By electronic submission

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BIOTECHNOLOGY INDUSTRY ORGANIZATION

2012 SPECIAL 301 SUBMISSION

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Executive Summary:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to participate in the Special 301 process and is hopeful that our contribution will assist the United States Trade Representative's (USTR) efforts in preserving strong intellectual property protections for United States' companies internationally. BIO appreciates the opportunity to comment on *2012 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing*.

BIO is a non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 States and a number of foreign countries. BIO's members research and develop health care, agricultural, industrial, and environmental biotechnology products. The U.S. life sciences industry, fueled by the strength of the U.S. patent system, supports more than 7.5 million jobs in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and other environmentally-beneficial products such as renewable fuels and bio-based plastics.

The vast majority of BIO's members are small and medium sized enterprises that currently do not have products on the market. As such BIO's members rely heavily on the strength and scope of their patents to generate investment to take their technologies to commercialization. More and more, BIO's members are looking abroad as they expand their markets and R&D and commercialization efforts.

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

To help in assessing the IP challenges abroad that may hinder our companies' activities, BIO has surveyed our members asking them to identify relevant IPR barriers in the identified nation's law, courts, enforcement regime, regulatory regime, import/export regime, etc. Our members have provided the information found in this submission and we have compiled the information in aggregate form. BIO has chosen to aggregate the issues to help identify

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

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.

Priority Foreign Country: BIO requests USTR to elevate Turkey to a Priority Foreign Country due to new alarming issues pertaining to IPR.

Priority Watch List: BIO requests USTR to keep Argentina, Brazil, Canada, Chile, China, India, Indonesia, Israel, Thailand 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 Colombia, Egypt, Mexico, Peru, Russia and Ukraine 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 IPR is properly protected.

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

BIO hopes this submission informs U.S. Government officials and the public about the IPR challenges U.S. biotechnology companies face around the world. Finally, we hope our submission helps the U.S. government 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 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 cleaning our environment and fighting global climate change by reducing our dependence on petroleum and fossil fuels. Biotechnology innovation, if supported by appropriate public policies, has the potential to provide treatments for some of the world's most intractable diseases and address some of the most pressing agricultural, energy, and environmental challenges facing our society today.

The biotechnology industry relies heavily on patents. The development of a single biotechnology product often takes more than a decade to be commercialized, and hundreds of millions (if not a billion) of dollars of capital investment, a significant amount of which comes from private sources. Biotechnology product development is also fraught with high risk – the vast majority of biotech products fail to ever reach the marketplace. In addition, while biotech health inventions are entitled to the same patent term as all other inventions − 20 years from the time they are filed – they have the additional hurdle of a rigorous pre-launch regulatory review process during which they may lose between 8 to 10 years of the patent life. Venture capital firms invest in capital-intensive, long-term, and high-risk research and development endeavors only if they believe there will be a return on their investment. Patents help provide this assurance. 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.

Access to Medicines

In May 2010, BIO released the Biotechnology Industry Organization Policy Statement: Options for Increasing Access to Medicines in the Developing World.[3] 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

[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://ssrn.com/abstract=1121224

[3] http://www.bio.org/healthcare/innovation/Access_to_Medicines_Policy_Statement_Final.pdf

such products as well as the existing range of medicines commonly utilized in the developed world."[4]

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."[5]

The Statement makes the following recommendations to BIO's members. "When entering into license agreements, explore creative strategies that help to expand access to medicines in the developing world...While researching and developing products, work to identify compounds or technologies that can have useful applications in the developing world…Where practicable, participate in partnerships that develop medicines and medical technologies for the developing world…When doing clinical trials, take into consideration the needs of people living in developing countries…When commercializing medical products, explore individualized strategies that will help improve the affordability of medicines in the developing world…Where practical, explore ways to overcome non-price barriers that hinder access to medicines and medical technologies in the developing world…Share individual experiences and approaches broadly to advance the goals of enhanced access in the developing world."[6]

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

Turkey

BIO did not make comments on Turkey in our 2011 Special 301 Report, but our members have raised serious concerns over egregious IP and market access deficiencies. Turkey requires significant progress in their intellectual property law as indicated by the European Union in the Turkey 2010 Progress Report on Accession.[7] BIO recommends that USTR retains Turkey be designated as a **Priority Foreign Country**.

One of the most serious issues in Turkey involves the requirement for the Ministry of Health to perform their own Good Manufacturing Practices (GMP) inspection at every pharmaceutical production facility. This requirement must occur before product registration in

[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] Turkey 2010 Progress Report on Accession, "Chapter 4.7: Intellectual Property Law."

Turkey and has caused significant registration delays among our companies trying to enter the Turkish market. The Ministry of Health does allow for GMP certificates from other competent authorities but that acceptance is conditioned on other countries recognizing Turkish GMP certification. However, this is difficult to accomplish as Turkey must join the Pharmaceutical Inspection Convention and Cooperation Scheme that dictates international GMP standards and Turkey will need to negotiate agreements directly with each participating country. Turkey's Ministry of Health neither has the staff nor resources to accomplish such a task and this directly results in a non-tariff barrier to trade.

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

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

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

Finally, price reimbursement remains a difficult issue for our members. The reimbursement decision criteria are not clearly defined, the process is not transparent, and involves a large amount of time to conclude the process (on average 345 days).[8] Drastic budget cuts directly targeting innovative medicines have occurred in the last few years during a period of rapid economic growth in Turkey without transparency on government pharmaceutical spending.

For these reasons, BIO recommends that USTR designate Turkey as a **Priority Foreign Country**.

[8] AIFD Market Access Survey, March 2011

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 more than a hundred member countries. Acceding to this widely accepted agreement would be a positive step toward reducing unnecessary expenses and facilitating the procurement of patent protection in Argentina for BIO's members. Further, the highly restrictive patent examination guidelines issued by the INPI in Argentina exclude protection for a wide range of biotechnological inventions. The criteria adopted by INPI, which denies patent claims directed to transgenic plants and animals, their parts and components, also appear to be inconsistent with the Argentine patent law. The patent law provides an 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. Finally, the INPI does not grant patents for polymorphs or salt forms of known pharmaceutical compounds.

Argentina also does not provide adequate protection for the data that must be generated in support of marketing authorization to prove that biotechnology products applicable to the pharmaceutical and agricultural chemical industries are safe and effective. 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 treatment contained in the Argentine Patent Law.

b) claims worded as Swiss-type claims, since the Patent Office will assume that the invention does not comply with the novelty requirement.

c) claims directed to the process for the manufacture of a medicament when the novelty of the process is based on a new use of a known compound, because the Patent Office will consider that the invention does not comply with the novelty requirement.

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

A lack of significant progress in the patent regime, data protection, and patent claim scope areas has convinced BIO to request the USTR to maintain Argentina on the **Priority Watch List**.

