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BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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By electronic submission

Jennifer Choe Groves, Senior Director for Intellectual Property and Innovation and Chair of the Special 301 Committee
Office of the United States Trade Representative
Washington, D.C.

Submitted electronically at http://www.regulations.gov, docket number USTR-2009-0001

Re: 2009 *Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment,* 74 Fed. Reg. 4263 (January 23, 2008).

Dear Ms. Groves:

The Biotechnology Industry Organization (BIO) is submitting this letter in response to the request by the United States Trade Representative (USTR) for comments involving the "Special 301" provisions of the Trade Act of 1974. BIO is very pleased to have the opportunity to submit these comments, and respectfully requests that USTR consider the following remarks.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations in the United States and 31 other nations. BIO Members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products and services.

These comments do not necessarily represent a unanimous view of all BIO members. Individual members may disagree with some of the recommendations made in these comments.

Intellectual property rights are the foundation of the biotechnology industry. BIO Members depend on obtaining patents and related rights in a timely and predictable manner, and the ability to enforce those patents is critical. Biotechnology is also a uniquely global enterprise. BIO Members have a particular interest in encouraging uniform and robust intellectual property protection in all countries and regions of the world. As a general matter, BIO notes with concern recent trends in a number of countries that undermine the intellectual property protection essential to provide an enabling environment for innovative biotech companies. This includes the persistence of exceptions for transgenic plants and animals in the patent laws of a number of countries that deprive important inventions of adequate protections.

We focus our comments this year on a limited number of countries that are of particular concern.

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

Priority Watch List. BIO requests that USTR place **Indonesia** and the **Philippines** on the Priority Watch List. BIO also requests that **Argentina**, **Chile**, **China**, **India**, **Israel, and Venezuela** maintain their current status on the Priority Watch List.

Watch List. BIO requests that USTR place **Switzerland** on the Watch List, and that **Brazil, Canada, Colombia**, **Egypt,** and **Mexico** maintain their current status on the Watch List.

Section 306 Monitoring. BIO requests that USTR continue to monitor **Paraguay** under Section 306.

PRIORITY FOREIGN COUNTRY

Thailand

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

The Thai Government continued its support of compulsory licensing of patented pharmaceutical products as part of its trade policy in 2008. Thailand has maintained its widely publicized compulsory licenses for SUSTIVA (efavirenz), KALETRA (lopinavir/retonavir) and PLAVIX (clopidogrel), and last year moved ahead with additional compulsory licenses on FEMARA (letrozole), TAXOTERE (docetaxel) and TARCEVA (erlotinib), which are patented drugs used for the treatment of types of cancer. These actions illustrate an unabated disregard for intellectual property rights that are critical for the development of new medicines, and they constitute an egregious and onerous policy that denies adequate and effective protection of intellectual property rights.

The Thai Government's issuance of compulsory licenses for drugs that treat non-communicable diseases, such as cancer, stroke, or myocardial infarction, is of particular concern. This also appears to go well beyond the letter and spirit of the Doha Declaration, which provides a mechanism for governments to deal with acute crises. 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 members appreciate that diseases that can be treated with drugs such as these 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 raise questions about ability to obtain protection of intellectual property that is important to BIO 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 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 exclusivity protection required to protect such data from "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.

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 members but a serious health risk to the Thai public.

We strongly urge USTR to designate Thailand as a Priority Foreign Country. Thailand's continued application of compulsory licensing as part of its trade policies denies U.S. industry adequate and effective protection of its intellectual property rights. The announcements of additional compulsory licenses in 2008 appears to confirm that this disregard for intellectual property rights, critical to innovative biotechnology companies, will continue unabated. In addition, the lack of effective protection for pharmaceutical test data and the apparent growth in counterfeit pharmaceutical products in Thailand raises significant concerns. More aggressive monitoring and engagement with Thailand on this issue is fully warranted.

