By electronic submission

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BIOTECHNOLOGY INDUSTRY ORGANIZATION

2011 SPECIAL 301 SUBMISSION

Submitted electronically to http://www.regulations.gov, docket number USTR-2010-0037
Re: 2011 *Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing,* 75 Fed. Reg. 250 (December 30, 2010).

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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 *2011 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing.*[1]

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 all 50 States and a number of foreign countries. BIO's members are involved in the research and development of 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 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. 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 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 2011 Special 301 submission.

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1 75 Fed. Reg. 250 (December 30, 2010

Priority Foreign Country: BIO requests USTR to elevate **Thailand** to a Priority Foreign Country due to a lack of progress in protecting U.S. IPR.

Priority Watch List: BIO requests USTR to keep **Argentina, Canada, Chile, China, India, Israel, Russia, and Venezuela** on the Priority Watch List. BIO requests USTR to elevate the **Philippines** to Priority Watch List status.

Watch List: BIO requests USTR to keep **Brazil, Colombia, Egypt, Mexico** and **Peru** on the Watch List.

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

Countries/Organizations of Concern: BIO requests USTR to observe developments in **Japan, Taiwan,** and the **European Patent Office** to ensure U.S. IPR is properly protected.

Among these Countries, 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 judicial standards for enforcement**, **compulsory licensing**, **data protection**, and a need for **harmonization** of processes across patent offices around the world. Issues unique to biotechnology include **patentability of biotechnology inventions**, **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 to use this submission to inform U.S. Government officials and the public of the IPR challenges U.S. biotechnology companies face around the world. Finally, we hope our submission helps the U.S. government indentify 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 pesticide damage to the environment, conserving natural resources of land, water and nutrients, and increasing farm income and economies worldwide. In the energy and environmental sector, biotech innovation is helping to clean our environment and fight 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. 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.[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.

The Benefits of Stronger IPR for Developing Countries

2 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://ssm.com/abstract=1121224

While it is important for the U.S. government to protect U.S. companies and their IPR abroad, research continues to show that stronger intellectual property regimes benefit the economies of developing countries as well.

The Organization for Economic Co-operation and Development (OECD) has two working papers that directly address the benefits arising from intellectual property rights in developing countries. The authors of the paper *Policy Complements to the Strengthening of IPRS in Developing Countries* find that IPR reform delivers positive economic results in developing countries.[3] The abstract also points out that "reforms concerning patent protection have tended to deliver the most substantial results…"[4] The second paper, *Policy Complements to the Strengthening of IPRS in Developing Countries – China's Intellectual Property Environment: A Firm-Level Perspective*, concludes in its abstract that "the momentum for IP reform is related to the economic potential in China."[5]

Two working papers, recently presented in a World Bank Symposium, enlighten our understanding on the economic benefits of stronger IPR regimes in developing countries. The authors find that "a strengthening of IPR protection in the South (the developing world) reduces the rate of imitation, which, in turn, increases the flow of foreign direct investment (FDI). The increase in FDI more than offsets the decline in production undertaken by Southern imitators, so that the South's share of goods produced by the global economy increases. Furthermore, real wages of Southern workers increase even though prices of goods produced by multinationals exceed those of Southern imitators."[6]

The second working paper adds to these findings and provides additional theory and data. The paper's model predicts and finds evidence that in a North-South model IPR reform "accelerates Southern industrial development. The South's share of global manufacturing and the pace at which production of recently invented goods shifts to the South both increase."[7] The

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3 Cepeda, Lippoldt, and Senft, *Policy Compliments to the Strengthening of IPRS in Developing Countrie,s,* 14, September 2010, accessed at http://www.oecd-ilibrary.org/fr/trade/policy-complements-to-the-strengthening-of-iprs-in-developing-countries_5km7fmwz85d4-en on January 24, 2011 (Working Paper)

4 Id.

5 Minyuan Zhao, *Policy Complements to the Strengthening of IPRS in Developing Countries – China's Intellectual Property Environment: A Firm-Level* Perspective, 14 Sep 2010, accessed at http://www.oecd-ilibrary.org/trade/policy-complements-to-the-strengthening-of-iprs-in-developing-countries-china-s-intellectual-property-environment_5km7fmtw4qmv-en;jsessionid=1p4jzo8xww6ep.delta on January 25, 2011.(Working Paper)

6 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.(Working Paper)

7 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.(Working Paper)

paper also discusses that, while manufacturing shifts to the South, "Northern resources will be reallocated to R&D, driving an increase in the global rate of innovation."[8]

Access to Medicines

In May 2010, BIO released the Biotechnology Industry Organization Policy Statement: Options for Increasing Access to Medicines in the Developing World.[9] 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."[10]

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."[11]

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

8 Zhao (abstract)

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

10 *Id.*

11 *Id.*

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."[12]

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

PRIORITY FOREIGN COUNTRY

Thailand

In light of continued egregious and onerous policies relating to compulsory licensing of patents, and the lack of any significant progress in addressing these policies, BIO urges USTR to designate Thailand as a **Priority Foreign Country**.