Brazil

When considering Brazil's history of intellectual property protection, Brazil has made significant improvements. In fact, the reforms have reaffirmed the fact that changes in the patent law have encouraged Brazilian biotech innovation.[9] While BIO is encouraged with Brazil's progress, biotechnology companies remain disappointed with Brazil's IP situation and Brazil's efforts to undermine IP internationally. BIO recommends that USTR elevate Brazil to the **Priority 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

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

that they filed 335 cases over 30 years with only 5 being granted. Only 2 patents have not expired with about 80 cases being abandoned by the company. Another company reports filing 200 patent applications with only 2 patents issued in the past dozen years. While conditions are improving, biotechnology companies are still hesitant to seek market authorization for their products.

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, or Japan.

Members also report that examiners abuse the obviousness standard. Members state that in their experience, examiners often rely heavily on hindsight reasoning to make obviousness arguments in biotech cases.

BIO Members also have other prosecution concerns. INPI prohibits amending claims to include classes or categories of claims not included in the original claim set. The applicant cannot broaden the claims after the examination request. Finally, members have inadequate access to INPI patent prosecution records. One company reported receiving notice of rejection of claims in a pending application but not receiving the substantive action until after the deadline for responding. There also is no way to access electronically INPI prosecution records or issued patents and claims. Viewing patents and file wrappers requires a physical visit to INPI to order the patents/file wrappers and then waiting a couple of months to receive the requested documents.

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

Law

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

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

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

Regulatory Issues

Biotechnology companies find operating in the current regulatory environment difficult; especially when unauthorized copies of products receive registrations on undisclosed tests and other confidential data. Brazil's lack of data protection for pharmaceuticals is inconsistent with TRIPS Article 39. Article 39.3 requires that members, requiring approval for pharmaceutical or agricultural chemical products, "protect data against unfair commercial use." While Brazil implemented 10 years of data exclusivity for agrochemical and veterinary products, it has yet to provide similar protections for pharmaceutical products. In fact, Lundbeck sued in the first-level federal court in Brazil on this issue and won but later lost at a higher level on purely political grounds. Similar suits by other parties have not been successful yet and the issue has not been addressed at the highest level court in Brazil. Allowing U.S. companies to have 5 years of data protection for pharmaceutical innovators and 12 years for biologics similar to U.S. law with some form of patent linkage 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

[10] 2.511/07 and 3.995/08

analysis of the sanitary risks of the patented drug to health.[11] The Attorney General found that any other analysis would entail an invasion of INPI's competence. Nonetheless, early indications are that this decision is not being followed. We have been told that ANVISA and INPI are discussing possible ways forward. We request that the USTR continue to monitoring implementation of this policy.

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. Brazilian law also requires a patentee to "make use of" a patent or allow others to do so within three years of issuance. Failure to comply results in INPI issuing a compulsory license to a third party with technical and economical capacity and legitimate interest in using the technology of the patent (in other words, the noninnovative competitor). In addition, according to Decree n. 4.820, Sept. 4, 2003, the patent holder may also be obligated to supply technical know-how to perform the invention or potentially have the patent declared invalid.

While BIO understands the challenges that countries face in providing affordable healthcare systems, BIO continues to believe that the most effective solutions will result from policies that respect and encourage innovation. The granting of compulsory licenses in this manner will undermine incentives needed to develop new medicines.

Enforcement

Licensing and IP enforcement laws remain difficult to navigate and weighted against the interests of the IP owner. For example, INPI requires registration of license agreements before they can be enforced, before royalty revenues can be exported, or before companies can utilize favorable tax rates. Further, INPI can dictate terms prohibiting parties from freely contracting and restricting the owner from fully exploiting their IP. For example, INPI can stipulate that royalty rates not exceed 5% of gross income per unit. Finally, confidentiality provisions extending beyond the term of the agreement are limited to five to ten years.

Brazilian law also prohibits licensing of non-patented IP and the law only permits the "transfer" of this technology providing unlimited rights of exploitation to the transferee after 5-10 years. As patents are either not granted for biotechnology or severely delayed, this provision forces the choice on innovator companies to either not work with Brazilian companies until after they receive their patents or risk losing their IP.

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

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

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.

For all of these reasons, BIO recommends that Brazil be placed 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 practices 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 Patentable Utility Requirements

Recently enacted Canadian Intellectual Property Office (CIPO) rules and requirements for establishing utility for a patentable invention exceed Canadian statutory authority and are contrary to settled Canadian case law. In December 2010, CIPO published changes to its Manual of Patent Office Practice (MOPOP) Chapter 9.04 "Establishing Utility" which are

broadly applicable to other areas of the guidelines. Concerns over the new Canadian utility requirements are as follows**:**

1. *The Statutory Basis for the Utility Requirements Described in Chapter 9.04.* The requirements set out in MOPOP Chapter 9.04 exceed statutory requirements under Section 27(3) of the *Canadian Patent Act* (*the Act*). Chapter 9.04 includes the requirement that the description in a patent application *as filed* provide whatever explanation is necessary to supplement the common general knowledge of the person skilled in the art so as to permit a person skilled in the art to *soundly predict* that an invention will have the proposed utility. Section 27(3) of *the Act* on the other hand, consistent with the vast majority of jurisdictions outside Canada, requires the inventor to correctly and fully describe the invention, its operation and its use as contemplated. It also requires the inventor to describe the invention in such full, clear, concise and exact terms as to enable a person skilled in the art to make or use the invention.

2. Contrary to MOPOP Chapter 9.04, Section 27(3) of *the Act* does not require, and has never required, the specification as filed to "soundly predict" that an invention will have the proposed utility. This relatively new requirement in Canada has evolved into a nearly impossible requirement for innovator pharmaceutical companies to meet based on the necessity to timely file their patent applications prior to completion of phase III clinical trials, and as such has become a primary means for Canadian generic companies to invalidate patents owned by innovative pharmaceutical companies – patents that protect significant research and development investments and that regularly withstand corresponding generic patent challenges worldwide.

3. *Legal Interpretation of the Description Requirements in MOPOP Chapter 9.* Settled Supreme Court precedent [12] on patent description requirements, even in the context of sound prediction and utility under Section 2 of *the Act*, establishes that the "use" requirement under Section 27(3) of *the Act* requires only the disclosure of a credible "use" in the patent application at the time of filing. In any event to the extent a sound prediction is relied upon as a requirement for patentability, it relates to "Utility and Subject Matter" and should be dealt with in Chapter 12 of the MOPOP.

4. *Sound Prediction.* Settled law[13] [14] on "sound prediction" of utility requires there to be a factual basis for the prediction that an invention will have the proposed utility and the *inventor* must have an articulable and "sound line of reasoning" from which a desired result can be inferred. Further, the Supreme Court of Canada has not required the factual basis or the "sound line of reasoning" to be disclosed in the patent specification as filed. Thus under settled law an inventor may submit evidence to support utility after the filing date of the patent application. MOPOP Chapter 9.04.01b however states the nature of the sound line of reasoning is only considered to the extent that a person of ordinary skill would have appreciated it based on the description in the patent application as filed.

[12] *Consolboard Inc. v. Macmillan Bloedel (Sask.) Ltd.*, [1981] 1 SCR 504, 56 CPR (2d) 145 [*Consolboard*].
[13] *Monsanto Co. v. The Commissioner of Patents*, [1979] 2 SCR 1108, 42 CPR (2d) 161 [*Monsanto*].
[14] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 SCR 153, 21 CPR (4th) 499 [*AZT*].

