



By electronic submission

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BIOTECHNOLOGY INDUSTRY ORGANIZATION

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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 *2014 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 1,100 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 patents 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 Foreign Country: BIO requests USTR to designate India a Priority Foreign Country.

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

Watch List: BIO requests USTR to place Australia, Colombia, Egypt, Mexico, Paraguay, Peru, Philippines, Russia, South Korea, 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 data protection**, 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/>

Access to Medicines

In May 2010, BIO released the Biotechnology Industry Organization Policy Statement: Options for Increasing Access to Medicines in the Developing World.⁷ In that document, it states that “BIO’s members believe that the goals of increasing access to medicines, respecting intellectual property rights, and maintaining commercial viability are not mutually exclusive... The public health concerns in this area are two-fold: developing products for diseases that disproportionately affect people in the developing world, while also increasing access to such products as well as the existing range of medicines commonly utilized in the developed world.”⁸

The Statement continues, “BIO’s members also recognize that many of the problems with access to medicines in the developing world are caused by factors outside the control of individual stakeholders, such as lack of adequate manufacturing, delivery and public health infrastructure, trade and tariff barriers, regulatory obstacles, lack of market incentives, local corruption, diversion of supply to more lucrative markets, and a chronic underinvestment in health in national budgets. Nonetheless, BIO believes that all participants in this complex arena – including BIO’s healthcare members – can help improve the lives of those suffering in the developing world from preventable or treatable conditions.”⁹

The Statement makes the following recommendations to BIO’s members. “When entering into license agreements, explore creative strategies that help to expand access to medicines in the developing world...While researching and developing products, work to identify compounds or technologies that can have useful applications in the developing world...Where practicable, participate in partnerships that develop medicines and medical technologies for the developing world...When doing clinical trials, take into consideration the needs of people living in developing countries...When commercializing medical products, explore individualized strategies that will help improve the affordability of medicines in the developing world...Where practical, explore ways to overcome non-price barriers that hinder access to medicines and medical technologies in the developing world...Share individual experiences and approaches broadly to advance the goals of enhanced access in the developing world.”¹⁰

With the above in mind, BIO would like to bring to USTR’s attention the following issues in markets of interest to the biotechnology industry.

⁷ http://www.bio.org/healthcare/innovation/Access_to_Medicines_Policy_Statement_Final.pdf

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

PRIORITY FOREIGN COUNTRY

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. Therefore, BIO requests that USTR designate India a **Priority Foreign Country** to monitor the recent deterioration of IP rights in India.

Patent Office

The Indian Intellectual Property Appellate Board (IPAB) revoked several pharmaceutical patents in post-grant opposition proceedings in the last two years including patents protecting Sutent,¹¹ Pegasys, Ganfort, Combigan, and Renadyl.¹² 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 have put the obligation on the Patentee to provide the information to the Indian Patent Office (IPO) and non-compliance leads to revocation. This information is easily accessible to the Examiner at the IPO and an unnecessary burden on the patent applicant. The situation is only made worse by the disproportionate punishment attached to this section.

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. 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. 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

¹¹ 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.

¹² IPAB revoked the process patent but upheld the product patent. However, the product patent is still being challenged in court.

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 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 generic copies of products that enjoy meaningful patent protection in other countries. Patent term extensions do not exist in India, which exacerbates the problem and contributes to a loss of value for legitimate U.S. biotech patents in India. 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 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 a yearly “statement of working” that proves that the patentee is exploiting its invention in India. 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 on 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 when a biotechnology company cannot work on the drug due to extraneous conditions (such as an FDA “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 filling in the country where research or product development is conducted for joint inventions or in the country where the patent applicant is located.

Patent Law

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.

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 has failed to extend the protection to all crops. Coupled with India's exclusion of patent protection for plants, the Indian government has created a significant gap in intellectual property protection. Currently, there is no mechanism for appeal and the transitional provision required by the law are not implemented. Finally, the Indian government must address significant inefficiencies in the registration procedures.

Finally, the Indian Patents Act includes Section 3(d), which 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 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 efficacy" *per se*. Even if not removed, new forms of a substance that has 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.