BIO recognizes the Thai government's efforts to create task forces dealing with IPR and appreciates this positive move. However, the Thai Government's continued its support of compulsory licensing of patented pharmaceutical products as part of its trade policy contradicts these efforts and indicates a continued disregard for intellectual property rights that are critical for the development of new medicines. In particular, BIO's members are concerned that this policy denies adequate and effective protection of intellectual property rights for innovative biotechnology products. BIO is aware of efforts by the Thai government to develop a biotechnology sector, and appreciates its outreach to the biotechnology industry. However, policies such as compulsory licensing will only serve to drive biotech investment away from Thailand.

The Thai Government's defense of compulsory licenses for drugs that treat non-communicable diseases (such as cancer, stroke, or myocardial infarction) is of particular concern, given that many of BIO's members' research and development efforts target such chronic diseases. These policies go well beyond the letter and spirit of the Doha Declaration, which 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

12 *Id.*

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 strongly urge USTR to designate Thailand as a Priority Foreign Country. Thailand's continued support of compulsory licensing as part of its trade policies denies U.S. industry adequate and effective protection of its intellectual property rights. The lack of effective protection for pharmaceutical test data and the apparent growth in counterfeit pharmaceutical products in Thailand also raise significant concerns. We believe that more aggressive monitoring and engagement with Thailand on this issue is fully warranted.

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**.

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 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 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 exclusion 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.

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. This protection is critical to the ability of biotechnology companies to develop and commercialize such biotechnology products in a particular market. Moreover, TRIPS Article 39.3 obligates Argentina to protect such data against "unfair commercial use." Persistent deficiencies in the patent and data protection regime in Argentina deny adequate and effective protection for the intellectual property rights of BIO's members.

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 therapeutical 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.

Canada

Canada continues to present challenges to the intellectual property rights of BIO's members. New patent application rules, inequitable evidence and enforcement rights in Canadian courts, and patent eligibility requirements in relation to biotechnology products have led BIO to request that Canada remain on the **Priority Watch List**.

Canadian Patent Office

New rules for patent applications proposed by the Canadian Intellectual Property Office (CIPO) in its Manual of Patent Office Practice Updates (MOPOP) exceed statutory requirements and are not based on settled law. The concerns include:

Statutory Basis for the Description Requirements – Description requirements in proposed Chapter 9.04 exceed the Canadian Patent Acts 27(3). Section 27(3) requires the inventor to correctly and fully describe the invention and its operation and use as contemplated by the inventor. It also requires the inventor to describe it in such full, clear, concise and exact terms as to enable a person skilled in the art to make or use the invention. Section 27(3) does not require the attributes of patentability for an invention (i.e., novelty, inventive step or utility, which are requirements for an "invention" under s. 2 of the *Patent Act*) to be substantiated in the patent specification as a description requirement.

1. *The Legal Interpretation of the Description Requirements*. Settled law[13] on the description requirement establishes that the disclosure of a "use" under s. 27(3) is different from and should not be confused with the "utility" requirement under s. 2 of the *Patent Act*. Only the disclosure of a credible "use" is required: the establishment of utility is considered under s. 2 and may be based upon a "sound prediction" to the extent a sound prediction is relied upon, it relates to "Utility" and should be dealt with in Chapter 12 of the MOPOP.

13 *Consolboard Inc. v. Macmillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504, 56 C.P.R. (2d) 145 [*Consolboard*].

2. *Sound Prediction.* Settled law,[14] on "sound prediction" of utility, says that there must be a factual basis for the prediction and the inventor must have an articulable and "sound line of reasoning" from which a desired result can be inferred. Nevertheless, as a matter of settled law, it has not been determined that the factual basis or the "sound line of reasoning" have to be disclosed in the patent specification as a disclosure requirement, and the inventor may submit evidence to support utility after the filing date of a patent application.

3. *Selection Patents*. Settled law[15] on "selection" patents does not recognize a description requirement other than a simple statement of an advantage for the selected range, sub-genus or species. The proposed Chapter 9.04.02 of the MOPOP confuses this simple description of an advantage with resolution of the obviousness inquiry. Evidence of non-obviousness need not be included in the specification and the inventor may submit evidence to support non-obviousness after the filing date of a patent application. In any event, settled law is clear that "selection" is a part of the law of obviousness. This should be dealt with in Chapter 15 of the MOPOP.