Thus under this new Canadian rule, an inventor may not submit evidence to support an invention's utility after the filing date of the patent.[15]

5. *Selection Patents*. MOPOP Chapter 9.04.02 confounds settled law [16] on "selection" invention patents with a heightened utility requirement. Chapter 9.04.02 indicates that a selection invention patent, whose utility has not been demonstrated or soundly predicted, is necessarily not an invention. However, according to well-settled Canadian case law and the practices of patent offices and courts worldwide, evidence of non-obviousness need not be included in the specification, and the inventor is able to submit evidence to support non-obviousness after the filing date of a patent application contrary to MOPOP Chapter 9.04.02. Furthermore, settled Canadian law is that the patentability of a "selection" invention is primarily assessed based on the law of obviousness and thus should be dealt with in Chapter 15 of the MOPOP.

6. *Non-authoritative, Non-precedential Decisions*. The new Canadian MOPOP requirement that the factual basis and sound line of reasoning be based exclusively on the patent specification as filed, is based in part on *Patented Medicines (Notice of Compliance)* decisions (*PM(NOC) decisions*). *PM(NOC) decisions* are by judicial design based on limited information and evidence (e.g., no witness testimony). Thus, precedent emanating from *PM(NOC) decisions* should not be the basis for MOPOP patent examination guidelines and significant policy changes because relevant issues have not been fully argued, comprehensive judicial analysis is lacking and full judicial review of the decisions is not available; the decisions are based on unsettled law and in particular are not based on Canadian Supreme Court principles. Moreover, they are not requirements under Section 27(3) of *the Act* as discussed above.

One of the most significant threats to biopharmaceutical innovation in Canada emanates from the heightened standards for patentable utility which are an increasing basis of attach and discriminate against pharmaceutical patents. Since 2008, of the 37 cases where lack of utility was alleged by a generic copier in the Canadian Federal Courts, only 2 were non-biopharmaceutical patents. Thus over the last 3 years inutility was alleged against biopharmaceutical patents almost exclusively, that is 95% of the time.

Under Canadian law an applicant must be in a position to establish the utility of their invention by demonstration or sound prediction, no later than the filing date of their application.[17] Where the utility of an invention is to be established by demonstration, the basis for the demonstration must exist at the filing date. If utility is not established via demonstration, for example by treatment of disease where indicated by the patent claims, then an applicant must meet the three requirements for sound prediction: there must be a factual basis for the prediction; the inventor must have an articulable line of reasoning from which the desired result can be inferred from the factual basis; and there must be proper disclosure of the factual basis and line

[15] See MOPOP Chapter 9.04.01*b*, fourth paragraph.
[16] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 SCR 265 [*Sanofi*].
[17] *AZT*, 2002 SCC 77, [2002] 4 S.C.R. 1 at paragraph 37.

of reasoning.[18] The enhanced disclosure requirements are also contrary to Canadian national law as articulated in *the Act* and international norms.

These heightened standards created by judicial interpretation of utility requirements have led to the invalidation for inutility or finding allegations of inutility justified in the *PM(NOC) Regulations* for at least eleven (11) patents [19] where the pharmaceutical is plainly useful [20]. As such there is substantial uncertainty as to how much work must be performed and disclosed when a patent application is filed due to the arbitrary judicial determination of the "promise" of the patent which occurs in litigation many years after the application is filed. The precedential effect of these decisions and the Canadian policies which require the "promised" utility to be demonstrated or "soundly predicted" at the time of filing are an *ultra vires* hurdle for patents directed to pharmaceuticals in view of the Act. If an innovator must delay filing a patent application until after the data is obtained it may result in loss of IP rights due to obligations to disclose planned and ongoing clinical trial information.

As evidenced by the reasoning contained within each of the eleven decisions, substantial uncertainty now exists on the part of BIO member companies as to how a Canadian court will construe the "promise" of a patent during enforcement litigation. The so-called "promise" of the patent is construed by the court at the outset of the utility analysis when an alleged infringer must demonstrate that the invention has not met its promised utility.[21] The promise of a patent, like claim construction, is a question of law.[22] Evidence of either a demonstration or sound prediction of utility is then compared to this promise to determine if the utility requirement is met. In some cases, after construction of an improperly elevated '"promise", Canadian courts have required long term clinical studies in patients [23] in order to find utility. The concern over an

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[18] AZT, 2002 SCC 77, [2002] 4 S.C.R. 1 at paragraph 186.

[19] Decisions invalidating pharmaceutical patents for a lack of utility in infringement or revocation proceedings include the following: *Strattera FCA*, 2011 FCA 220, 94 CPR (4th) 95, leave to appeal to SCC refused [2011] SCCA No 362 (QL); *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2011 FCA 300, [*Ramipril FCA*]; *Ratiopharm Inc. v. Pfizer Ltd.*, 2009 FC 711, 76 CPR (4th) 241 [*Amlodipine besylate*], affirmed 2010 FCA 204, 87 CPR (4th) 185 (FCA does not comment on utility), and *Olanzapine*, 2011 FC 1288. Decisions where allegations of inutility were found to be justified in *PM(NOC)* (s. 55.2) hearings include the following: *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, 95 CPR (4th) 193 [*Latanoprost FCA*]; *Evista*, 2009 FCA 97, 78 CPR (4th) 388, leave to appeal to SCC refused [2009] SCCA No 219 (QL); *Pfizer Canada Inc. v. Ratiopharm Inc.*, 2010 FC 612 [*Revatio FC*]; *AstraZeneca Canada Inc. v. Apotex Inc.*, 2010 FC 714, 88 CPR (4th) 28 [*Esomeprazole*] ; *GlaxoSmithKline Inc. v. Pharmascience Inc.*, 2008 FC 593, 72 CPR (4th) 295 [*Valacyclovir*]; and *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 26, 59 CPR (4th) 183 [*Viagra*], affirmed 2007 FCA 195, 60 CPR (4th) 177, leave to appeal to SCC refused [2007] SCCA No 371 (QL); *Sanofi-Aventis v. Apotex*, 2011 FC 12782) [*Plavix*]. Collectively these products represent billions of dollars of sales lost due to judge-made heightened standards of utility.

[20] Utility in fact is all that is required by treaty. (as discussed in section (g))

[21] See *Consolboard*, [1981] 1 S.C.R. 504 (at page 525: the alleged infringer must demonstrate that "the invention will not work, either in the sense that it will not operate at all, or, more broadly, that it will not do what the specification promises that it will do").

[22] *Bristol Meyers-Squibb Co. v. Apotex Inc.*, 2007 FCA 379 (at paragraph 27: construction of the promise requires assistance of expert evidence).

