patent protection.

²⁹ IPAB revoked the process patent but upheld the product patent. However, the product patent is still being challenged in court.

accessible to the Examiner at the IPO and an unnecessary burden on the patent applicant. The situation was only made worse by the disproportionate punishment attached to this section. However, a recent Delhi High Court decision ruled that a Section 8 violation is no longer fatal to a patent application and that Section 8 violations only require invalidation if the patent applicant deliberately failed to provide the information.

There is an additional administrative burden for the patent applicant by the introduction of the form 1 requirement with a recent IPAB decision requiring that ‘proof of right’ to file an application should be established for all patent applications where the applicants are not the inventors.

The lack of consistent adherence to patent rules and procedures between the regional patent offices create 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 patent examiner guidelines should assist in this matter. In addition, improved transparency would help guide future prosecution. Expediting pending oppositions would also help alleviate the negative effects on U.S. business in India. India needs a more robust infrastructure for searching and procuring patents, including the ability to identify assignment records and other basic patent filing information. In this regard, we recognize that the IPO issued a Request For Proposals to design a new database for providing access to patent literature.³⁰ Finally, coordination with other international patent offices through work sharing programs will help standardize the patent application process.

Another concern involves the delay in processing applications coupled with the opposition procedures. The timelines and processes for opposition procedures are not well-defined. Companies often wait dozens of years for a patent application to enter into the examination process only to have the claims opposed in a pre-grant proceeding. The 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, one company reported waiting almost a year for a decision. Finally, the existence of both a pre and post-grant opposition proceeding creates problems as a U.S. company will survive a pre-grant opposition proceeding and have the patent granted only to 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 pre 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 issues coupled with a lack of centrally

³⁰ http://www.ipindia.nic.in/rfp/RFP_PatentLiterature_29December2014.pdf

located and electronically accessible records and requirements to have local agents to obtain basic documentation make the whole process expensive and time consuming.

The Patent Office announced on December 24, 2009, that all patentees must submit Form 27, a yearly “statement of working” that proves that the patentee is exploiting its invention in India. The Patent Office most recently reiterated this requirement in a Public Notice dated January 13, 2015.³¹ If the company does not comply, the government may issue a compulsory license. The regulation allows the patent office to cancel a patent if it has not been continuously “worked” for a period of more than two years after falling under certain specified conditions. This provision may result in the loss of intellectual property rights in India when a biotechnology company cannot work on the drug 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 not commercializing in three years from the patent grant. U.S. law recognizes this challenge by allowing patent term restoration to compensate for the loss of patent life caused by product development and delays in regulatory approval.

A final issue involves the administrative burden of first filing in India for inventions made by Indian residents. This process hampers 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.

Courts

India in late 2004 passed amendments to its Patent Law, recognizing patent protection for pharmaceutical compounds. As a result, the courts in India had limited experience and case law in dealing with patent enforcement issues and are still developing the standards for claim interpretation, trial, and enforcement of injunctions, etc. Generally, the courts have no standards for issuing injunctions and have not given deference to the determinations of the Indian Patent Office. Historically, the courts have granted injunctions to protect U.S. company patents only in limited circumstances. The courts also often decline to uphold patents that have been granted with the same or similar claims in jurisdictions with higher patentability requirements. The courts have also declined to consider granted patents when deciding whether to approve marketing applications by generics if a patent is being tested in the courts or in opposition. While there has been some improvement of companies being able to receive preliminary injunctions in the courts, USTR should continue to monitor the situation to ensure this positive trend continues.

In 2013, the Supreme Court of India denied an appeal for a patent revocation of a cancer medicine, Glivec. The Court found that the medicine was anticipated by prior art and did not satisfy the criteria under section 3(d) described previously. Glivec was a breakthrough cancer therapy and is protected by patents around the world. This unique, and arguably TRIPS non-

³¹ http://www.ipindia.nic.in/iponew/publicNotice_21January2015.pdf

compliant feature of Indian law, results in creating vast disparities in outcomes that the law and international trade agreements are designed to protect against.

Other recent case law developments have drawn concern from our member companies for their seeming arbitrariness. A recent case involving Roche and Cipla resulted in the Court deciding Cipla's unauthorized generic copy did not infringe Roche's patent but the court also found that the patent was still valid. The court rendered a claim interpretation not in line with international standards. The appeal is still pending since October 2012 and the hearing still has not occurred. In March, 2013, Glenmark launched a generic version of Januvia/Janumet prior to patent expiration and the innovator was not able to obtain a preliminary injunction. By January 2014, Glenmark earned Rs 16 crore (\$2.6 million) on these medicines while the patent owner was waiting for a final decision.³² Other judicial interpretations of the obviousness standard for dosage forms and other similar inventions have also drawn concern.³³ The second issue involves the interpretation of the novelty and obviousness standards in the context of an enantiomer product.³⁴ The final issue is the rejection of any applications for new methods for known compounds.³⁵

Biotechnology companies would find it helpful if the United States or other nations experienced with patents were able to offer training to the Indian court system to help handle the various issues involved in a patent case. Patent cases are often difficult and require specialized training. Such training would be beneficial to the Indian court system to help them make consistent decisions and create uniform standards for enforcement. Consolidating patent cases into a few specialized patent courts might also help these issues as consolidation would allow judges to gain expertise in a very new and complicated area of law. We note that this suggestion was also made in the recent National IPR Policy drafted by the National IPR Think Tank created by India's Department of Industrial Policy & Promotion.