Courts

Indian law recently recognized patent protection for pharmaceutical compounds. As a result, the courts in India have only recently dealt with patent enforcement issues and are still finding their way in handling complex patent issues. The standards for claim interpretation, trial, and enforcement of injunctions are still under development. Generally, the courts have no standards for issuing injunctions and have not given deference to the determinations of the Indian Patent Office. The courts have often not enforced injunctions to protect U.S. company patents. 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.

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). Glivec was a breakthrough cancer therapy and is protected by patents around the world. This unique, and arguably TRIPS non-compliant feature of India 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. 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. While the case is still pending, Glenmark has earned Rs 16 crore (\$2.6 million) on these medicines.¹³ The patent owner still is waiting for a final decision on the preliminary injunction. Other judicial interpretations of the obviousness standard for dosage forms and other similar inventions have also drawn concern.¹⁴ The second issue involves the interpretation of the novelty and obviousness standards in the context of an enantiomer product.¹⁵ The final issue is the rejection of any applications for new methods for known compounds.¹⁶

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.

¹³ See http://articles.economictimes.indiatimes.com/2014-01-09/news/46030254_1_glenmark-pharmaceuticals-januvia-and-janumet-diabetes-drugs

¹⁴ including Aventis Pharmaceuticals, 1021/CHENP/2006 (2009), and Novartis AG, 728/CHENP/2006 (2009).

¹⁵ Astra Aktiebolag, 1255/DEL1995 (2009)

¹⁶ GlycoScience Labs 1752/CHE/2006 (2009)

Enforcement

Failure to recognize or enforce patents gives generic companies an unfair global competitive advantage. Indian generic companies, who are primarily export-oriented, 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.

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 and undermines U.S. IPR.

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 Report¹⁷ 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

¹⁷ 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."

industry that the regulatory agency is not following the biosimilar guidelines in place since August 2012.¹⁸ A biologics pathway consistent with U.S. and European law is necessary for U.S. companies and Indian manufacturers and it will improve access to safe and effective biotechnology products in India.

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 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 government published a document on August 24, 2010, titled, “Discussion Paper, Subject: Compulsory Licensing,” which asks for response regarding India’s compulsory licensing regime. The document discusses how India has not yet granted a license, although the government did receive three requests in 2007. The government never acted on the applications as they were withdrawn before the government could evaluate the claims. The document highlights the need for increasing access to essential medicines for the “common man particularly the poorer sections of the population.” We hope that the United States government will engage with the Indian government on this issue and highlight the need to work with and not against the biopharmaceutical industry. Alternative mechanisms may also achieve their goals through the creation of incentives, including strengthening intellectual property protection, to enter the Indian market and ensure the steady supply of next generation medicines for India’s population.¹⁹

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 facts and legal reasoning are still in doubt for all three requirements, 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.”

Early in 2013, the Indian Health Ministry began the process to compulsory license 3 cancer drugs. In September of 2013, the Ministry limited the scope of their initial request and filed a petition to compulsory license Sprycel.²⁰ While this petition is pending, the Indian Patent

¹⁸ See http://articles.economictimes.indiatimes.com/2013-05-14/news/39256077_1_cipla-drug-controller-biotech

¹⁹ BIO’s comments to this discussion paper can be found at the following link <http://www.bio.org/ip/international/20100929.pdf>.

²⁰ 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.

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 and could also still be compulsory licensed per the Health Ministry's request. In providing access to medicines, other tools are more appropriate. BIO's members cannot continue to bring new investment into countries which abuse the compulsory licensing process in violation of their obligations under TRIPs.

Finally, it is interesting to note that in India 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%, Cameroon 1.5%, on healthcare. This data provides new perspective to the access to medicines debate and renders India's policies about IP in this context less credible.²¹

BIO recommends that USTR elevate India to a **Priority Foreign Country**.

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."

²¹ 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.

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.²²

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.