4. *Non-authoritative, Non-precedential Decisions*. To the extent that relevant issues have not been fully argued exhausting all available routes of appeal, adjudications (not receiving such thorough judicial analysis) should not be relied upon. As such, typically proceedings under the *PM(NOC) Regulations* are non-authoritative and should not be the basis for changing the examination guidelines. Proposed requirements under Chapters 9.04.01, 9.04.01a and 9.04.01b, such as the inclusion of the factual basis for selections and utility and "sound prediction" in the patent specification, are based on *PM(NOC)* decisions where full judicial review was not available. They are not in accordance with Supreme Court of Canada principles. Moreover, they are not requirements under Section 27(3) of the Canadian Patent Act.

Canadian Law

Canadian patent law still prohibits the patenting of higher life forms, including transgenic plants, and animals, which denies patent protection to a wide array of valuable biotechnology inventions. In addition, patent term restoration is not available in Canada. Patent term

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14 *Monsanto Co. v. The Commissioner of Patents*, [1979] 2 S.C.R. 1108, 42 C.P.R. (2d) 161 [*Monsanto*].

15 *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 [*Sanofi*].

restoration covers the loss to patent life caused by clinical trials and the regulatory approval process. Finally, the Data Package Exclusivity provision adopted in 2006 is currently being challenged in the courts by the generic industry. The Federal Court dismissed the challenge in the first instance, but that decision is currently under appeal.

Canadian Courts

The lack of an equitable right of appeal remains the most significant enforcement challenge in Canada. The Patent Medicines (Notice of Compliance) (PMNOC) regulations create a process and a forum to resolve patent infringement issues and validity between generic and brand companies. However, practically, the regulations provide unequal appeal rights in favor of the generic company. Once a Notice of Compliance has been issued, a patent holder has no right to appeal the Notice as the appeal will be dismissed due to mootness. However, a generic company can appeal the decision in a Notice of Compliance proceeding. Even with a patent infringement action, complete redress remains illusory.

The PMNOC challenge to an allegation of non-infringement or patentability proceeds by way of summary judicial review toward determining whether an allegation is justified (unlike the United States). There is a lack of full discovery in this process and limitations are placed on the presentation of evidence (for example, no live witnesses are allowed).

Another enforcement challenge in Canada involves jurisprudence that takes the view that monetary damages are sufficient. Interlocutory injunctions to prevent market entry are rarely granted. Even if the biopharmaceutical patentee prevails, significant loss to reasonable opportunities to enjoy the full benefits of the patent occurs. 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).

A third challenge involves the Federal Court having heightened patentability requirements for biopharmaceutical patentees by requiring disclosure of experimental results in the patent application as filed. (*Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406, aff'd *Eli Lilly Canada Inc. v. Apotex, Inc.*, 2009 FCA 97, 78 C.P.R. (4th) 388.) Traditionally, and consistent with international norms, a patentee has not been required to have

conducted conclusive clinical trials nor has it been required to disclose such results in their patent application. However, in September 2010, the Federal Court invalidated a pharmaceutical patent by effectively requiring the patentee to have conducted large scale, long-term conclusive human clinical trials before filing its patent application. (*Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915).

TRIPS Article 29 offers an international standard that should inform the Canadian courts and the Patent Office of the requirements for sufficient disclosure. The article indicates that the description of a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. While TRIPS does not have implementing regulations, other treaties like the Patent Cooperation Treaty mirrors TRIPS language and provides further insight into the requirements for sufficient disclosure. Rule 5 of the PCT Regulations sets out the formal requirements for the contents of an international patent application and requires only that a patentee disclose the invention as claimed in such terms that the technical problem and its solution can be understood. Therefore, under the PCT there is no requirement to disclose facts supporting the utility of the invention; as suggested by recent Canadian Federal Court cases. Similarly, the PCT does not impose a different disclosure requirement for patent applications based on a sound prediction of utility. Consequently, additional description requirements imposed by the Federal Court are inconsistent with those under the PCT.

Further, the PCT, like the EPO, TRIPS and NAFTA, uses the term "industrially applicable". The requirement, in so far as it relates to international applications under the PCT, is contained in Article 33(4), which states: "a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry…" Industrial applicability is elaborated upon in the Guidelines for the Processing by International Searching and Preliminary Examining Authorities of International Applications under the Patent Cooperation Treaty ('the PCT Guidelines') at Chapter 14.[16] Chapter 14.01 notes that "industrially applicable" and "utility" may be deemed synonymous by some offices and cf. TRIPS Article 27(1) and NAFTA Article 1709(1).