Enforcement

Failure to recognize or enforce patents gives generic companies an unfair global competitive advantage. Those Indian generic companies, who are primarily export-oriented, routinely ship generic medicines to countries where patent protection does not exist making it difficult to bring innovations to these markets. Innovators also find it difficult to stop Indian generic companies from exporting into countries with patent protection.

Indian generic finished products and API are advertised as being equivalent to the innovator product. These products are sold in countries illegally without regulatory approval in that country, often through internet pharmacies. Even with strong IPR, law enforcement is often slow to take action unless the generic is proven to be counterfeit.

³² See http://articles.economictimes.indiatimes.com/2014-01-09/news/46030254_1_glenmark-pharmaceuticals-januvia-and-janumet-diabetes-drugs

³³ including Aventis Pharmaceuticals, 1021/CHENP/2006 (2009), and Novartis AG, 728/CHENP/2006 (2009).

³⁴ Astra Aktiebolag, 1255/DEL1995 (2009)

³⁵ GlycoScience Labs 1752/CHE/2006 (2009)

Drug Regulatory Body

India's drug regulatory agency approves generic company applications to market generic drugs if a patent is being challenged. Accordingly, a generic company need only challenge a patent to apply for marketing approval. This loophole creates an unfair advantage for Indian generic companies.

India also has not yet 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, protection must be extended against unfair commercial use of such data by makers of generic copies of innovator products (i.e., products that must be shown for the first time to be safe and effective, or to not cause significant risk to the environment). BIO views the 2007 Reddy Report³⁶ and its recognition that the present legal provisions in India do not adequately meet the spirit of TRIPS Article 39.3 as a positive development. Further, BIO views positively the suggestion in that report that India should adopt a five-year fixed data protection term during which the relevant regulatory officials will not rely upon data submitted by the originator when approving second and subsequent applications for the same product. Nonetheless, it appears that meaningful protection for this data will not be implemented in the near term. In addition, even the suggested post-transition period protection suggested in the Reddy Report is subject to numerous, and apparently wide-ranging, proposed "safeguards," a number of which would appear to undermine the proposed protection almost entirely. Effective market exclusivity for regulated pharmaceutical and agricultural chemical products would contribute significantly to providing adequate and effective protection of intellectual property rights in India for BIO's members.

A clear biologic medicine regulatory approval pathway is still under development in India. Nonetheless, the regulatory system has many shortcomings, such as the ability to seek marketing authorization for biologics with as few as 100-patient clinical trials. Biosimilars of Embrel, Rituxamab and Herceptin have been approved in India with accusations from Indian industry that the regulatory agency is not following the biosimilar guidelines in place since August 2012.³⁷ A biologics pathway consistent with U.S. and European law is not only necessary for U.S. companies and but also it will ensure that Indian manufacturers develop products which are globally competitive as well as safe and effective for Indian patients. .

Finally, India should adopt a patent linkage system so that they are not inducing companies to violate innovator patents.

Compulsory Licensing

The Indian Patents Act also unreasonably restricts the use of patent rights. The Act provides broad exceptions for use of patented technology by the Indian Government or third

³⁶ SATWANT REDDY AND GURDIAL SINGH SANDHU, REPORT ON STEPS TO BE TAKEN BY THE GOVERNMENT OF INDIA IN THE CONTEXT OF DATA PROTECTION PROVISIONS OF ARTICLE 39.3 OF THE TRIPS AGREEMENT (May 31, 2007). E.g., see safeguard (xi), which states that "[i]n cases where repeating the clinical trials for a drug is not considered essential, the Regulatory Authority may allow marketing approval to subsequent applicants of a drug similar to an earlier approved drug by placing reliance on the first applicant's undisclosed data."

³⁷ See http://articles.economictimes.indiatimes.com/2013-05-14/news/39256077_1_cipla-drug-controller-biotech

parties. It also provides extensive authority for the grant of compulsory licenses, including licenses justified only on the basis that the products falling under the patent are not manufactured in India.

The Indian generic company Natco Pharma received a compulsory license on Bayer's Sorafenib which treats liver and kidney cancer. The Controller General found that the compulsory license was justified on three grounds; "reasonable requirements of the public" are not met, the invention is not available to the public, and the invention is not "worked" in India. The Controller interprets the working requirement to require 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"³⁸, 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. Finally, the Supreme Court of India on December 12, 2014 dismissed a "Special Leave Petition" filed by Bayer challenging the compulsory license. However, the court was very careful in noting that all "questions of law remain open".