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. Acceding to 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 preexisting 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

²² 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/>

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

Some of 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

When considering Brazil's history of intellectual property protection, Brazil has made significant improvements. In fact, the reforms have reaffirmed the fact that changes in the patent law have encouraged Brazilian biotech innovation.²³ While BIO is encouraged with Brazil's progress led by the Brazilian Patent Office, biotechnology companies remain disappointed with efforts by other ministries in the Brazilian government to roll back IP protections domestically, regionally, and internationally. BIO recommends that USTR place Brazil on the **Priority Watch List**

²³ 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).

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. Our understanding is that, thus far, the judges in Brazil have rejected these requests for injunctions.

INPI recently released proposed rules which would result in new Biotechnology Patent Examination Guidelines.²⁴ BIO requests the U.S. Government ensures that innovative biotechnology companies are adequately protected in the new Guidelines.

We understand that the Brazilian Patent Office has also increased hiring of biotechnology trained patent examiners. However, a large backlog (especially in small molecule pharmaceutical inventions) still exists which is estimated at 20,000+ in pharmaceutical cases. Companies routinely wait for eight to ten years before examination occurs. 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.

Another problem involves an INPI interpretation that states that if an unfavorable decision exists in the parent case, a divisional application may be directly rejected without regard to the claimed subject matter. INPI also limits applicants to claims present when examination was requested. The examiners reject amendments or added claims. This prevents the applicant from adding claims to preferred embodiments that 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

²⁴ For BIO’s Comments see, <http://www.bio.org/advocacy/letters/bio-comments-inpi-guidelines-examination-patent-applications>

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.

BIO Members also have other prosecution concerns. 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. Finally, members 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. There also is no way to access electronically INPI prosecution records or issued patents and claims. Viewing patents and file wrappers requires a physical visit to INPI to order the patents/file wrappers and then waiting a couple of months to receive the requested documents.

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

Patent Law

Representatives of the lower House of Congress proposed a bill to revise Brazilian patent law to take into account the country's "social interest" and "technological and economic development." The bill represents many of the policy asks of the generic industry and anti-IP NGO community. These provisions include reducing the scope of patentable subject matter, restrictive patentability requirements, solidifying the drug regulatory agency's duplicative role in the review of patents, expanding the ability to use compulsory licenses, additional patent opposition procedures, and other anti-innovator positions, such as removing Brazil's 10-year guaranteed minimum patent term.

The bill was launched with a hearing that included supportive statements from the Ministry of Trade, Ministry of Health, and the Brazilian health regulatory authority (ANVISA). Representatives from the governments of South Africa and Argentina also participated, signaling a broader international effort.

The patent term in Brazil is 20 years from priority date instead of filing date for pipeline patents. This effectively cuts off one year of patent life to the patent. BIO is concerned with this interpretation as it is inconsistent with the Paris Convention of which Brazil is a signatory.

Brazil also lacks meaningful patent protection for secondary claims covering novel uses. In fact, two proposed bills seek to exclude second medical uses altogether.²⁵ 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

²⁵ 2.511/07 and 3.995/08

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

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, thus making a decision in this case likely in the next few months. 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.

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.²⁶ 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.

BIO remains concerned about two key provisions of the proposed rule. ANVISA's proposed rule 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, how does a patent "present a health risk?" Risks and benefits of a biopharmaceutical only become clear after years of clinical and toxicological testing. Or is ANVISA only referring to those products whose only application is dangerous to the public health? BIO also does not understand which patents are "of interest to the policies regulating the universal access to medicine and pharmaceutical assistance as provided for under SUS." BIO understands that the Brazilian Health Ministry recently published a new Ordinance 3089/2013 which creates a new list of essential drugs delving into new therapeutic categories and almost doubling the number of API. Further, the ordinance does not include a specific list attached to the ordinance but merely refers interested parties to the Ministry of Health's homepage. BIO is concerned that this could potentially allow the Ministry of Health to change the list at will and without notice.

Finally, the rules seem to implement previous ANVISA practice of reviewing patent applications for patentability requirements which is outside their competence and directly contrary to the Attorney General's opinion. With the new strategic list of essential drugs, ANVISA's duplicative patent analysis list has almost doubled.