16 Industrial applicability is elaborated upon in the Guidelines for the Processing by International Searching and Preliminary Examining Authorities of International Applications Under the Patent Cooperation Treaty Chapter 14.01.

Further, utility, according to the PCT Guidelines, has three requirements. The utility must be (1) specific, (2) substantial and (3) credible. According to the PCT Guidelines, the utility is credible *unless* (i) the underlying logic is seriously flawed or (ii) the facts upon which the assertion is based are inconsistent with the underlying logic. Unlike the additional disclosure requirements being imposed by the Canadian Federal Courts, none of these possibilities calls for proof of utility to be contained within the patent application as filed.

Failure to adhere to the standards of the PCT is a failure to implement adequate and effective protection for patents in Canada.

Losses

According to IMS data, one company reported that the loss of one drug's exclusivity in 2007 due to a PMNOC decision resulted in monthly revenues for a drug from 2007 to 2010 to fall from $24 million CDN to $5.5 million CDN (a $18.5 million CDN loss). The company also had job losses due to the PMNOC decision. The company lost 60 full time employees who primarily had bachelor's degrees, but also included those with advanced degrees.

Equitable patent application rules, evidence, enforcement rights, and patent eligibility requirements have led BIO to request that Canada remain on the Priority Watch List.

Chile

Lack of effective data protection, U.S.-Chile FTA noncompliance, lack of patent term extensions, and other patentability issues, has convinced BIO to request that Chile remain on the **Priority Watch List**.

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 Free Trade Agreement (FTA). This protection is essential for marketing of biopharmaceuticals in key markets. 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 provided under the FTA.

In addition, Chile's patent laws do not provide sufficient patent term extensions, 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 extensively short deadlines. Some members have been asked to respond to Office Actions in one month or less, which are among the shortest in the world and appear to be arbitrary. Other countries typically allow six months to respond to their office actions.

Other members have encountered difficulty obtaining claims addressing dosage regimens (i.e., where drugs are administered at a specific dose or in combination with other drugs). Increasing the types of patent protection available to cover approved uses of drugs would help biotechnology companies in Chile. Countries that restrict the patentability of human treatment typically allow coverage for the use of the drug for treatment so that there is patent coverage of commercial sales of the drugs (rather than the treatment method per se).

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

China

China's large consumer market presents unique opportunities for U.S. biotechnology companies to increase exports and create jobs in the United States. However, failure to adequately protect U.S. IPR limits the success of small-to-medium-size enterprises (SME) in China. Sometimes the challenges are so great that SMEs do not enter the Chinese market at all. For the reasons stated below, BIO requests that China remain 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.

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

The Chinese Patent Office has a new requirement involving confidentiality examination, which requires filing in China an invention "made in China" prior to filing in another patent office. The requirement creates confusion on when an invention is "made in China." Is an invention "made in China" only when the Chinese inventors are physically located in China or does "made in China" mean the invention is made within the national boundaries of China, but by multinational inventors? The latter situation would require applying to the United States for a foreign filing license prior to any filing in China, which would violate the Chinese requirement and result in a loss of rights in China. Confusion also remains when trying to evaluate when to file a request for a secrecy examination in SIPO versus filing an expedited request for a foreign license in the United States Patent and Trademark Office.

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.

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 extensions. Other nations include a patent term extension to compensate for the time it takes to gain regulatory approval for pharmaceutical and agricultural products.

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. The company that reported this disparity stated that it has not encountered such difficulty in any country of the world but China.

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.

Finally, 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. However, significant clarification regarding the events that would trigger compulsory licensing, as well as the scope and duration of the licenses granted, is needed.

Enforcement

Some biotechnology companies have commented that China's processes and remedies for patent infringement and trade secret misappropriation are ineffective. China requires U.S. companies to pursue enforcement actions at the provincial level with no central coordination. This allows suspects to escape prosecution through the use of diffuse networks to sell counterfeit goods. Local politics also makes it difficult to affect change. Enforcement authorities generally are skeptical or dismissive of infringement claims by local competitors and usually try to dissuade any attempt to use the courts, preferring "local arbitration or mediation," which tends to produce few results.

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

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. As you are aware, 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.

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

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.

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.