Early in 2013, the Indian Health Ministry called for the government to issue compulsory licenses for three cancer drugs. In September of 2013, the Ministry limited the scope of their initial request and filed a petition to compulsory license Sprycel.³⁹ While this petition is pending, the Indian Patent Office rejected BDR's petition for a compulsory license on Sprycel for failing to make a "prima facie" case holding the petitioner failed to adequately seek a voluntary license from the patent holder. However, the patent is being litigated in the courts under an infringement suit. In the meantime, we understand that the Department of Industrial Policy & Promotion (DIPP) has, as of November 2014, denied the Health Ministry's request for a compulsory license for Sprycel. In providing access to medicines, other tools are more appropriate. Naturally, BIO's members are hesitant to bring new investment into countries which threaten to issue compulsory licenses for their products. Finally, 95% of the World Health Organization's Essential Medicines List are not patented anywhere in the world.⁴⁰ Yet, the World Health Organization states that the drugs on the EDL are affordable to only 20% of India's population.⁴¹ Meanwhile, India's negative IP environment is resulting in delayed launches of new drugs in India. A September 2014 study published in Health Affairs found that 50% of FDA approved drugs launched in India with a lag of more than five years. The authors conclude that these drugs were subject to weaker patent protection in India which discouraged manufacturers from launching in India which resulted in limited access. Yet, once those drugs were became available in India multiple

³⁸ *Bayer Corp. vs Union of India*, OA/35/2012/PT/MUM (para 46)

³⁹ In 2013, Roche dropped patent protection for Herceptin likely due to the deteriorating IP environment in India. The Health Ministry dropped Ixempra from compulsory license consideration around the same time.

⁴⁰ See http://www.wto.org/english/tratop_e/trips_e/techsymp_feb11_e/laing_18.2.11_e.pdf and http://cameroninstitute.com/attachments/043_Pharmaceutical%20Access%20in%20Least%20Developed%20Countries.Fall2010.Draft-1.pdf

⁴¹ "Health workforce, infrastructure, essential medicines", World Health Statistics 2009, The World Health Organization.

manufacturers produced and sold the same drug within one year of innovator launch.⁴² It also is interesting to note that in Indian government spends only 1.19% of its GDP on healthcare. This is well below the expenditure of other least developed and developing countries. For example, Brazil's government spends 4.23% of their GDP, China 2.73%, South Africa 3.9%, Botswana 6%, Angola 2.39%, Burkina Faso 3.4%, Congo 3.35%, Gambia 2.89%, and Cameroon 1.5% on healthcare. BIO hopes the new government moves to rectify this situation.⁴³

BIO recommends that USTR designate India to the **Priority Watch List** with an **Out of Cycle Review**.

Indonesia

The protection of intellectual property rights in Indonesia continues to suffer from considerable gaps that raise problems for BIO's membership. BIO urges USTR to place Indonesia on the **Priority Watch List**.

On September 3, 2012 Indonesia issued a decree authorizing government use of patents for nine patented pharmaceutical products. 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 a group. Article 31 (i) requires the ability to appeal the compulsory license to a judicial or other independent body. No such appeal seems to be present in this compulsory license. Finally the indiscriminate use of compulsory licenses draws investment away from the biotechnology sector which is heavily reliant on patents to generate investment funding. Indonesia's actions on compulsory licenses is inconsistent with their stated desire to create an enabling environment for innovation in the life sciences.

Indonesia does not provide sufficient data protection. Article 39.3 of the TRIPS Agreement requires that protection against "unfair commercial use" be provided for test data generated to prove the safety and efficacy of pharmaceutical and agricultural chemical products. Indonesia still does not have a law to fulfill its obligation under TRIPS Article 39.3. The introduction of effective market exclusivity 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. Indonesia's patent law also has considerable gaps that deny protection to a wide range of biotechnology inventions, including transgenic plants and animals.

⁴² Berndt and Cockburn, *The Hidden Cost of Low Prices: Limited Access to New Drugs in India*, vol. 33 no. 9 (Sept 2014)

⁴³ Data through 2011 accessed from the World Bank at <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS/countries>. Specific percentages given are a combination of the Health Expenditure, total (% of GDP) which measures public and private spending and the Health Expenditure, public (% of total health expenditure) to calculate public spending as percentage of GDP.

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 is another challenge in Indonesia when trying to enforce a patent. BIO requests that USTR further engage with Indonesia to put in 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. Finally, customs enforcement of counterfeit pharmaceuticals should be enhanced worldwide.

Finally, there remains the unavailability of provisions that enable patent term extension in appropriate circumstances. This has a detrimental effect on the value of biopharmaceutical patents in Indonesia.

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

South Korea

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

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 almost all 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.⁴⁴ 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

⁴⁴ 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)).

applicant or patent owner to submit such data in response to an office action or post-issue invalidation proceeding.⁴⁵

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 problems for innovative biopharmaceutical companies because 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.

A particularly challenging aspect of South Korea's data requirement is related to prior art references. During the original patent prosecution or in post-issue invalidation proceedings, if a prior art reference is cited against the application or patent in making an obviousness argument, the applicant/patent owner is not allowed to submit any comparison data (or any other data) between the invention that is the subject of the patent and the compounds in the prior art reference in order to rebut the obviousness argument. This means that unless the patent applicant provides comparison data in the original patent application to essentially every single reasonably close prior art compound (which in many cases is a practical impossibility), it is unlikely that the patent will issue in South Korea or, if the patent issues, survive a post-grant validity attack.