PRIORITY WATCH LIST

Indonesia

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

Indonesia does not provide sufficient protection for data that must be generated to prove that pharmaceutical and agricultural chemical products are safe and effective. Article 39.3 of the TRIPS Agreement requires that protection against unfair commercial use be provided for test data required for submission to prove the safety and efficacy of new 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 Members.

Indonesia's patent law also still has considerable gaps that deny protection to a wide range of biotechnology inventions, including transgenic plants and animals.

BIO Members also report problems with counterfeit medicines despite recent steps taken by Indonesia, including the establishment of a National Anti-counterfeiting Task Force.

BIO requests that USTR further engage Indonesia to put in a place a system that provides adequate and effective protection for intellectual property rights. We request that Indonesia be placed on the Priority Watch List.

The 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 weaken the protection of biopharmaceutical inventions in the Philippines and deny adequate and effective intellectual property protection for BIO Members. As a result, BIO urges USTR to place the Philippines on the Priority Watch List.

The recently passed amendments deny 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 pharmaceuticals area. For example, a new form of a known substance with improved heat stability for tropical climates, or having other benefits that may not result in "enhanced efficacy" *per se*, would be denied patent protection even if it met all other patentability criteria. This additional patentability requirement appears to be inconsistent with the obligations of the Philippines under Article 27.1 of the TRIPS Agreement, which provides that patents be made available to "any inventions … in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."

Moreover, this additional requirement applies only to drugs or medicines, and therefore creates a higher standard of patentability for this category of invention. This is inconsistent with the non-discrimination requirement of Article 27.1 of the TRIPS Agreement that "patents shall be available and patent rights enjoyable without discrimination as to the … field of technology."

R.A. 9502 also contains provisions that expand the grounds on which compulsory licenses may be granted. This includes a new ground that permits a compulsory license "where the demand for the patented drugs and medicines is not being met to an adequate extent and on reasonable terms, as determined by the Department of Health." This provision, which apparently can be invoked at the discretion of a government agency, has the potential to undermine adequate and effective protection of patent rights for biopharmaceuticals and is not consistent with the non-discrimination clause of TRIPS Article 27.1.

The Philippines also does not provide a formal system to prevent regulatory approval of generic versions of pharmaceuticals that are still covered by a valid patent. The lack of such a "patent linkage" mechanism facilitates patent infringement leading to potential loss of exclusivity for patented inventions in the biopharmaceuticals area and increased litigation costs.

R.A. 9502 also expands permissible grounds for parallel importation of patent-protected products only with regard to "drugs and medicines." This provision violates the non-discrimination clause of TRIPS Article 27.1. In addition, the provision permits importation of patented drugs and medicines from a country where the product was placed on the market by the "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 recent 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 further engage with the Philippines to revisit the provisions of this legislation and to 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.

Argentina

Argentina continues to have 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 maintain Argentina 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 Members. We understand the Argentina has taken steps in recent years to reduce its backlog, but excessive delays are persistent. In addition, Argentina remains outside of the Patent Cooperation Treaty (PCT), which facilitates the filing and examination of patent applications in 139 member countries. Acceding to this widely accepted agreement would be a positive step toward facilitating the procurement of patent protection in Argentina for BIO Members.

Further, the highly restrictive patent examination guidelines issued by the National Institute of Industrial Property (INPI) in Argentina provide for the denial of patent claims directed to transgenic plants and animals. This excludes protection for a wide class of biotechnological inventions. It also appears to be inconsistent with the Argentine patent law, which provides an exclusion to patentability only for living material that is "pre-existing in nature." BIO Members also continue to experience difficulties enforcing patent and plant variety protections in Argentina.

Argentina also does not provide adequate protection for the data that must be generated in support of marketing authorization to prove that pharmaceutical and agricultural chemical

products are safe and effective. This protection is critical to the ability of biotechnology companies to develop and commercialize such pharmaceutical products in a particular market. It is moreover an obligation of Argentina under Article 39.3 of the TRIPS Agreement that requires such data to be protected 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 Members.