²⁶ 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

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. Allowing companies to have 5 years of data protection for pharmaceutical innovators 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.

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. Finally, confidentiality provisions extending beyond the term of the agreement are limited to five to ten years.

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.²⁷ 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.

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 lead BIO to request that Canada be placed on the **Priority Watch List** in 2013.

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 asserted 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) and 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 stated practical and credible utility; for pharmaceutical inventions, in practice this standard is met by disclosing a specific disease against which the claimed invention is useful.

²⁷ See <http://www.cosmeticsdesign.com/Market-Trends/Natura-accused-of-not-respecting-Brazil-s-biodiversity-laws>

Over the past eight years, 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)*.²⁸ 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 at the outset of the utility analysis.²⁹ In some cases, after construction of an improperly elevated "promise," Canadian courts have required evidence of long-term clinical studies in patients in order to find utility particularly if the drug involves treatment of a chronic condition.³⁰ BIO member companies typically must file their patent applications early in the development process, and in many cases before conclusive clinical data exists to conclusively prove utility. As such, in many cases the practical effect of Canada's "promise doctrine" may be a bar to patentability for any drug claimed as useful for treatment of a chronic condition.

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

Since 2008, of the 46 Federal Court decisions where lack of utility was alleged by a competitor in the Canadian Federal Courts, only 4-5 were non-biopharmaceutical patents. Thus

²⁸ Decisions invalidating pharmaceutical patents for a lack of utility in infringement or revocation proceedings include the following: *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 PM(NOC) (s. 55.2) 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.

²⁹ 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.

³⁰ 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.").

among decisions issued during the last 5 years, inutility was alleged against biopharmaceutical patents almost exclusively, that is 89% of the time. 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. Canadian Intellectual Property Office (CIPO) requirements for establishing utility for a patentable invention are also contrary to the practice of other countries. BIO is particularly concerned about MOPOP Chapter 9.04 which 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. The requirement is contrary to Section 27(3) of the Canadian Patent Act and settled Supreme Court case law. It also violates the requirements of NAFTA, TRIPS and the PCT, all of which are in force and binding upon Canada. A statement of advantages will however be construed as promises of utility for the claimed invention, and an elevated utility standard will be imposed if the listed advantages are construed as “promises of utility in the patent”. However, according to well-settled Canadian case law and the practices of patent offices and courts worldwide, evidence of non-obviousness need not be included in the specification, and the inventor is able to submit evidence to support non-obviousness after the filing date of a patent application contrary to MOPOP Chapter 9.04.02. If however, the same advantage is also a promise of utility, such data will be rejected if generated subsequent to the filing date. Furthermore, settled Canadian law is that the patentability of a “selection” invention is primarily assessed based on the law of obviousness and thus should be dealt with in Chapter 15 of the MOPOP. These statements in MOPOP are clearly at odds with the jurisprudential utility requirements. Legislation is clearly required to correct the erroneous principles of law that the jurisprudence has introduced.

Similarly, under the PCT applicants may seek patent protection in some or all member countries by filing a single international application. The PCT requires that a claimed invention be industrially applicable, which is satisfied if the invention can be made or used in any kind of industry.³¹ If the 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, then the invention will be patentable as possessing industrial applicability, as occurs in Europe.³² 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.³³ Thus “useful” in fact and “industrial applicability” are synonymous, and the EU and US have approached the issue in practically the same manner. Further, while the sufficiency requirements of the PCT provide that the applicant disclose the invention in a manner sufficiently clear and complete for

³¹ Patent Cooperation Treaty, Article 33(4).

³² 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).

³³ See *Eli Lilly and Co. v. Actavis Elizabeth LLC*, No. 10-01500, 2011 BL 197400 (Fed. Cir. July 29, 2011).

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.³⁴

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).³⁵ The Canadian standard remains subjective and unpredictable, as a patentee cannot reliably know the construction of a patent's promised utility. Thus the standard remains inconsistent with international norms.