[23] See *Strattera FCA,* 2011 FCA 220, 94 CPR (4th) 95, leave to appeal to SCC refused [2011] SCCA No 362 (QL) (at paragraph 19, quoting the trial judge: "In the case of the '735 Patent, the inventors claimed a new use for atomoxetine to effectively treat humans with ADHD. What is implicit in this promise is that atomoxetine will work in the longer term."). See also *Olanzapine*, 2011 FC 1288 (at paragraph 232: "The chronic nature of the condition treated by a patented compound must be taken into account when determining whether a patent's promise has

improperly elevated "promise" is manifest not only in litigation but also at the time of application filing as in either case it is very uncertain how a Canadian judge will construe the "promise" of the patent, particularly when involving treatment of a chronic condition.[24] In any event, BIO member companies must file their patent applications early in the development process and in many cases before conclusive clinical data or even models exist which more conclusively prove utility. As such, construction of the "promise" of a Canadian patent can be a bar to patentability for any drug claimed as useful for treatment of a chronic condition and therefore is in effect discriminatory toward pharmaceutical patents relative to other types of subject matter.[25]

Canadian Supreme Court precedent confirms that patent law is wholly statutory and must find firm foundation in *the Act*.[26] Further, Supreme Court cases have reiterated that the sufficiency requirement (the requirement that a patentee indicate how to make and use their invention) found within *the Act* requires only that the patentee set out what is the invention and how to put it into practice. (See section 27(3) of *the Act*[27]) Yet, in the eleven decisions noted above, the Federal Court has held that there are additional requirements to establish utility, which find no basis within Section 2 of *the Act*. Section 2 defines an invention as "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter"[28] The Canadian courts have approached the question of whether an invention is 'useful' under Section 2 by engrafting an entirely judge-made test that requires demonstration or a disclosure of a 'sound prediction' of a 'promised' utility at the time of filing. Under *the Act* a pharmaceutical patent should only be rendered invalid for inutility if there is a failure to state a utility in the patent or if the invention is devoid of utility in fact.

Canadian utility requirements are also in sharp contrast with international norms. The patent statutes in the US, Canada and Europe are remarkably similar in that they require an invention to

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been demonstrated or can be soundly predicted"); and *Latanoprost FCA,* 2011 FCA 236, 95 CPR (4th) 193 leave to appeal to SCC dismissed February 2, 2012 (No. 34497)(at paragraph 30: "In our case utility would be demonstrated if the patent disclosed studies showing latanoprost when administered on a chronic basis reduced intraocular pressure without causing substantial side effects.").

[24] See *Strattera FCA,* 2011 FCA 220, 94 CPR (4th) 95, leave to appeal to SCC refused [2011] SCCA No 362 (QL); *Olanzapine,* 2011 FC 1288; and *Latanoprost FCA,* 2011 FCA 236, 95 CPR (4th) 193.

[25] The courts acknowledge that utility only requires a scintilla of utility where there is no promise of a pharmaceutical use. See *Consolboard*, [1981] 1 SCR 504; *Pfizer Canada Inc. v. Canada* (*Minister of Health*), 2008 FCA 108, [2009] 1 FC 253 [*Ranbaxy*]. A scintilla of utility as the test for "utility" for ***any*** invention -- a pharmaceutical use or otherwise -- is a standard analogous to the European, credible or plausible test for industrial applicability, or the U.S. specific and substantial (non-trivial) test for useful.

[26] Most recently in *Corlac Inc. v. Weatherford Canada Ltd*., 2011 FCA 228, 95 CPR (4th) 101, at paragraph 141, the Federal Court of Appeal confirmed that "[i]t is well established that Canadian patent law is entirely statutory in nature…..the Act and Regulations are described by this Court as a "complete code"."

[27] Patent Act (R.S.C, 1985, c. P-4, as amended).

[28] Section 2 of the Canadian *Patent Act* corresponds to Article 27.1 of TRIPS and also Article 1709.1 of NAFTA which mandates that signatory nations such as Canada "shall "provide patent protection to inventions which are "new, involve an inventive step and are capable of industrial application." Further, Article 29.1 of TRIPS merely requires the applicant to "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art". This language is identical to that found in the PCT Article 27 which has been specifically introduced into the Canadian Statute.

be "useful" in order to be patentable.[29] It is not quite as simple as saying, however, that the Canadian requirement that a patent disclose the basis of a sound prediction for the asserted utility is in conflict with the US requirement that the patent simply contain an assertion of a specific, substantial utility and that the utility is in fact true, it has to also be a credible utility and disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the field of the invention. The focus of the utility inquiry in the US, consistent with *the Act*, is on utility in fact. Accordingly, an invention may not be patentable if it is alleged to operate in a manner clearly contrary to well-established physical laws (such as a perpetual motion machine[30]). The Canadian approach is also out of step with practice in Europe since there, as in the US, the focus is on utility in fact.[31] European practice requires that a patent disclose the "industrial applicability" of the invention (the way in which the invention is exploited in industry" but does not require proof of operability of the invention).[32] The outcomes in the Lilly atomoxetine cases this year, where the Canadian Court of Appeals invalidated a patent for inutility while the US Courts upheld the same patent despite common statutory language in both countries, highlights the divergence of Canada with international norms.[33]

It is clear that there is absolutely no statutory basis for "heightened utility" requirements in Canada. These requirements, which encompass an arbitrary judicial determination of a patent's 'promise' are discriminatory in that they apply almost exclusively to biopharmaceutical patents and contravene Canada's obligations under both TRIPS and NAFTA as discussed below. The utility requirements are also out of step with international norms as discussed above. The utility requirements place biopharmaceutical innovators in a difficult "Catch 22" dilemma in view of the other substantive requirements for patentability.[34] If an innovator seeks to comply with the enhanced obligations for proof of utility, then they increase the risk of invalidity on the basis of novelty or obviousness. In other words, a biopharmaceutical innovator who might seek to establish utility for a drug which treats a chronic condition by conducting longer term clinical studies before filing their patent application would potentially be exposed to an allegation of invalidity based on anticipation.[35] BIO members also conduct significant research in scientific areas and to treat diseases in which conclusive efficacy models may not yet exist [36]. Thus awaiting longer term study results may effectively deprive a biopharmaceutical innovator of its patent right in Canada. BIO members urge the U.S. Government to engage with the Government

[29] Compare U.S.C. section 112 para. 1 with Section 27(3) of *the Act.*

[30] Guidelines for Examination in the European Patent Office, Part C – Chapter IV, Section 5.1.

[31] In the US an invention may not be patentable if it is alleged to operate in a manner clearly contrary to well-established physical laws, such as a "perpetual motion machine.

[32] European Patent Convention, Articles 52 and 57.

[33] Compare the result in *Eli Lilly and Co. v. Actavis Elizabeth LLC*, No. 10-01500, 2011 BL 197400 (Fed. Cir. July 29, 2011) with the result in *Eli Lilly and Co. v. Teva Canada Ltd*., 2011 FCA 220. See also: *Useful in the United States, but Not in Canada: Divergent Applications of the Statutory Utility Requirements*, Bloomberg Law Reports (Contributed by Charles E. Lipsey and L. Scott Burwell), October 3, 2011, available online at: <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=59ab301b-1d14-441d-85db-67b67f9243ed>.