Chile

Chile does not provide adequate protection of data that is required for submission in support of applications for marketing authorization for pharmaceuticals consistent with its obligations under Article 17.10.1 of the US-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, public non-commercial use," among other circumstances. These provisions are not consistent with Chile's obligations under either the FTA or the 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 protection is highly important to prevent infringement of the patents of BIO Members covering valuable inventions. The lack of such protection is particularly troubling in light of Chile's clear obligations provided under the FTA.

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

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 deficiencies of the intellectual property regime in Chile, and particularly in light of its apparent lack of compliance with the US-Chile FTA provisions, BIO requests that Chile remain on the Priority Watch List.

China

China has made important improvements in its intellectual property system in recent years. Nonetheless, many areas of concern remain in regard to the protection of biotechnological inventions in China. BIO requests that USTR maintain China on the Priority Watch List.

BIO Members remain deeply concerned about the trafficking of counterfeit pharmaceuticals and biologics in China. Counterfeiting not only deprives the owners of intellectual property of the value of their assets, but poses a threat to public health, along with the

consequent economic costs. Counterfeit medications place the public at unnecessary risk and divert the resources of industry and government agencies. BIO urges USTR to continue to promote more effective interdiction and enforcement directed toward traffickers and distributors of counterfeit biopharmaceuticals in China.

China recently enacted the Third Patent Law Amendments in December 2008. The amendments are expected to enter into force in October 2009. BIO Members are concerned about some of the changes made in these amendments. In particular, upon the entry into force of the amendments, Article 5 of the Chinese Patent law will prohibit 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, provisions such as those imposed by the Third Patent Law Amendments 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 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, these amendments 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 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 to Articles 48 to 52 of China's patent law provide changes with respect to compulsory licensing of inventions. BIO applauds a number of changes in this area, including the elimination of compulsory licenses for failure to obtain a voluntary license (Article 48) and the introduction of limitations on the use of patented inventions under compulsory license in accordance with the TRIPS Agreement (Article 52). However, significant clarification regarding the events that would trigger compulsory licensing, as well as the scope and duration of the licenses granted, is needed.

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.

In addition, although China has implemented a 6-year data exclusivity term, it 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 sufficient protection that is critical for biopharmaceutical entities in bring products to market and permits unfair commercial use of pharmaceutical test data from innovators.

BIO urges USTR to engage with China to improve these amendments prior to their planned effective date to achieve a patent law that is fully TRIPS-compliant and that adequately and effectively protects intellectual property rights.

India

At the outset, BIO notes with appreciation the several steps that India has taken toward enhancing both its intellectual property laws and the capacity of its patent office to examine and grant patents. However, the reforms to date fail to achieve adequate and effective protection for intellectual property rights in the biotechnology industry. BIO requests, therefore, that India remain on the Priority Watch List.

The Indian patent system still excludes from protection many biotechnology inventions. The Patent Office has determined that the Indian Patents Act excludes from eligibility many living organisms, such as transgenic plants and animals. Inventions of tissues, cells, viruses, and the processes of preparing them are not eligible for patent protection. Additionally, it remains unclear whether polypeptides, nucleic acids, and other biomolecules are eligible for patents under the Act. These are valuable inventions for which protection is mandated by the TRIPS Agreement provided they are new, involve an inventive step, and have industrial applicability. Thus, it remains difficult to obtain legal rights in India of any significant commercial value for biotechnology inventions.

The 2005 amendment to the Indian Patents Act introduced a new Section 3(d) which explicitly excludes from patentability new forms of a known substance which does not result in "enhancement of the known efficacy of that substance." This type of requirement excludes from patentability many significant inventions in the pharmaceuticals area, e.g., new forms of known substances with improved heat stability for tropical climates, or having safety or other benefits that may not result in "enhanced efficacy" *per se*. In addition, this provision appears to be inconsistent with India's obligations pursuant to Article 27 of the TRIPS Agreement, which requires that patents be made available to "any inventions … in all fields of technology, provided that they are new, involve an inventive 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 the TRIPS Agreement.