India

According to the WIPO publication *World Intellectual Property Indicators 2010*, the Indian pharmaceutical and biopharmaceutical sector accounts for a large portion of the Indian economies innovation. Between 2003 and 2007, 58.27% of the total domestic patent filings were in pharmaceuticals, biotechnology, and organic fine chemistry.[17] While patent filings are not the only measure of innovation, the numbers seem to indicate that the Indian pharmaceutical and biotechnology sectors are emerging from imitator to innovator status. Therefore, increasing patent protection will help grow both India's domestic industry and allow U.S. biotechnology

17 See http://www.wipo.int/ipstats/en/statistics/patents/ "Patent applications by field of technology (2003-2007 average) *by leading countries*"

companies to compete on a level playing field in the Indian market. 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 U.S. biotechnology companies and BIO requests that India remain on the **Priority Watch List**.

Patent Office

First, the lack of consistent adherence to Patent Law rules and procedures between the regional patent offices creates problems. U.S. companies in India have reported filing in separate regional patent offices and getting opposite results. Increased training on the inventive step 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. 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. Companies often wait dozens of years for a patent application to enter into the examination process only to have the claims opposed in a pre-grant proceeding. Companies have also reported delays in the post-grant opposition proceedings, one company reported waiting almost a year for a decision. The delay in the process results in applications being held up indefinitely, resulting in the loss of the majority of the patent term. 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 process to delay U.S. biotechnology patents to produce their own counterfeits. 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.

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 a patent term extension to compensate for the loss of patent life caused by product development and regulatory approval.

Patent Law

U.S. biotechnology companies have limited capability to obtain additional patent life through the grant of new patents that capture innovations on formulations, dosage forms, or chemical variations of an earlier patented product. India imposes higher standards in these areas than are found in other major countries. These claims are crucial to incentivize biotechnology companies to continue to investigate their discoveries and improve their own products. The patent law does allow inventions that enhance the known efficacy of the substance, or results in a new product, or employs at least one new reactant, but the law prohibits mere discovery of a new form, property, or use of a known substance.

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 nations (such as the European Patent Office) that prohibit method claims 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 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 Report[18] 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.

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. 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. These requirements pose unacceptable risks for patent applicants 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.

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*. 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

18 SATWANT REDDY AND GURDIAL SINGH SANDHU, REPORT ON STEPS TO BE TAKEN BY THE GOVERNMENT OF INDIA IN THE CONTEXT OF DATA ROTECTION 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."

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 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.

Biotechnology companies would find it helpful if the United States or other patent-friendly nations 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.

Enforcement

Failure to recognize or enforce patents gives generic companies an unfair competitive advantage. Indian generic companies, who are primarily export-oriented, ship infringing products to countries where patent protection does not exist and those products also find their way to countries with protection. These generic counterfeits create a worldwide problem as industry has difficulty in stopping infringing products that have been imported 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 characterized as a counterfeit. The public and medical professionals in India and around the world need to understand the risks of counterfeit medicines before they purchase from unauthorized suppliers or on internet pharmacies.

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.

Harm to U.S. Companies

While studies are hard to conduct on the revenue effects of IPR violations, it seems theoretically clear that with less infringing products on the market the innovator product would increase revenues. Additionally, increase in product distribution in India would lead to more employees hired in India to handle sales and distribution. Finally, increased intellectual property protection would entice U.S. companies to set up manufacturing and research and development facilities in India to take advantage of the high level of education and experience found in the Indian population.

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

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 retain Indonesia on the **Priority Watch List**.

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 maintained on the Priority Watch List.

Israel

While Israel has made progress in working with USTR and passing significant intellectual property rights legislation, BIO requests that Israel remain on the **Priority Watch List** to monitor the implementation process.

On February 18, 2010, the Government of Israel and the USTR reached an agreement where Israel committed to improving key aspects of its intellectual property environment relating to pharmaceuticals, specifically in the areas of regulatory data protection, registration delays, patent term extensions and the timely publication of patent applications. In exchange, the parties agreed that Israel be removed from the 301 lists once these improvements enter into effect.

To date, however, none of the commitments that Israel made have been implemented. In some cases (especially in the areas of patent term extension and publication of patent applications), the suggested improvements by Israel are being offset by other changes that seek to reduce and restrict the rights granted to U.S.-based innovators. These restrictions may even put U.S.-based companies in a situation that is worse off than the current state of affairs.

Israel's regime for protection of data submitted by the originator of a new drug to support its application to market the drug remains inconsistent with international standards. The linkage of the exclusivity period (5.5 years) to the earliest registration in any of a list of "recognized countries" substantially reduces the protection available for U.S. companies in Israel.

Compounding the problem, significant delays in the registration process for innovative products further erode the exclusivity period.