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

[35] See *Strattera FC*, 2010 FC 915, 87 CPR (4th) 301 at paragraphs 46 through 48, where Novopharm argued that two oral conversations that fell outside the one-year grace period rendered the invention anticipated.

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

of Canada toward adopting regulatory changes which overrule these cases through legislative action.

The Canadian requirement that a patent demonstrate or disclose the basis of a sound prediction for the asserted utility in the application at the time of filing is also out of step with TRIPS, NAFTA and the PCT. Article 27.1 of TRIPS as well as Article 1709.1 of NAFTA mandate that signatory nations "shall" provide patent protection to inventions which are "new, involve an inventive step and are capable of industrial application."[37] Under generally accepted rules for interpretation of international treaties, Canada is not allowed to contravene a clear commitment to grant patents for which it made as a signatory to the TRIPS Agreement or NAFTA.

Similarly, under the PCT applicants may seek patent protection in some or all member countries by filing a single international application. The PCT requires that a claimed invention be industrially applicable, which as discussed above is satisfied if the invention can be made or used in any kind of industry[38]. Like the European approach if the invention is alleged to have a "credible or plausible" utility, so long as the invention does not operate in a manner contrary to well-established physical laws, then the invention will be patentable as possessing industrial applicability[39]. Similarly, like the US approach, supporting submissions are required only in circumstances where the USPTO provides evidence that the stated specific and substantial utility is incredible[40]. Thus "useful" and "industrial applicability" are synonymous with the PCT and practically both the EU and US have approached the issue in the same manner. Further, while the PCT sufficiency requirements provide that the applicant disclose the invention in a manner sufficiently clear and complete for the utility of the invention to be carried out by a person of ordinary skill in the art, it does not require that proof of utility be contained within the application as filed[41]. Thus, the "heightened utility" requirements in Canada are inconsistent with these international standards.

These provisions make it very clear that if the description is clear enough for one of ordinary skill to carry it out, no office can require more information in the specification as filed, though they certainly could require more information to establish inventive step, etc, during prosecution.

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 restoration

[37] NAFTA and TRIPS expressly provide that "useful" and "industrial applicability" are synonymous. Article 27.1 of TRIPS and also Article 1709.1 of NAFTA mandate that signatory nations such as Canada "shall" provide patent protection to inventions which are "new, involve an inventive step and are capable of industrial application."

[38] Patent Cooperation Treaty, Article 33(4).

[39] Patent Cooperation Treaty International Search and Preliminary Examination Guidelines, Chapter 14; See also *Human Genome Sciences Inc v Eli Lilly & Co*., [2011] UKSC 51, reversing [2010] EWCA Civ 33, affirming [2008] EWHC 1903 (Pat).

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

[41] Patent Cooperation Treaty, Article 5.

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.

Lack of an Equitable Right of Appeal and Injunctive Relief

The lack of an equitable right of appeal also remains an 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).

A related issue is that the jurisprudence 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).

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.

This same company had three products invalidated, two of which were in 2011 with no means of appeal due to the inequitable PMNOC regulations or reasonable means to obtain a preliminary injunction which damaged its ability to enforce its patent rights in Canada.

Patent eligibility requirements related to utility, an inequitable right of appeal in PMNOC decisions and lack of injunctive relief 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 adjustment or patent term restoration, and other patentability issues, has convinced BIO to request that Chile remain on the **Priority Watch List**.

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

Chile does not provide adequate protection of data that is required for submission in support of applications for marketing authorization for biopharmaceuticals consistent with its obligations under Article 17.10.1 of the U.S.-Chile 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 under the FTA.

In addition, Chile's patent laws do not provide sufficient patent term restoration, consistent with obligations under the FTA, to fully compensate for unwarranted delays in the marketing approvals process. The patent law in Chile also excludes transgenic plants and animals from patent protection, thereby further limiting the availability of meaningful protection for valuable biotech innovations. To the extent that protection is available, significant backlogs delay ability to obtain rights essential to adequately protecting these inventions.

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

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

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

China

China's large consumer market presents unique opportunities for U.S. biotechnology companies to increase exports and create jobs in the United States. However, failure to adequately protect U.S. IPR greatly affects BIO's members. In fact, the United States International Trade Commission reported that in 2009 U.S. businesses that operated in China lost approximately $48.2 billion in sales, royalties, or license fees due to IPR infringement.[42] Of that number, $11.6 billion was attributable to lost royalty and license payments among other unspecified losses (not including sales). 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. Finally, SIPO should consider accelerated examination processes to help compensate for the examination backlog.

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.

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

In addition, the information co-developed with foreign entities is already shared which eliminates secrecy examination as an option. Waiving this requirement would help promote international collaborations with Chinese entities. Alternatively, SIPO could simplify the process by allowing retroactive filing for secrecy examinations when the application enters the national phase or providing an express clearance process based on English-language filling and less than 1 week time.

Another difficulty in secrecy examination involves adding new matter to an existing application. While the new matter does not change the general nature of the invention, the rules remain unclear on whether a second secrecy examination is required for the new matter. BIO members believe a second examination should not be required as the general nature of the invention remains unchanged.

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.

This narrow reading is compounded by the fact that the applicant cannot provide supplemental data in the application to rebut the examiner's position. BIO members believe that such requirements are not found in Chinese patent law. If SIPO required Examiners to provide specific reasons for lack of enablement supported by Chinese patent law this would largely solve this and other problems. Simply rejecting claims based on lack of data at the time of the application ignores the reality of biotechnology innovation.

Finally, SIPO should set up an electronic system where the public can access information about published pending applications and issued patents in China.

Patent Law

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

Another challenge for biotechnology companies in China involves the lack of patent term restoration provisions to compensate for regulatory review and patent office delays. The patent

examination backlog at SIPO and regulatory review delays at SFDA significantly curtail the rights of IP owners. Other nations include patent term adjustments for patent review delays and patent term extensions to compensate for the time it takes to gain regulatory approval for pharmaceutical and agricultural products. This is particularly true of countries, that has so-called Bolar provisions, which allow the development of generic products during the term of the patent. China has adopted a Bolar provision without a system of patent term restoration. A Bolar provision without the ability to recoup the time lost for regulatory delay represents an imbalanced system and is detrimental to innovator companies.

Chinese law also makes it difficult to establish claim priority from earlier-filed applications. Chinese law allows priority for a provisional or other application only through providing evidence that the inventors listed have assigned their rights to the applicant. This evidence may not be available as inventorship often is not fully determined in a provisional application. Under U.S. law, a provisional application need not recite any claims that precisely define what the inventor believes his invention to be. As a result, it is common practice for inventorship to differ between a provisional application and subsequent non-provisional (or international) application. If an applicant cannot produce an agreement from the inventor which expressly assigns his rights to the applicant, then Chinese law will not permit the applicant to claim priority from the application.

China enacted the Third Patent Law Amendments in December 2008. The amendments entered into force in October 2009. BIO's members are concerned about some of the changes made in these amendments. In particular, Article 5 of the Chinese Patent law prohibits patents for inventions "relying" on genetic resources where the acquisition or use of those resources is contrary to the "relevant laws and administrative regulations." This could result in the rejection of applications for deserving new and useful inventions, or even the revocation of granted patents later found inconsistent with these provisions.