India's Patents Act also 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. Requirements such as these pose unacceptable risks for patent applicants and would 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.

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

The capacity of the Indian patent office to review and grant patent applications is not yet sufficient to support the industries that depend on intellectual property. Moreover, patent litigation remains rare in the Indian courts and there is a lack of experienced judicial and enforcement officials.

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[1] 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 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, significant concerns remain. First, no transition period for implementing data exclusivity has been identified. Thus, 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 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

[1] SATWANT REDDY AND GURDIAL SINGH SANDHU, REPORT ON STEPS TO BE TAKEN BY THE GOVERNMENT OF INDIA IN THE CONTEXT OF DATA PROTECTION PROVISIONS OF ARTICLE 39.3 OF THE TRIPS AGREEMENT (May 31, 2007). *But 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." This is illustrative of so-called "safeguards" that would appear to undermine the proposed data protection.

contribute significantly to providing adequate and effective protection of intellectual property rights in India for BIO Members.

BIO continues to urge USTR to place significant emphasis on the need for India reform its intellectual property laws to achieve full compliance with obligations under the TRIPS Agreement to provide an adequate and effective level of protection for biotechnology inventions. BIO believes that India should remain on the Priority Watch List.

Israel

Israel continues to fail to provide adequate and effective legal protection for biotechnology inventions. Accordingly, BIO requests that USTR maintain Israel as a Priority Watch List country.

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

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

Israel's pre-grant opposition regime for patents also continues to be of serious concern to BIO 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.

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

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

Venezuela

BIO Members are very concerned about developments in Venezuela that deny adequate and effective intellectual property protection.

The Venezuelan patent office (Servicio Autónomo de Propriedad Intelectual or SAPI) has recently issued an official notice informing that pursuant to the withdrawal of Venezuela from the Cartagena Agreement, the Venezuelan Industrial Property Law of 1955 would now be applicable instead of Andean Community regulations. This raises a number of serious concerns for BIO Members as the 1955 Law does not appear to be consistent with a number of the obligations of Venezuela under the TRIPS Agreement.

The term of patent protection now appears to be a maximum of 10 years from the date of grant. This is not consistent with requirement under TRIPS Article 33 that the term of protection "shall not end before the expiration of a period of twenty years counted from the filing date." In addition, chemical compounds are excluded from patentability. This appears to violate the obligations of Venezuela to make patents available "without discrimination as to … the field of technology." These changes, among others, serious erode the ability to obtain patent protection for a wide swath of biotechnology inventions and denies adequate intellectual property protection to BIO Members.

In addition, SAPI continues to deny protection to valuable inventions by delaying the grant of properly filed patent applications. Further, Venezuela remains outside of the Patent Cooperation Treaty (PCT), which facilitates the filing and examination of patent applications in 139 member countries. Acceding to this widely accepted agreement would be a positive step toward facilitating the procurement of patent protection in Paraguay for BIO Members.

Venezuela also no longer appears to be providing protection for test data needed for marketing approval of biopharmaceutical products. This is not consistent with obligations of Venezuela under TRIPS Article 39.3 to protect such data from "unfair commercial use."

In light of these developments, BIO requests that USTR retain Venezuela on the Priority Watch List.

WATCH LIST

Switzerland

BIO Members remain concerned about the potential of amendments made to the Swiss patent laws in 2007 to undermine the availability of adequate and effective patent protection for certain biotechnology inventions.

Article 40b provides that any user of a patented biotechnological invention used as "an instrument or tool for research" shall be entitled to a non-exclusive compulsory license. The intent of the provision appears to be to prevent the improper use of patent rights from stifling research. BIO supports this objective, but the legislation, as drafted, is not limited to non-commercial research. Article 40b seems to categorically exempt the users of biotechnology inventions from liability for infringement, without regard to the commercial or non-commercial nature of the activity. As this provision appears to go well beyond the legitimate policy objectives of the amendment, BIO urges USTR to further engage the Swiss Government to revisit this provision.