In addition, the laws relating to patent term extension are burdensome and severely restrict the ability to obtain the extensions needed to compensate innovators for the loss of exclusivity due to the lengthy research and development periods and delays in the approvals process. Moreover, such extensions, where available, are significantly limited, as extensions of the patent term are linked to the shortest extension given in one of a number of reference countries. Israel has not corrected these matters despite years of engagement by the United States. Israel continues to fall well short of international standards, particularly those adopted by most member countries of the Organization for Economic Cooperation and Development (OECD), to which Israel hopes to accede in the near term.

Israel's pre-grant opposition regime for patents also continues to be of serious concern to BIO's members. While we understand that Israel has taken certain actions in an attempt to address some of the most egregious abuses of the opposition procedure, the patent statute nonetheless continues to provide that any person may file an opposition against any pending application within three months after the application is published. The U.S. government has long recognized that such pre-grant opposition proceedings have the potential to cause significant harm to U.S. applicants. Domestic entities in Israel have a long history of using pre-grant oppositions to delay or deny the grant of patents for the deserving inventions of foreign interests.

Moreover, early in 2010, the Government of Israel published a Memorandum regarding a proposal for an amendment to the Patents Law regarding Publication of Patent Applications. The proposal is aimed at allowing the publication of patent applications within a period of 18 months from the priority filing date. BIO supports the concept of timely publication of patent applications within such a period, which is similar to publication periods used in other major patent offices. Unfortunately, the proposal in the Memorandum also includes a series of additional amendments that would narrow and excessively restrict the ability of the owners to obtain adequate and effective protection in Israel. For example, there are proposals that would change existing Israeli law to restrict the ability to amend the application after publication, to limit the ability to obtain certain remedies for infringement that are not consistent with existing Israeli laws, and to apply these changes retroactively to applications that have already been filed.

These changes, which are not consistent with many other jurisdictions including the United States, raise significant concerns.

Israel is a modern, technologically-advanced country and is looking to become a member of the OECD. It enjoys preferential access to the U.S. market for pharmaceutical products made by its domestic industry. Israeli interests routinely procure U.S. patents, litigate them in U.S. courts, and generally benefit from adequate and effective intellectual property protection under U.S. law. The failure of Israel to provide comparable protection for U.S. interests in Israel improperly and significantly distorts the trade in biotechnology products between the United States and Israel.

BIO considers that these policies warrant continued close scrutiny by USTR and urges USTR to maintain Israel on the Priority Watch List.

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 urges USTR to place the Philippines on the **Priority 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 non-discrimination 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 for 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 Priority Watch List.

Russia

BIO did not include Russia in our 2010 submission, however, our members have expressed certain challenges in operating in Russia. Russian improved their patent laws in 2008 bringing patent practice closer to Western patent systems. However, problems remain and BIO requests Russia remain on the **Priority Watch List**.

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 whose only difference is 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.

Biotechnology companies are not able to "repurpose" known compounds for new legitimate uses. 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.

Venezuela

BIO did not highlight Venezuela in the 2010 Special 301 Report submission but this year some of our members have highlighted their intellectual property concerns. BIO requests USTR to maintain Venezuela on the **Priority Watch List**.

Venezuela does not permit methods of treatment or "Swiss-type" (use) claims. Additionally, 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.

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.

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

Brazil

When considering Brazil's history of intellectual property protection, Brazil has made significant improvements. While BIO is encouraged with Brazil's progress, biotechnology companies are eager for further improvements to enable U.S. biotechnology companies to enter and compete on a level playing field in the Brazilian market. BIO recommends Brazil remain on the **Watch List**.

Brazilian Patent and Trademark Office (INPI)

We understand that the Brazilian Patent Office has 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. While conditions are improving, biotechnology companies are still hesitant to seek market authorization for their products.

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 takes the position that any product of nature, even in an isolated form, is unpatentable. Claims to "isolated" DNA, proteins, and antibodies are routinely rejected, as are claims to "recombinant" products. For biotechnology, these claims are the basis for a large amount of biotechnology products. The Patent Office 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.

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 the Patent Office before allowance. These particular administrative hurdles are not found in Europe, China, Japan, or India.

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

Law

The patent term in Brazil is 20 years from priority date instead of filing date. 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. 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 U.S. biotechnology companies' progress in Brazil.

Regulatory Issues

Biotechnology companies find operating in the current regulatory environment difficult; especially when unauthorized copies of products receive registrations on undisclosed tests and other confidential data. Brazil's lack of any form of data protection 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." Allowing U.S. companies to have 5 years of data protection for innovators and adopting Hatch-Waxman like legislation on data exclusivity and patent litigation between innovators and generics would help U.S. biotechnology companies enter and succeed in the Brazilian market.