Further, the amendments to Article 26 for the first time require patent applicants to indicate the "direct source" and the "original source" of genetic resources if the completion of the claimed invention relies on genetic resources. These amendments appear to be intended to promote compliance with provisions of the Convention on Biological Diversity (CBD) relating to access to genetic resources and equitable sharing of benefits from utilization of these resources. However, such provisions will not further these goals, which can be accomplished most effectively by improved transparency in national access and benefit-sharing regimes. The failure to identify the "direct source" of a biological material used in the invention is apparently also a basis for denying a patent to an otherwise deserving invention. In the case of the "original source," failure to disclose may also result in denial of a patent unless the inventor can "state the reasons" that the original source "could not be explained." These special disclosure requirements impose unreasonable burdens on patent applicants, subjecting valuable patent rights to great uncertainty. Moreover, the Implementing Regulations define "genetic resource" to include "material from the human body." This goes beyond the scope of the CBD, which excludes human genetic resources and, consequently, the scope of requirements is additionally complicated.

These amendments also do not appear to be consistent with China's obligations under the TRIPS Agreement to make patents available for "any inventions" that are new, have an inventive

step, and are capable of industrial applicability. Further, the additional requirement for inventions in a particular field of technology (i.e., inventions involving genetic resources) is not consistent with China's obligation to make such patents available, and patent rights enjoyable, "without discrimination … as to field of technology." The amendments concern BIO as they could prevent the issuance of patents for new and useful biotechnology inventions, or perhaps the revocation of granted patents later found inconsistent with these provisions. Thus, these requirements should be deleted. To the extent that rules remain in force, however, we suggest that, at a minimum, the initial burden shift to the examiner to first identify which material the applicant must show "source." Without such identification, the requirement should not apply.

The amendments to Articles 48 to 52 of China's patent law provide changes with respect to compulsory licensing of inventions. BIO supports a number of changes in this area. For example, SIPO should clarify what constitutes inadequate working in China and should state that clinical and/or preclinical works related to getting SFDA approval should be considered adequate working in China. However, significant clarification regarding the events that would trigger compulsory licensing, as well as the scope and duration of the licenses granted, is needed.

Finally, China did issue *Draft Measures for the Compulsory Licensing of Patents* in October of 2011 to try to clarify the compulsory license process and seek comment. BIO commented on the Draft Measures requesting clarification on key terms, recommending that importation of the patented product constitutes exploitation of the patent in China, calling for a prohibition on the export of compulsory license product to developed countries, as well as some procedural recommendations.[43]

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.

Chinese manufacturers that only export their products are not subject to regulatory oversight or review. As a result, infringing products manufactured in China are often of low quality. Some companies have suggested that evidence exists that competing pharmaceutical

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

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.

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

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

Courts

BIO recently responded to requests from the United States Patent and Trademark Office for more information on patent enforcement in China. In BIO's submission[44], our companies identified several issues that make it difficult to enforce a patent in China mainly involving the Courts.

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

Even when our innovator company wins an infringement suit, damages are insufficient to cover the true nature of the loss. China provides statutory compensation for infringement which is minimal and considers sales in China and not outside the country. When combined with the inability to get preliminary injunctions, low damages does not serve as a deterrent for infringers. Further, cumbersome notarization requirements, problems with discovery procedures, and lack of compliance with court orders (because they are not enforced upon the infringing party) greatly hinders the innovator's ability to prevail in an infringement suit. Finally, China restricts expert

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

testimony to government or court-sanctioned experts who are not familiar with the technology and cannot adequately testify in an infringement action.

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

Regulatory Bodies

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

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

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

A final issue involves government sponsorship of the manufacture of infringing products. The National Program for the Development of Major Drugs is a government sponsored program which funds the manufacture of generic versions of U.S. patented pharmaceuticals. The Ministry of Health and the State Food and Drug Administration are both stakeholders in this program.

This creates a conflict of interest and a specific challenge for U.S. biotech innovators as often their competition is the Chinese government itself.

Other Laws Affecting U.S. Intellectual Property Rights

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

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

India

India is an important market to biotechnology companies and patents on key products result in sales of hundreds of millions of dollars. However, difficulty in obtaining and enforcing intellectual property rights in India remains a barrier to 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 patentability criteria would help alleviate some of the disparities that our companies face on a regular basis. In addition, improved transparency would help guide future prosecution. Expediting pending oppositions would also help alleviate the negative effects on U.S. business in India. India needs a more robust infrastructure for searching and procuring patents, including the ability to identify assignment records and other basic patent filing information. Finally, coordination with other

international patent offices through work sharing programs will help standardize the patent application process.

Another concern involves the delay in processing applications coupled with the opposition procedures. The timelines and processes for opposition procedures are not well-defined. Companies often wait dozens of years for a patent application to enter into the 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 opposition process to delay the grant of U.S. biotechnology patents in order to produce their own generic copies of products that enjoy meaningful patent protection in other countries. Patent term extensions do not exist in India, which exacerbates the problem and contributes to a loss of value for legitimate U.S. biotech patents in India. Due to the broad nature of post-grant challenges, unlimited pre-grant opposition should be abolished or severely curtailed to better reflect international practice. The ability of third parties to submit references pre patent grant provides sufficient opportunity to weed out applications that do not meet novelty and inventive step requirements; and should be the preferred method of challenge pre-grant. All of these issues coupled with a lack of centrally located and electronically accessible records and requirements to have local agents to obtain basic documentation make the whole process expensive and time consuming.

The Patent Office announced on December 24, 2009, that all patentees must submit a yearly "statement of working" that proves that the patentee is exploiting its invention in India. If the company does not comply, the government may issue a compulsory license. The regulation allows the patent office to cancel a patent if it has not been continuously worked on for a period of more than two years after falling under certain specified conditions. This provision may result in the loss of intellectual property rights when a biotechnology company cannot work on the drug due to extraneous conditions (such as an FDA "clinical hold"). Additionally, the biotechnology industry requires long-term development and investment, which results in biotech products not commercializing in three years from the patent grant. U.S. law recognizes this challenge by allowing patent term restoration to compensate for the loss of patent life caused by product development and delays in regulatory approval.

A final issue involves the administrative burden of first filing in India for inventions made by Indian residents. This process hampers efficient patent application filing, especially when the patent applicant is a non-Indian entity that has joint inventions with Indian residents and institutions. India should consider accepting first filling in the country where research or product development is conducted for joint inventions or in the country where the patent applicant is located.

Patent Law

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

While TRIPS Article 27.3 allows member states to exclude method of treatment claims, pursuing that course may not be in India's best interests. India excludes method of treatment claims, which prevents U.S. biotechnology companies with needed treatment methods from entering the Indian market to provide life saving products. Further, other patent offices that prohibit method claims (such as the European Patent Office and the State Intellectual Property Office (SIPO) in China) allow claims for the "use of compound X in preparation of a medicament for treating disease Y" or "compound X for use in treating disease Y." The lack of flexibility in India's law prevents biotechnology companies from seeking protection and bringing their products to India.