In addition, Article 49a requires that patent applicants disclose the source of a genetic resource, "insofar as the invention depends directly" on the resource. The Swiss law appears to attempt to lessen burdens on applicants by providing that if the source is not known to the applicant, they may so state. However, such a provision raises a new potential ground of challenge that may be asserted in litigation or during the application process to prevent the grant of a patent notwithstanding the fact that the information that is the subject of the requirement is not relevant to the requirements for patentability of the invention set forth in TRIPS Article 27.1 or the disclosure of invention requirements of TRIPS Article 29.

These changes to the patent law in Switzerland merits further monitoring to ensure that adequate and effective patent protection for biotechnological inventions in Switzerland is not undermined. BIO therefore requests that Switzerland be placed on the Watch List.

Brazil

Brazil's intellectual property regime, including the grant of a compulsory license for a patented pharmaceutical product in 2007 and other persistent deficiencies, continues to deny adequate and effective intellectual property protection for the biotechnology sector. BIO urges USTR to maintain Brazil on the Watch List.

In 2007, Brazil granted a compulsory license for SUSTIVA (efavirenz). This act raises significant concerns about whether intellectual property rights can be adequately and effectively protected in Brazil. While BIO understands the challenges that countries face in providing affordable healthcare systems, BIO Members continue 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.

The Brazilian patent law also remains a cause for concern. Brazil maintains a provision in its patent law that requires all drug patents to be approved not only by its patent office (the National Institute for Industrial Property or "INPI"), but also by the Ministry of Health (through the drug regulatory agency, "ANVISA"). Brazil therefore has imposed a special, higher and discriminatory standard for obtaining a patent on pharmaceutical technology. This higher standard is not consistent with Brazil's obligations under the TRIPS Agreement that patents be available "without discrimination … as to field of technology." Technology-specific conditions, such as the approval by ANVISA of drug patents that have already been found to satisfy the criteria of novelty, inventive step, and industrial applicability under Brazilian law, are inconsistent with the provisions of the TRIPS agreement.

Brazil's pursuit of compulsory licensing as part of its trade policy as well as the continued deficiency of its patent regime with respect to pharmaceutical products deny adequate and effective intellectual property protection for BIO Members. We urge USTR to continue its engagement with Brazil to implement an intellectual property regime that respects patent rights, provides an enabling environment for innovation and is fully compliant with the TRIPS Agreement.

Canada

BIO Members recognize that Canada has recently implemented positive regulatory changes, namely data exclusivity regulations granting eight years of data protection with an additional six-month period for pediatric studies, that recognize the importance of intellectual property protection. However, the inability to procure patents for transgenic plant and animals and certain inequitable features of the Canada Patented Medicines Notice of Compliance (PM NOC) regulations raise concerns for BIO Members operating in Canada. In that light, BIO requests that USTR maintain Canada on the Watch List.

The *Patented Medicines (Notice of Compliance) Regulations (PM NOC Regulations)* of Canada remain of concern to BIO Members. Simply summarized, patent owners are required to list their patents in the Patent Register established under the PM NOC Regulations, which is a Canadian counterpart to the U.S. Hatch-Waxman Act. If a patent is listed by Health Canada and the generic drug company seeks approval prior to expiry, then generic drug entity must file a Notice of Allegation (NOA) for each patent listed. The NOA provides the grounds under which the generic drug company asserts the patent is non-infringed or invalid. The patent holder then must file an action seeking an order prohibiting the Health Minister from granting a market authorization to the generic drug company because the allegations of invalidity or non-infringement are unjustified. This order for prohibition is a summary proceeding with limited procedural safeguards to the effectuate IP enforcement.