In addition, Brazil's regulatory authority (ANVISA) creates problems as they have been tasked with approving pharmaceutical patents before they are granted by the INPI. ANVISA reviews each pharmaceutical patent application INPI deems allowable to evaluate whether the patent would be against the public interest. In almost every case, ANVISA alleges that the patents are not allowable because the claims lack novelty, inventive step, and/or industrial applicability. ANVISA is operating outside their legislative mandate and they are overriding INPI's expertise. This is inconsistent with TRIPS Articles 27 and 62.2, as ANVISA requires applicants to reargue their claims already deemed allowable by the INPI and contributes to the backlog at INPI. However, we have been informed that on January 25, 2010 the Brazilian Attorney General of the Union (AGU) resolved this issue by restricting ANVISA's review to only analyze the sanitary risks of the patented drug to health.[19] The Attorney General found that any other analysis would entail an invasion of INPI's competence. We also understand that the AGU's opinion cannot be appealed and ANVISA must comply with its terms. We will be monitoring implementation of this policy with great interest.

19 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/TemplateImagemTextoThumb.aspx?idConteudo%3D153676%26id_site%3D3

Finally, 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. 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.

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 we 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 but many do begin as there is currently no mechanism of verifying unauthorized access. However, it is not possible to on 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. 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. It is our understanding that the Brazilian scientific community also finds the regime onerous. We believe that the Nagoya Protocol of the Convention of Biological Diversity may result in movement in Brazil on these issues and we ask USTR to monitor Nagoya Protocol implementation efforts.

Colombia

The Colombian patent law raises a number of concerns for BIO's members that warrant further monitoring. In light of the deficiencies of the law, BIO requests that Colombia remain on the **Watch List**.

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 germ plasm 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 Agreement that require patents to be made available to "any inventions … provided they are new, involve an inventive step, and are capable of industrial application." 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 pharmaceutical inventions, essentially denying protection for these inventions.

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.

BIO also has concerns relating to the recent set of government decrees relating to the health care system in Colombia. These decrees are reported to be far-reaching in nature and may have the potential to undermine the intellectual property rights of BIO's members in Colombia. These recent actions warrant further monitoring.

Egypt

BIO requests that USTR retain 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.

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 remain 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 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.

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

Biosimilar legislation approved by Congress in April 2009 has not resulted in implementing regulations. We hope that the United States government continues to monitor implementation efforts to ensure U.S. biotechnology companies which create innovative products are adequately protected.

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 retained on the Watch List.

Peru

Peru was not part of BIO's 2010 submission but due to ongoing intellectual property challenges without significant progress BIO requests USTR to maintain 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. Increasing the patent protection to cover approved uses of drugs allows biotechnology companies to protect their substantial investment to approve and market drugs in a particular country while preventing counterfeits.

Further, some companies have expressed concerns about patent examiners. One example involved a Peruvian patent examiner issuing a final rejection on a patent application as part of their first office action without allowing the applicant any opportunity to respond. The applicant then pursued an appeal, at great expense, all the way to the Peruvian Supreme Court and the applicant was successful in having the final rejection declared null and void. BIO hopes that such abuses are uncommon and do not occur in the future.

SECTION 306

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 continue to monitor Paraguay under **Section 306**.

Paraguay's patent examination system suffers from a great 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. Paraguay needs to identify measures to reduce its excessive backlog. 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's patent laws also do not provide for sufficient patent term extensions to fully compensate for unwarranted delays in the patent application 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, although the Law states the obligation of safeguarding the scientific or technical information contained in the documents submitted for the registration of phytosanitary or zoosanitary products. 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 "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.

Other Countries/Organizations of Concern

European Patent Office

New EPO rules implemented in April 2010 have, unfortunately, have a negative effect on patent procurement in Europe.[20] These changes have resulted in biotech companies having to make intellectual property filing decisions much earlier requiring larger upfront investments before knowing whether their invention is commercially viable.

First, the new time limit for filing divisional applications creates filing problems. Prior to the new rules, divisional applications relating to pending earlier European patent applications could be filed at any stage of the grant procedure of that earlier application. The new rule restricts the filing of divisional applications to 24 months from either the first official Examining Division communication regarding the earliest application for which a communication has been issued (or sometimes called "voluntary" division) **or** from any communication in which a lack of unity objection has been raised for the first time in respect to the earlier application.