India's Patents Act requires applicants to disclose the source and geographical origin of biological materials used to make an invention that is the subject of a patent application. These special disclosure requirements impose unreasonable burdens on patent applicants, subjecting valuable patent rights to great uncertainty. Under the Indian law, the failure to identify the geographical source of a biological material may be a basis for opposition or revocation proceedings; however, the necessary relationship to the patented invention is not clear. These requirements pose unacceptable risks for patent applicants 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*. Even if not removed, new forms of a substance that has benefits to the patient with clear support for its therapeutic improvement should be central to the concept of "improved efficacy" yet are noticeably absent in consideration for granting a patent. In addition, this provision appears to be inconsistent with India's obligations pursuant to Article 27 of the TRIPS Agreement, which requires that patents be made available to "any inventions … in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." Section 3(d) also creates an additional hurdle to patentability that is applied only to certain chemical products, and therefore appears to violate the non-discrimination clause with respect to field of technology set forth in TRIPS Article 27. We eagerly await a decision from the Supreme Court regarding this issue in the Novartis AG v. Ministry of Industry and Commerce case which may have a bearing on the interpretation of this provision.

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.

Recent case law developments have drawn concern from our member companies in the areas of obviousness, novelty and rejection of new methods for known compounds. The interpretation of the obviousness standard for dosage forms and other similar inventions has drawn concern.[45] The second issue involves the interpretation of the novelty and obviousness standards in the context of an enantiomer product.[46] The final issue is the rejection of any applications for new methods for known compounds. [47]

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 proven to be 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.

[45] including Aventis Pharmaceuticals, 1021/CHENP/2006 (2009), and Novartis AG, 728/CHENP/2006 (2009).
[46] Astra Aktiebolag, 1255/DEL1995 (2009)
[47] GlycoScience Labs 1752/CHE/2006 (2009)

Drug Regulatory Body

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

India also has not yet implemented any meaningful protection for the data that must be generated to prove that pharmaceutical and agricultural chemical products are safe and effective. Under Article 39.3 of the TRIPS Agreement, protection must be extended against unfair commercial use of such data by makers of generic copies of innovator products (i.e., products that must be shown for the first time to be safe and effective, or to not cause significant risk to the environment). BIO views the 2007 Reddy Report[48] and its recognition that the present legal provisions in India do not adequately meet the spirit of TRIPS Article 39.3 as a positive development. Further, BIO views positively the suggestion in that report that India should adopt a five-year fixed data protection term during which the relevant regulatory officials will not rely upon data submitted by the originator when approving second and subsequent applications for the same product. Nonetheless, it appears that meaningful protection for this data will not be implemented in the near term. In addition, even the suggested post-transition period protection suggested in the Reddy Report is subject to numerous, and apparently wide-ranging, proposed "safeguards," a number of which would appear to undermine the proposed protection almost entirely. Effective market exclusivity for regulated pharmaceutical and agricultural chemical products would contribute significantly to providing adequate and effective protection of intellectual property rights in India for BIO's members.

A clear biologic medicine regulatory approval pathway is still under development in India. Nonetheless, the regulatory system has many shortcomings, such as the ability to seek marketing authorization for biologics with as few as 100-patient clinical trials. A biologics pathway consistent with U.S. and European law is necessary for U.S. companies and Indian manufacturers and it will improve access to safe and effective biotechnology products in India.

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

Compulsory Licensing

The Indian Patents Act also unreasonably restricts the use of patent rights. The Act provides broad exceptions for use of patented technology by the Indian Government or third parties. It also provides extensive authority for the grant of compulsory licenses, including licenses justified only on the basis that the products falling under the patent are not manufactured in India.

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[48] 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."

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.[49]

Finally, the Indian generic company Natco Pharma has requested a compulsory license on Bayer's Sorafenib which treats liver and kidney cancer. The most recent update we have received is that an oral hearing has occurred where the Controller General of Patents has asked the patentee to submit cost data including research and development expenditure to justify the "substantially high price."[50] TRIPS outlines procedures for compulsory licensing which focuses the inquiry on the use of this mechanism for exceptional circumstances. However, the Controller's focus on the cost of the drug and whether or not someone can make it cheaper rather than a TRIPS focused analysis of exceptional circumstances are not consistent with the letter or spirit of the TRIPS Agreement.

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.

[49] BIO's comments to this discussion paper can be found at the following link http://www.bio.org/ip/international/20100929.pdf.
[50] See news article at http://www.livemint.com/2012/01/13232308/Bayer-asked-to-give-cost-data.html

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 restoration 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 restoration 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 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 (6.5 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 restoration 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 marketing approval process. Moreover, such extensions, where available, are significantly limited, as restoration of the patent term is 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 acceded to the OECD in 2011. 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.

Finally, Israel has proposed patent legislation that would prohibit broadening amendments during prosecution even if the amendments are supported by the Specification. BIO will seek the opportunity to comment on this proposal and we hope the United States Government will comment and closely monitor developments.

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 nondiscrimination clause of TRIPS Article 27.1. In addition, the provision permits importation of patented drugs and medicines from a country where the product was placed on the market by "any party authorized to use the invention." This appears to permit importation of goods even where they are placed on the foreign market without authorization of the patent owner, e.g., where the "authorized party" in the foreign market was operating under a compulsory license. Thus, the amendment effectively gives extraterritorial effect to a foreign compulsory license,

even where the rationale for the compulsory license was based on factors related solely to the national market in the jurisdiction that imposed the license. This is highly inequitable and appears to be inconsistent with recognized standards of "international exhaustion" of patented inventions.

In addition, the Philippines does not provide 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**.

Thailand

In light of continued onerous policies relating to compulsory licensing of patents, and the lack of any significant progress in addressing these policies, BIO requests USTR to maintain Thailand on the **Priority Watch List**.

BIO recognizes the Thai government's efforts to create task forces dealing with IPR and appreciates this positive move. However, the Thai Government's continued 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 noncommunicable diseases (such as cancer, stroke, or myocardial infarction) is of particular concern, given that many of BIO's members' research and development efforts target such chronic diseases. These policies go well beyond the letter and spirit of the Doha Declaration, which provides a mechanism for governments to deal with acute public health crises, and impact the ability of biotechnology research and development efforts to recoup their massive investments. The medical management of non-communicable diseases may be complex and

costly, but it does not rise to the level of a public health emergency. These extraordinary measures should not be used systematically to facilitate budgetary planning.

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

Thailand also fails to provide meaningful protection for the pharmaceutical test data required to prove safety and efficacy of new drug products. The implementing regulations for the Trade Secrets Act provide a five-year term of protection for "maintenance of the trade secrets" of pharmaceutical test data. However, the regulations do not appear to provide the data protection against "unfair commercial use" in a manner consistent with Thailand's obligations under Article 39.3 of the TRIPS Agreement. This protection is critical to biopharmaceutical companies and their ability to successfully launch a product in a particular market.