Finally, our members have reported problems that 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.

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

⁴⁵ 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.

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, the Ministry of Health and Welfare (MOHW) has proposed amendments to the National Health Insurance Act that include a provision enabling the Korean Government to recover so-called “improper profits” resulting 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). The draft provision would punish patent owners for enforcing legitimate patent rights in good faith and fails to clearly define the specific circumstances regarding how these damages would be calculated or collected. This would lead to significant uncertainty for innovators and would undermine confidence in the ability to meaningfully enforce intellectual property rights in Korea in a way that is both troubling and contrary to well-accepted international norms. Further, the proposed amendments contradict the purpose of the patent enforcement mechanism, i.e., to provide a balanced and predictable approach for resolution of patent disputes before launch of a follow-on product.

We urge the USG to engage their Korean counterparts to secure passage of an appropriate patent enforcement mechanism consistent with KORUS provisions, and to work with MOHW to reconsider the troubling amendments to the NHIA

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**.

BIO recognizes the Thai government’s efforts to create task forces dealing with IPR and appreciates this positive move. 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.

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 noncommunicable 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 provides a mechanism for governments to deal with acute public health crises, and impact the ability of biotechnology research and development efforts to recoup their massive investments. The medical management of non-communicable diseases may be complex and costly, but it does not rise to the level of a public health emergency. These extraordinary measures should not be used systematically to facilitate budgetary planning.

BIO appreciates that diseases that can be treated with drugs affect a great many people and are matters of national concern for many governments. At the same time, the decision to maintain policies relying on compulsory licenses continues to undermine the adequate protection of intellectual property that is important to BIO's members, and consequently provides a powerful disincentive for our members to do business in Thailand. BIO continues to believe that the most effective global solutions will result from policies that respect and encourage innovation.

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.

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.

Finally, our members report a growth in availability of counterfeit pharmaceutical products in the Thai market. 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.

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

Turkey

BIO remains concerned over Turkey's IP and market access deficiencies. Turkey requires significant progress in their intellectual property law as indicated by the European Union in the Turkey 2010 Progress Report on Accession.⁴⁶ BIO recommends that USTR place Turkey on the **Priority Watch List**.

One of the most serious issues in Turkey involves the requirement for the Ministry of Health to perform their own Good Manufacturing Practices (GMP) inspection at every pharmaceutical production facility. This requirement must occur before product registration in Turkey and has caused significant registration delays among our companies trying to enter the Turkish market. 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 difficult to accomplish as Turkey must join the Pharmaceutical Inspection Convention and Cooperation Scheme that dictates international GMP standards and Turkey will need to negotiate agreements directly with each participating country. Turkey's Ministry of Health neither has the staff nor resources to accomplish such a task and this directly results in a non-tariff barrier to trade.

Orphan drugs has 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, as early as 2010. However, not only have these guidelines been stuck since 2010, but also in the latest draft certain clauses regarding the prevalence of rare disease diverge widely from other standards in place across the world. Indeed, the draft defines "a prevalence of not more than 1 in 10,000 persons in the population" contradicting the EU standard of "a prevalence of not more than 5 in 10,000 persons." This divergence would exclude from the legislation many patients with a rare disease, which would greatly undermine the interest of these guidelines. 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.

Additionally, Turkey lacks an effective mechanism for resolving patent issues before the marketing of follow-on products such as generics. Providing effective mechanisms that gives the innovator notice of infringement as is found in the United States and elsewhere would help resolve patent issues before marketing approval and product launch.

A necessary step in European Union Accession involves Supplementary Protection Certificates (SPC) that compensate for regulatory delay. Turkey should pursue compliance with

⁴⁶ Turkey 2010 Progress Report on Accession, "Chapter 4.7: Intellectual Property Law."

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.

Data protection is undermined by regulatory delays in Turkey. Currently, regulatory approval times exceed 850 days and will likely reach four years with new Good Manufacturing Practice standards being implemented in Turkey. Turkey should either try to reduce regulatory approval time to 210 days or commence the six year data protection period from the date of regulatory approval rather than marketing approval in any EU country. Otherwise, the effective amount of data protection an innovator receives may only be one to two years. Data protection for combination products is also inadequate. Finally, the Regulation to Amend the Registration Regulation of Medicinal Products for Human Use may affect data protection and would conflict with EU standards by eliminating data protection for combination products.

Finally, price reimbursement remains a difficult issue for our members. 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 345 days).⁴⁷ Drastic budget cuts directly targeting innovative medicines have occurred in the last few years during a period of rapid economic growth in Turkey without transparency on government pharmaceutical spending.

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

Venezuela

BIO requests USTR to place Venezuela on the **Priority Watch List**.

As of 2006, Decision 486 of the Commission of the Andean Community is no longer in force and Venezuela has re-adopted the Intellectual Property Law of 1955. Article 15(1) of this law prohibits the patentability of pharmaceutical and chemical preparations. Interpretation by the Registrar is still pending and a number of issues remain for the interpretation of this law. However, patents previously granted have been revoked on technical grounds under this change. Finally, we have been told that no patents have been granted in Venezuela in at least the last 6 years.