Canada's utility requirements place biopharmaceutical innovators in a difficult Catch 22 dilemma in view of the other substantive requirements for patentability.³⁶ 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.³⁷ BIO members also conduct significant research to treat diseases in scientific areas where conclusive efficacy models may not yet exist.³⁸ 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.

Restrictive Listing Requirements, Lack of an Equitable Right of Appeal, Injunctive Relief and Patent Term Restoration

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 specific claim language in order to list patents, precluding listing of, *inter alia*, genus patents that encompass commercial

³⁴ Patent Cooperation Treaty, Article 5.

³⁵ *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.

³⁶ All the patent laws of major countries require an invention to be new and non-obvious in addition to possessing utility.

³⁷ 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.

³⁸ It is questionable whether conclusive models exist which would, for example, prove efficacy in a number of disease states for which there is high patient unmet medical need.

products and that will be infringed necessarily by early working. This judicial interpretation of listing requirements is inconsistent with the principles for patent enforcement set out in NAFTA and TRIPS.

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.”³⁹ However, the USTR will need to monitor implementation to ensure that innovators are adequately protected by this provision.

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).

Finally Canada lacks patent term restoration which restores the loss to patent term caused by lengthy clinical trials and the regulatory approval process. 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.

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

³⁹ 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>

suffered damages of more than \$730 million from the premature loss of patent protection based solely on Canada's outlier patent utility standard based on IMS sales data.

Patent requirements related to utility, eligibility for listing, an inequitable right of appeal in PM(NOC) decisions and lack of both injunctive relief and patent term restoration have led BIO to request that Canada be elevated to the **Priority Watch List**. 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 be placed 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 be placed 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.⁴⁰ 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 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

⁴⁰ 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.

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.

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. In addition, the secrecy examination takes time, on average two weeks, which can be problematic when added matter has to be considered at the very end of the priority year.

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.

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. The extent to which this agreement actually will move the day-to-day operations of SIPO and the Chinese courts in the correct direction, however, remains to be seen. As such, BIO urges USTR both to continue to maintain a close watch on this issue and specifically to address this issue in its 2014 Special 301 Report.

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.

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.⁴¹

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

⁴¹ 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>

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 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 submission⁴², 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

⁴² See <http://www.bio.org/advocacy/amicus-brief/china-patent-enforcement-comments-uspto>

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 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. Generic products are allowed to reference data and approvals existing outside of China, using procedures intended for the innovator companies who generated that data. 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.

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

Since BIO’s last 301 submission, the Ecuadorian Institute of Intellectual Property (IEPI) issued its 3rd compulsory license. The additional compulsory license is for Ritonavir and issued to the applicant Eskegroup. This follows IEPI’s issuance of a compulsory license for the combination of drugs Abacavir and Lamivudine which treats HIV/AIDS.⁴³ This represents a

⁴³ See <http://www.iepi.gob.ec/module-contenido-viewpub-tid-4-pid-184.html>

dramatic shift in direction for their respect of intellectual property rights and there are reports that 13 more compulsory license applications for medicines in the cancer and other non-HIV/AIDS spaces have been filed in Ecuador and are still pending.

BIO appreciates the dramatic nature of the HIV/AIDS epidemic and governments' desire to address these issues. 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. The amounts are 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.

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.

European Union

BIO Member face several challenges in the European Union and, in particular, with respect to current and proposed 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 **Priority Watch List**.

These current and proposed practices of the EMA to disclose clinical trial data and other confidential commercial information submitted in marketing approval applications without restriction will substantially harm patient privacy, the integrity of the regulatory system, and incentives for pharmaceutical research and development. In addition, such practices are not consistent with the international obligations of the European Union to protect such information under the TRIPS Agreement.

For example, the EMA's draft *Publication and Access to Clinical-Trial Data* policy that was issued for public comment on June 24, 2013, indicates that the EMA intends to publish full clinical study reports following approval of the relevant medicine's marketing authorization application.

Similarly, the new Clinical Trials Regulation to be adopted by European Parliament in March 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 would 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.

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.⁴⁴ The case is currently on appeal by the European Commission to the European Court of Justice with a decision likely in 2015.