Thailand also does not provide a formal system to prevent regulatory approval of generic versions of pharmaceuticals that are still covered by a valid patent. The lack of such a "patent linkage" mechanism facilitates patent infringement in the Thai market, leading to potential loss of exclusivity for patented inventions in the biopharmaceuticals area and increased enforcement costs. This is particularly harmful in the biotech sector as biotech drug development can cost a billion dollars or more and can take more than a decade. Without assurance of recoupment of investment, and in particular in these difficult economic times, biotechnology research and development will diminish.

Finally, our members report a growth in availability of counterfeit pharmaceutical products in the Thai market. This raises a number of significant concerns and constitutes not only a risk to the valuable intellectual property rights of BIO's members, but a serious health risk to the Thai public.

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

Venezuela

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

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

Finally, we have been told that no patents have been granted in Venezuela in at least the last 6 years.

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

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

WATCH LIST

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 germplasm of any living thing." This exception categorically excludes a wide array of biotechnological inventions from the patent system in Colombia. This exception is inconsistent with obligations of Colombia under the TRIPS 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." The Andean Decision also excludes the patenting of use claims. In addition, BIO's members are systematically being denied protection in Colombia for inventions in chemical polymorphs and isolates that are routinely patented in other jurisdictions. This practice also appears to be inconsistent with the requirements of Article 27.1.

BIO also notes with concern significant delays in Colombia in the processing of patent applications for commercially valuable 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.

Regulatory issues related to patents also arise in Colombia. There is a lack of linkage between the Patent Office and Regulatory Agency and a lack of due process in the implementation of price control regimes in Colombia.

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.

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

Egypt

BIO requests that USTR 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 section 6 to provide a five-year protection period against reliance by subsequent applicants on the data supplied by the originator. Nevertheless, Mexico still does not provide protection consistent with these obligations. The Industrial Property Law states that Mexican law will implement requirements under its various international obligations. However, we are not aware of any implementing regulations or practices that provide for a five-year term of non-reliance consistent with Mexico's international obligations.

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.

In addition, extensive periods of time pass before patent infringement cases are decided. Companies report that IP enforcement cases proceed in two stages before the Mexican Patent Office which can last 4-5 years. Two additional appeal stages then follow before a final decision is made in the case. This problem is particularly acute as the possibility to recover damages is delayed until after all appeals are exhausted.

Even then, innovators are not allowed to receive damages in court and must initiate a second proceeding before a Civil Court to receive a damage award. While some may argue that injunctions prevent this problem, the infringer can post bond without providing evidence of noninfringement and have the injunction lifted and allow the infringing products to remain on the market. This causes extensive delay which can last up to 10-12 years between initiation of proceedings and recovery of damages. This process is extremely costly and inequitable to the innovator.

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

Biosimilar legislation approved by Congress in April 2009 has not resulted in implementing regulations. The legislation also does not have data exclusivity provisions. 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 and receive regulatory data protection.

Finally, linkage between the Regulatory Agency and the Patent Office only covers patents covering a pharmaceutical active ingredient per se. Patents covering formulations or uses are not included. Several Court Decisions have ordered the publication of formulation and use patents to satisfy linkage requirements but the Mexican Patent Office refuses to publish these patents without litigation and the Regulatory Agency has shown reluctance to observe these patents. The linkage system also does not allow for a full review of whether a generic drug would infringe patent rights.

Mexico is a member of the OECD. The data protection regime and enforcement of intellectual property rights fall far short of standards widely implemented in OECD countries. In

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

Peru

Peru has ongoing intellectual property challenges without significant progress and 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.

The patent system also suffers greatly from excessive delays in examination of patents. 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.

While Peru has implemented a data protection regime for small molecules, the government has taken the position that biologics are not included under this regime. This is an incorrect interpretation of Peru's obligations under the US-Peru Trade Promotion Agreement. BIO members urge USTR to continue to monitor Peru's implementation and enforcement of data protection. Finally, there is no linkage between the Patent Office and the Regulatory Agency in approving generic drug sanitary applications. Additionally, enforcement of patent rights in Peru is difficult due to a lack of technical expertise on IP and a perceived lack of independence of the judicial branch on IP sensitive decisions.

Russia

BIO's have expressed certain challenges in operating in Russia. Russian improved their patent laws in 2008, thereby bringing patent practice closer to Western patent systems. In addition, Russia is progressing on data protection issues, coordination between their regulatory agency and patent office, and is pursuing WTO Accession. While problems remain for our member companies in Russia, BIO requests that USTR recognize Russia's progress and place Russia on the **Watch List**.

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

Another issue arises from the failure of Russian law to recognize requests for generic marketing authorization as an act of infringement. In other words, an innovator cannot sue for patent infringement upon first learning of a request for generic marketing approval, rather the patent-holder must wait until the generic drug is approved. Russian courts compound this problem by not typically granting preliminary injunctions or even permanent injunctions at the end of successful litigation.

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

Ukraine

Ukraine was not part of BIO's 2011 submission but our members have highlighted Ukraine as a country of concern for intellectual property rights. BIO requests USTR maintain Ukraine on the **Watch List**.

Ukraine should institute and enforce meaningful data protection prohibiting the Regulatory Agency and generic drug applicants from relying on innovator proprietary data for a fixed period of time. One company reported that while existing law contains data protection requirements, the Regulatory Agency still approved a generic drug applicant. This violates the data exclusivity rights of our member company. This company even notified the relevant agencies and the generic company of their rights prior to approval and the Regulatory Agency still approved the product.

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

Finally, BIO is concerned about the lack of an effective mechanism to enforce preliminary injunctions in Ukraine. In addition, procedures for filing and obtaining appeals do not consistently comport with due process. For these reasons BIO requests USTR to maintain Ukraine on the **Watch List**.

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

Europe

EPO rules implemented in April 2010 have, unfortunately, had a negative effect on patent procurement in Europe.[51] 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).

A second disadvantage occurs as the ability under the previous laws 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.

[51] 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/legaltexts/journal/informationEPO/archive/20100401.html?update

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.

Finally, the European Patent Office is implementing increasingly heightened standards of patentability. For example, with respect to antibodies, the European Patent Office is requiring that patent applications include data demonstrating utility for each species of antibody described in the patent specification. This requirement goes beyond a fair and reasonable showing of possession and enablement of the invention and weakens the scope of meaningful IP protection especially against future biosimilars.

Europe also needs a mechanism to resolve patent disputes before generic products are launched. Some form of patent linkage where notice is provided to the innovator of regulatory approval and subsequent infringement would ensure patent issues are resolved prior to infringement.

A final concern for BIO members involves the creation of the European Patent Court. Questions remain as to the location of trial and appellate courts, discovery rules, and the nature of the proceeding. BIO members are generally supportive of the idea of not having to litigate patents in every European country, but the final details of the European Patent Court will be crucial to ensure that biotechnology companies receive fair process in patent disputes.

With the substantial expense involved in prosecuting a patent in Europe, these additional problems add to the difficulty of obtaining a patent in Europe for our member companies.

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 noncommercial, 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
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