A second concern for biotechnology firms involves the requirement to publish the details of the patent application in a newspaper. Some biotechnology firms are confused about the purpose and additional fees necessary for this requirement. Another difficulty is that Venezuela does not have patent linkage nor does it provide protection for pharmaceutical data.

⁴⁷ AIFD Market Access Survey, March 2011

Finally, some biotechnology companies have indicated an interest in Venezuela joining the Patent Cooperation Treaty (PCT) or other harmonization efforts. While the politics involved in encouraging the Venezuelans to join may be complicated, Venezuela's entrance into the PCT or other programs would enable biotechnology firms to mitigate the high application translation costs required in Venezuela. Additionally, if Venezuela were a PCT member a company could designate Venezuela in their PCT filing and save the costs of filing a national application if the compound is no longer suited for further development.

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**.

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 pharmacy 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 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 points above are 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. Recently, the government revised its damages claim to approximately AUD 450 million. The commercial impact of such figures is obvious. The context in which a decision is made to seek an injunction when faced with the risk of a \$450 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.

Finally, the Australian government has issued reports which 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.

Colombia

The Colombian patent law raises a number of concerns for BIO's members that warrant further monitoring. In light of these concerns, BIO requests that Colombia be placed on the **Watch List** with and **Out of Cycle Review** to monitor pending IP developments.

The Colombian government recently passed a third comparability pathway allowing substandard biosimilars to enter the Colombian market. In addition to providing a biosimilar pathway, the Colombian biologic regime allows biosimilar applicants to apply through a 3rd pathway that requires far less information than is required under WHO, EMA, or US guidelines. Several regulators, including the USFDA, warned the Colombian government that such an approach would endanger patient safety. The Colombian government disregarded these views. BIO supports policies that make biosimilars accessible to patients as many of our members produce biosimilars. However, the 3rd pathway unnecessarily endangers patient safety and runs counter to internationally accepted norms for biosimilars pathways.

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.” This exception categorically excludes a wide array of biotechnological inventions from the patent system in Colombia. This exception is inconsistent with obligations of Colombia under the TRIPS Article 27.1 requires that patents to be made available to “any inventions . . . provided they are new, involve an inventive step, and are capable of industrial application.” The Andean Decision also excludes the patenting of use claims. In addition, BIO’s members are systematically being denied protection in Colombia for inventions in chemical polymorphs and isolates that are routinely patented in other jurisdictions. This practice also appears to be inconsistent with the requirements of Article 27.1.

BIO also notes with concern significant delays in Colombia in the processing of patent applications for commercially valuable biopharmaceutical inventions, essentially denying protection for these inventions. Such concerns could be exacerbated by legislative proposals that seek to implement a secondary patent review for medicines by the drug regulatory agency.

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. 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.

Regulatory issues related to patents also arise in Colombia. To comply with the US-Colombia Free Trade Agreement, Colombia issued a decree for “transparency” making public processes for sanitary registration. While this is an improvement, the lack of effective linkage between the Patent Office and Regulatory Agency still creates problems.

Finally, our members report that it is difficult to enforce a patent in Colombia. A general lack of technical knowledge on IP matters compounds a perceived lack of independence of the judicial branch on IP sensitive decisions. These actions warrant further monitoring.

Egypt

BIO requests that USTR place Egypt on the **Watch List** due to continued concerns for U.S. biotechnology companies.

The Egyptian patent law prohibits patent protection for many valuable biotechnology innovations. Inventions 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.

Egypt also does not provide patent linkage and has slow new medicines approvals in an unreformed, opaque system.

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

European Union

BIO Member face several challenges in the European Union and, in particular, with respect to policies of the European Medicines Agency (EMA) relating to the potential disclosure of clinical trial data and other confidential commercial information submitted to the EMA for the purposes of obtaining marketing approval for pharmaceutical products. As a result, BIO urges the United States to place the European Union on the **Watch List**.

After a lengthy consultation process, the EMA adopted a final “policy on publication of clinical data for medicinal products for human use” in October 2014. While this policy appears to make significant improvements when compared to the draft policy from June 2013, BIO remains concerned that the EMA policy implementation may harm patient privacy, the integrity of the regulatory system, and incentives for pharmaceutical research and development. If implemented in a manner that does not adequately protect confidential commercial information from disclosure, moreover, these practices would not be consistent with the international obligations of the European Union to protect such information under the TRIPS Agreement.

The Clinical Trials Regulation adopted by European Parliament in 2014 is also of concern as it states that, in general, clinical study reports do not contain commercially confidential information (recital 20a). While the regulation could provide a degree of protection

for such information (see Art. 78), we are concerned that the publication of clinical study reports 30 days after authorization and without adequate protection mechanisms could undermine the competitiveness of the biopharmaceutical sector and create a precedent for other sectors regarding the disclosure of commercially sensitive information.

BIO is highly concerned that such an approach could undermine patient privacy by increasing the risk of re-identification of individual patients even if steps are taken to anonymize patient level data; will undermine patient trust in the safety and effectiveness of approved medicines by encouraging “second-guessing” of EMA’s regulatory determinations; and will undermine incentives for innovation by making confidential commercial information available to competitors in the market. Moreover, once disclosed in Europe, such data may be subject to use by competitors seeking in approvals for follow-on products in other markets, thereby undermining or eliminating the ability to obtain appropriate data protection periods in other markets.