However, aspects of this proceeding are biased against the patent holder and should be modified to ensure adequate and effective protection for patent holders. For example:

- A generic drug company is not required to address patents listed after the generic Abbreviated New Drug Submission (ANDS) is filed. The difference between submission of a patent and actual listing can take months or even more than a year due to

administrative delays, an aggressive filing by the generic company can obviate the PM NOC regulations entirely. The Canadian government should provide the benefit of the PM NOC regulations to any properly submitted patent irrespective of the generic ANDS submission date or at least as of the date of submission for listing by the patent holder.

- The patent holder is the plaintiff in any action seeking an order of prohibition. As such, the courts have held that the patent holder carries the burden to prove that the allegations of invalidity are unjustified. This has the practical effect of forcing the patent holder to prove its patent is valid, obviating the presumption of validity recognized under Canadian law. Furthermore, the summary proceeding does not provide sufficient discovery or other means to compel the generic drug company to produce sufficient evidence (e.g., product samples) to demonstrate non-infringement.
- The patent holder generally does not have a right of appeal if it is not successful in the first instance, while the generic drug company does. This is highly inequitable. Once the order of prohibition is denied, Health Canada issues the approval (Notice of Compliance or NOC) to the generic drug company. So, for the patent holder, the first instance summary proceeding for the order of prohibition is the only proceeding available to enforce the patent and maintain product exclusivity.

If the patent holder must pursue an action for infringement (e.g., due to a dismissal of an PM NOC proceeding), an interlocutory injunction to maintain its rights, and particularly, to prevent market entry of the generic product, rarely succeeds under Canadian law even when there is compelling evidence of infringement and validity.

Patents

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, Canada does not provide for patent term restoration or extensions to compensate for regulatory delays in the approval of new biopharmaceutical products. These items further limit intellectual property protection critical for BIO Members in Canada.

Data Protection

Canada provides data protection to prevent unfair commercial use of regulatory data through its 2006 regulations implementing eight years of data protection. The 2006 regulations are a profound step forward in improving Canada's intellectual property regime and attracting investment of biopharmaceutical industry. However, these regulations are now subject to legal challenge which could undermine this protection and warrants further monitoring.

BIO Members encourage USTR to work with Canada in order to assist in providing a patent regime, data protection and means for enforcing these rights in a manner that is supportive of adequate and effective for protection of intellectual property rights.

Colombia

The Colombian patent law raises a number of matters of concern to BIO Members that warrant further monitoring. In light of the deficiencies of the law, BIO requests that Colombia be placed on the Watch List.

Andean Community Decision 486, which applies in Colombia, denies patents to inventions of "biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing." This exception categorically excludes a wide array of biotechnological inventions from the patent system in Colombia. This exception is inconsistent with obligations of Colombia under the TRIPS Agreement that require patents to be made available to "any inventions … provided they are new, involve an inventive step, and are capable of industrial application." In addition, BIO 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 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.

Egypt

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 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

Mexico continues to inadequately implement its obligations relating to test data required by regulatory agencies to obtain marketing approval for pharmaceuticals. Mexico has obligations under TRIPS Article 39.3 to provide protection for pharmaceutical test data against "unfair commercial use" and under the North American Free Trade Agreement (NAFTA) Article 1711 to provide a five-year protection period against reliance by subsequent applicants on the data supplied by the originator. Nevertheless, Mexico still does not provide protection consistent with these obligations. The industrial property law states that Mexican law will implement requirements under its various international obligations. However, we are not aware of any implementing regulations or practices that provide for a five-year term of reliance consistent with Mexico's international obligations.

BIO Members are also concerned that 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.

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.

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 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 139 member countries. Acceding to this widely accepted agreement would be a positive step toward facilitating the procurement of patent protection in Paraguay for BIO 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 that requires such data to be protected against "unfair commercial use."

Persistent deficiencies in the patent and data protection regime in Paraguay deny adequate and effective protection for the intellectual property rights of BIO Members.

Concluding Comments

BIO appreciates this opportunity to submit its views for consideration by USTR. We are prepared to work with USTR to provide additional information regarding the countries we have identified.

Sincerely,

Lila Feisee
Managing Director, Intellectual Property
Biotechnology Industry Organization