One effect of this rule change results from the fact that any point of contention in the parent application may not have been resolved by the divisional filing deadline. In effect, the divisional application filing deadline may arrive much earlier than the issue date of the parent application. This is problematic because the deadline arrives before an applicant knows whether or not they need to file a divisional application. The change completely alters patent prosecution strategy in Europe. Applicants may no longer have the opportunity to take narrow claims in a parent application and file a divisional application to pursue broader subject matter (which is available in the United States).

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20 Amendment to the Guildelines for Examination in the European Patent Office. Press release accessed on February 10, 2011 at http://www.epo.org/patents/law/legal-texts/journal/informationEPO/archive/20100401.html?update

A second disadvantage occurs as the ability under the previous laws allowing the ability to file a divisional application derived from an earlier divisional application is much more limited because the filing deadlines require earlier, less informed, filing decisions. This problem is particularly difficult in the drug development process where the large amounts of time required do not enable companies to make correct decisions when filing a divisional application.

Another problem with the new rules involves unity of invention rejections being issued earlier during the patent process. Prior to the rule change, the unity of invention rejection occurred during the examination phase. The new rule will likely result in the objection being raised earlier in the procedure, or in other words, before the issuance of the European Search Report. While filers previously had the option to address the objections directly during the examination process, the new rule will result in filers having to file precautionary divisional applications before the outcome of the arguments are known. The new rule seems to result in duplicative and probably unnecessary filings to protect from the possibility of a unity of invention objection.

The third challenge is that a compulsory response is required at an earlier stage of the patent procedure. Prior to the new rules, the Examining Division advised applicants (without making it mandatory) to respond to the search report issued with a written opinion. Without a response from the applicant, the Examining Division would generally refer to the written opinion in the first official communication. The new Rule 70bis requires a response to the European Search Reports if the written opinion contains objections. The response must be made within the time period for requesting examination (6 months from the publication of the European Search Report) when examination has not yet been requested or within the period specified by the EPO for confirming the examination request when the examination has already been requested. If no response is filed, the application will be deemed withdrawn. Applicants are forced to respond and put statements on the record to objections raised in the search opinion long before the filers know what is important to pursue in prosecution.

Japan

While Japan has one of the best patent systems in the world, biotechnology companies have encountered difficulty with enforcement of their intellectual property rights.

One reported case involved the internet sales of infringing medicinal product imported from India. Even though the company had a patent for the product in Japan, Japanese law does not make it an act of patent infringement to import infringing medicinal products for non-commercial, personal use. As a result, internet sales of potentially dangerous and inferior counterfeit medicines are imported legally in Japan. This provision is inconsistent with TRIPS Article 30 responsibilities as the enforcement exception "unreasonably conflicts" with "normal exploitation of patents and "unreasonably prejudice[s] the legitimate interests of the patent owner." While some might argue that the legitimate interests of third parties under Article 30 or the "public interest" exception of 27.1 and 27.3 applies, such arguments fail to take into account the dangers of imported counterfeit medicines which have likely not been regulated by Japanese health authorities.

Biotechnology companies also encounter problems when they try to both file patents before competitors and to prove the efficacy of a new chemical entity ("NCE"). Often, the biotechnology company will file a patent for the NCE when there is only in vitro data or basic animal data regarding efficacy. The Japanese Patent Examiner then questions whether the NCE is effective for its stated purpose but not allow the company to bring in post-filing data derived from human clinical trials proving the NCE's effectiveness. Ultimately, the company is left with narrow or no patent protection at all.

Taiwan

The Fundamental Science and Technology Act presents an IPR concern for BIO. This law has the same purpose as the United States' counterpart commonly referred to as the Bayh-Dole Act which facilitates technology transfer from federally funded university research to the market place. Unfortunately, the Taiwanese law does not work well for American companies seeking to license Taiwanese intellectual property.

Article 9 of the Fundamental Science and Technology Act prohibits Taiwanese academic institutions from licensing to non-domestic companies without government permission. This permission often takes two to three years to receive and is frequently refused. The Bayh-Dole Act makes no domicile distinction but instead requires the licensee to substantially manufacture in the United States products that will be sold in the United States. This allows foreign companies in the U.S. equal opportunity to obtain a U.S. license as domestic companies.

BIO's members do not have the opportunity to develop and commercialize breakthrough technology in Taiwan because they cannot license the technology. Additionally, local Taiwanese innovation suffers as there may not be enough Taiwanese companies to commercialize all of the innovation that occurs in Taiwan.

Conclusion

The Biotechnology Industry Organization 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,

Lila Feisee
Vice President, Global Intellectual Property Policy
Biotechnology Industry Organization