For future products approved in the European Union, USTR should monitor the implementation of the Clinical Trails Regulation by the EMA. In particular, the EMA’s online portal for clinical study reports still creates challenges for BIO’s members. While the “terms of use” section does require certain protections for how the information might be used, all a user needs is an unverified email address. EMA will not confirm registrants of the system are who they say they are and the EMA will not enforce the “terms of use.” EMA also cannot bind regulatory agencies in third countries from accepting competitors’ clinical dossiers based on the innovators intellectual property. In addition, the EMA is still defining what information may be redacted by innovators in the clinical study reports.

Likewise, BIO’s agricultural membership face similar disclosure concerns. Recently, European regulatory bodies such as the European Food Safety Authority (EFSA) and various member states have received a significant increase in document access requests and associated litigation. In October 2013, the EU General Court issued Decision T-545/11 which expanded the definition of data relating to “emissions into the environment” to data that is only connected “in a sufficiently direct manner to emissions into the environment.” This change greatly increased the data subject to irrefutable public disclosure in spite of significant damage to protection of commercial confidential data, intellectual property or other rights.⁴⁸ The case is currently on appeal by the European Commission to the European Court of Justice with a decision likely in 2015.

Our members also lack an effective means to resolve patent disputes prior to market launch of a follow-on biologic. While generic producers are able to challenge innovator patents, the laws of the European Union and its Member States do not provide an equivalent mechanism for innovators prior to market launch. Innovators must then sue after market launch which may not adequately compensate for the loss of market share that occurred while the infringing product was on the market.

⁴⁸ The data disclosed included: (i) the impurity profile (ii) the analytical profile of test batches including the minimum, median and maximum impurity content; and (iii) the composition of plant protection products, including quantities of active substance and surfactant.

In October 2014 the new EU regulation EC No 511/2014 entered into force implementing the Nagoya protocol in the EU. The implications for companies will need to be monitored.

Finally, members have noted a concern with referrals to the enlarged board of appeal of the European patent office with regard to essentially biological processes. Specifically, there is the G1/08 decision on essentially biological processes which has created some uncertainty about the patentability of certain technical processes. In addition, there is a pending referral G2/13 in which the patentability of claims to products obtained through essentially biological processes is at stake.

As a result, BIO recommends that USTR place the European Union on the **Watch List**.

Mexico

BIO recommends that Mexico be placed on the **Watch List** due to continued difficulty in protecting and enforcing intellectual property rights.

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 a five-year protection period 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..

BIO is also concerned about the lack of adequate enforcement procedures in Mexico that undermine the ability to enforce patents on biopharmaceutical products. We also remain concerned about the apparent proliferation of counterfeit medicines in Mexico and the consequent economic and public health risks.

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 which 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 noninfringement and have the injunction lifted and allow the infringing products to remain on the market. This causes extensive delay which 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.

A final wrinkle involves IMPI using independent technical analysis regardless of expert witness opinions submitted by the parties. This practice creates further obscurity in the resulting decisions.

Linkage between the regulatory agency and the patent office only covers patents covering a pharmaceutical active ingredient per se and patents covering formulations. Patents covering formulations or uses are not included. 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. Also, some patents are not included if not requested for inclusion into the gazette immediately following the grant of the patent. The linkage system also does not allow for a full review of whether a generic drug would infringe patent rights.

Market access for orphan drugs is also a challenge for our companies in Mexico. Consejo de Salubridad General's (CSG) health technology assessment process has changed multiple times in the past few years. The agency will release new guidance without opportunity for public comment and new submission guidance will be effective immediately. Manufacturers of drugs currently under review have had to re-submit different applications multiple times to adhere to the new process. Additionally, the CSG's reasons for denying applications are inconsistent from one submission to the next.

Finally, Mexico has numerous biosimilars on the market (known as "biolimbos") which have not undergone any marketing authorization review consistent with globally accepted standards for the approval of biosimilars. The Mexican government is currently reviewing its biologic regulatory regime but recent additions and updates are not specific on how new regulatory standards would apply to biolimbos currently on the market.

Mexico is a member of the OECD. The data protection regime and enforcement of intellectual property rights fall far short of standards widely implemented in OECD countries. In light of these concerns, BIO requests that USTR continue to monitor events and that Mexico be placed on the **Watch List**.

Paraguay

Paraguay continues to have great deficiencies with respect to its patent system and the protection of data supplied to regulatory agencies in support of product marketing authorizations. BIO requests that USTR to place Paraguay on the **Watch List** and monitor the country under **Section 306**.