Finally, our members 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.

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

⁴⁴ 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.

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.

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 a place a system that provides adequate and effective protection for intellectual property rights.

Counterfeit biopharmaceuticals produced in Indonesia also pose a substantial safety risk for patients. More international oversight is required to regulate the normal distribution channels of counterfeits including internet pharmacies. Enhanced education in the medical sector could help warn of the dangers of obtaining dangerous counterfeit medicines from unauthorized suppliers. 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.⁴⁵ If such pharmacological data is not included in the original specification, the application will be rejected (or the granted patent subsequently invalidated). Moreover, South Korea does not permit the applicant or patent owner to submit such data in response to an office action or post-issue invalidation proceeding.⁴⁶

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,

⁴⁵ 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)).

⁴⁶ 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.

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

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 new 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.⁴⁷ BIO recommends that USTR place Turkey on the **Priority Watch List**.

⁴⁷ Turkey 2010 Progress Report on Accession, "Chapter 4.7: Intellectual Property Law."

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.

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 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).⁴⁸ 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**.

⁴⁸ AIFD Market Access Survey, March 2011

Ukraine

Ukraine as a country of concern for intellectual property rights. BIO requests USTR place Ukraine on the **Priority Watch List**.

Ukraine should institute and enforce meaningful data protection prohibiting the regulatory agency and generic drug applicants from relying on innovator proprietary data for a fixed period of time. One company reported that while existing law contains data protection requirements, the regulatory agency still approved a generic drug applicant. This violates the data exclusivity rights of our member company. This company even notified the relevant agencies and the generic company of their rights prior to approval and the regulatory agency still approved the product. Other companies have also experienced other drugs that were registered in Ukraine even though patent protection still covered the product.

Ukraine needs effective patent and data exclusivity enforcement to prevent infringement of patents prior to regulatory approval. In the courts, one of our company members expressed concern that the regulatory agency was not providing the court a full and complete generic dossier necessary to prove a violation of the data exclusivity law. This prevented our member company from obtaining the necessary evidence to prove that an obvious violation of Ukrainian law had occurred.

BIO members have also noted that enforcement of counterfeit seeds and crop protection products is ineffective due to lack of ex officio authority to interdict shipments headed to 3rd country markets. Criminal investigations often last too long and are ineffective with one member reporting the pre-trial criminal investigation on fraud and trademark infringement still ongoing after almost a year. Finally, counterfeits are sold openly on the market and advertised online. Along with providing ex officio authority, the U.S. government should ensure that Ukrainian police officials and prosecutors have additional training on intellectual property rights and additional resources to transport and seize counterfeits, conduct controlled test purchases, and complete forensic analyses.

BIO is also concerned about the lack of an effective mechanism to enforce preliminary injunctions in Ukraine. In addition, procedures for filing and obtaining appeals do not consistently comport with due process. Finally, Ukraine has relaxed their compulsory license legislation. For these reasons, BIO requests USTR to place Ukraine 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.

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 is now intervening in the suits and requesting 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 in a position where it is, in effect, now 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).

The new 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.

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.

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 taking on additional obligations under a new trade 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.

Finally, linkage between the regulatory agency and the patent office only covers patents covering a pharmaceutical active ingredient per se. 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. The linkage system also does not allow for a full review of whether a generic drug would infringe patent rights.

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.

Paraguay also 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. 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. 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.

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 progressing on data protection issues, coordination between their regulatory agency and patent office, 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**.

Russia has no laws similar to the Hatch-Waxman Act or the Biologics Price Competition and Innovation Act in the United States which protect intellectual property rights of biopharmaceutical innovators. These laws require a data exclusivity period of five years for small molecule drugs and twelve years for biologic drugs. Adopting the U.S. standard would help resolve innovator and generic launch patent issues in Russia and should be adopted.

Another issue arises from the failure of Russian law 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.

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.

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.

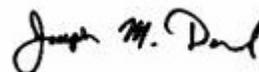
Vietnam

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 place 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,



Joseph Damond

Senior Vice President

International Affairs

Biotechnology Industry Organization