Paraguay's patent examination system suffers from a backlog that delays the grant of patent protection for valuable inventions and thereby denies the adequate and effective protection of intellectual property rights for BIO's members. We understand that the National Direction of Intellectual Property (DINAPI) has taken steps to reduce this backlog through the collaboration agreement between DINAPI and the Brazilian National Industrial Property Institute (INPI) that conducts the prior art search for the Paraguayan patent applications. The DINAPI performs substantive examinations in a chronological order according to the date of filing of the application. The lack of qualified human and technical resources within DINAPI constitutes a great obstacle to reduce the backlog that has already accumulated. Further, Paraguay remains outside of the Patent Cooperation Treaty (PCT), which facilitates the filing and examination of patent applications in 142 member countries. Acceding to this widely accepted agreement would be a positive step toward facilitating the procurement of patent protection in Paraguay for BIO's members.

BIO has heard reports that Paraguay has a double patent review system where their drug regulatory authority conducts a secondary patentability review. Duplicative patent reviews discriminates against the biotech industry and likely violates Paraguay's treaty obligations.

Paraguay's patent laws also do not provide for sufficient patent term extensions to fully compensate for unwarranted delays in the patent application process. Thus, inventors seeking patents remain exposed to a substantial loss of rights (term) due to delays in the examination, and cannot enforce a patent application in cases of an infringement while the patent application is still under the patent prosecution process. The patent law in Paraguay also excludes transgenic plants and animals from patent protection, thereby further limiting the availability of meaningful protection for many valuable biotechnology innovations.

Paraguay does not provide adequate protection for the data that must be generated in support of marketing authorization to prove that agricultural chemical products are safe and effective. Law No. 3519/2008 of Testing Data Protection distorts the general principles set forth by Article 39.3 of TRIPS since it only provides protection to new chemical entities with no prior registration in Paraguay or in any country in the world. This requirement is impossible to achieve since registrations of new products are obtained first in the country of origin and then are extended to other jurisdictions. In addition, Law No. 3519/2008 allows regulatory agencies to use data (which constitutes proprietary information for an applicant) in support of any other agricultural chemical product application, filed by third parties, by similarity and allows the disclosure and use of confidential information after a period of time (5 years). We believe it is necessary to amend Law No. 3519/2008 in order to grant real protection to all confidential and secret information which has a significant commercial value including testing data provided to regulatory agencies for product marketing authorizations. This protection is critical to the ability

of biotechnology companies to develop and commercialize such pharmaceutical and chemical products in a particular market. It is moreover an obligation of Paraguay under Article 39.3 of the TRIPS Agreement, which requires such data to be protected against both disclosure and “unfair commercial use.”

Persistent deficiencies in the patent and data protection regime in Paraguay raise issues in respect of Paraguay’s bilateral and international obligations and deny adequate and effective protection for the intellectual property rights of BIO’s members.

Peru

Peru has ongoing intellectual property challenges without significant progress and BIO requests USTR to place Peru on the **Watch List**.

Biotechnology companies are concerned that the use of a drug in a method of treatment remains unpatentable in any claim format. Other countries where method of treating humans is not patentable allow patents to cover the use of the drug for treatment which protects the commercial sales of the drug and not the treatment method per se. Nevertheless, even though Peru did provide this protection in the past, current patent law does not allow the patent office to grant patents on new uses either. Restoring the patent protection to cover new uses of drugs would allow biotechnology companies to protect their substantial investment to approve and market drugs in a particular country while preventing counterfeits. The patent system also suffers greatly from excessive delays in examination of patents.

While Peru has implemented a data protection regime for small molecules, the government has taken the position that biologics are not included under this regime. This is an incorrect interpretation of Peru’s obligations under TRIPS and the US-Peru Trade Promotion Agreement (USPTPA). BIO members urge USTR to continue to monitor Peru’s implementation and enforcement of data protection. Finally, there is no linkage between the Patent Office and the Regulatory Agency in approving generic drug sanitary applications. The legal obligation provided in implementation of the USPTPA to publish any marketing approval application within 48 hours of filing is permanently infringed. Additionally, enforcement of patent rights in Peru is difficult due to a lack of technical expertise on IP and a perceived lack of independence of the judicial branch on IP sensitive decisions.

With regards to market access barriers, although a revised Pharmaceutical Products Law was enacted five years ago to improve the regulatory process for seeking marketing approval of biopharmaceuticals in Peru, the MoH has repeatedly delayed issuing regulations to implement this Law. When implemented, the new regulations are expected to significantly improve the currently subpar safety and efficacy standards in Peru. Current draft guidelines include a transition mechanism that would further delay implementation of the Pharmaceutical Products Law for four more years.

Philippines

In 2008, the Philippine government enacted the Republic Act 9502 (R.A. 9502), also known as the “Universally Accessible Cheaper and Quality Medicines Act of 2008.” This legislation amended the Intellectual Property Code of the Philippines. The amendments weakened the protection of biopharmaceutical inventions in the Philippines. As a result, BIO’s members are denied adequate and effective intellectual property protection. BIO requests USTR to place the Philippines on the **Watch List**.

The amendments introduced a provision into Philippine law that denies patent protection for a new form of a known substance which does not result in “enhancement of the known efficacy, safety and purity of that substance.” The amendments appear to exclude from patentability many significant inventions in the biopharmaceuticals area. For example, a new form of a known substance with improved heat stability for tropical climates, or having other benefits that may not result in “enhanced efficacy” *per se*, would be denied patent protection even if it met all other patentability criteria. This additional patentability requirement appears to be inconsistent with the obligations of the Philippines under Article 27.1 of the TRIPS Agreement, which provides 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.”

Moreover, this additional requirement applies only to drugs or medicines, and therefore creates a higher standard of patentability for this category of invention. This is inconsistent with the non-discrimination requirement of Article 27.1 of the TRIPS Agreement that “patents shall be available and patent rights enjoyable without discrimination as to the ... field of technology.” R.A. 9502 also contains provisions that expand the grounds on which compulsory licenses may be granted. This includes a new ground that permits a compulsory license “where the demand for the patented drugs and medicines is not being met to an adequate extent and on reasonable terms, as determined by the Department of Health.” This provision, which apparently can be invoked at the discretion of a government agency, has the potential to undermine adequate and effective protection of patent rights for biopharmaceuticals and is not consistent with the non-discrimination clause of TRIPS Article 27.1.

The Philippines 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, leading to potential loss of exclusivity for patented inventions in the biopharmaceuticals area and increased litigation costs.

R.A. 9502 also expands permissible grounds for parallel importation of patent-protected products only with regard to “drugs and medicines.” This provision violates the nondiscrimination clause of TRIPS Article 27.1. In addition, the provision permits importation of patented drugs and medicines from a country where the product was placed on the market by “any party authorized to use the invention.” This appears to permit importation of goods even where they are placed on the foreign market without authorization of the patent owner, e.g.,

where the “authorized party” in the foreign market was operating under a compulsory license. Thus, the amendment effectively gives extraterritorial effect to a foreign compulsory license, even where the rationale for the compulsory license was based on factors related solely to the national market in the jurisdiction that imposed the license. This is highly inequitable and appears to be inconsistent with recognized standards of “international exhaustion” of patented inventions.

In addition, the Philippines does not provide meaningful protection for pharmaceutical test data required to prove safety and efficacy of new drug products. The implementing regulations of R. A. 9502 purport to provide protection against “unfair commercial use.” However, the same regulations clarify that “[t]he [Bureau of Food and Drugs] shall not be precluded from using all data, including, but not limited to, pre-clinical and clinical trials, of an applicant when evaluating other applications.” This appears to expressly permit “unfair commercial use” by generic competitors of the pharmaceutical test data generated by innovators to support marketing approval applications without any data exclusivity period to protect these data.

BIO requests that USTR work with the Philippines to provide for an intellectual property regime that provides adequate and effective protection of intellectual property rights for U.S. rights holders in that country. In light of this weakening of patent protection for biotechnological inventions, BIO requests that USTR place the Philippines on the **Watch List**.

Russia

BIO’s have expressed certain challenges in operating in Russia. Russian improved their patent laws in 2008, thereby bringing patent practice closer to Western patent systems. In addition, Russia is, coordinating between their regulatory agency and patent office, creating a new IP Court and is a new WTO member. Problems remain for our member companies in Russia and BIO requests that USTR place Russia on the **Watch List**.

Russian law fails to recognize requests for generic marketing authorization as an act of infringement. In other words, 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.

Innovators operating in this difficult environment also find challenges with the latest revision of FL 61 which significantly lowers regulatory data protection. The amendments to the law allow applying for a registration for 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, the generic can be placed on the market prior to the expiration of the six-year data protection period. In addition, FL 61 contains no specific provisions on the protection of pre-clinical or clinical trial data to be used for generic

registration prior to the expiration of the RDP period, industry is concerned that the amendments to FL 61 will further weaken RDP in Russia.

The revised law's novelty requirement for chemical, medical, or other compositions present a challenge for biotechnology companies. The new novelty regulation excludes from patentability those claims that involve the use of the known composition. In other words, use claims are not patentable if the compound is already known. It remains unclear if method of treatment claims remain acceptable under the new regulations but practically the Russian Patent Office requires extensive data (usually only in vivo data) to prove the viability of the treatment. Refusing to patent this secondary patenting creates a disincentive for companies to invest in research on their existing products to help unique patient populations, create new treatment pathways, or use the product for new disease indications.

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 been amending the rules for the inclusion of drugs into the Vital and Essential Drugs List (EDL) delaying the update of this list and inclusion of 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.

One member claims that in a court case a Markush claim has not been held infringed because the claim does not specifically state the chemical structure of the infringing product. However, the specific claim reading on the infringing product had not been held infringed because claim 1 which is the Markush claim had not been held infringed. In a similar case, the same judge held a Markush claim infringed because the infringing company had been a Chinese and not Russian generic company.

More recently, senior Russian government officials have indicated a desire to more systematically use compulsory licensing. This raises serious concerns about the ability of innovators to meaningfully enforce patents in Russia. We urge the USG to monitor this situation closely and to encourage their Russian counterparts to avoid misuse of this tool, which is permitted only in certain circumstances where particular conditions must be met and in extraordinary circumstances as a last resort.

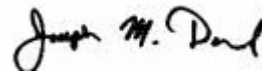
Vietnam

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

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,

A handwritten signature in black ink that reads "Joseph M. Damond". The signature is written in a cursive style with a large initial "J" and "D".

Joseph Damond

Senior Vice President

International Affairs

Biotechnology Industry Organization