By electronic mail and fax

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Re: *Special 301: Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment*, 73 Fed. Reg. 2958 (January 16, 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 1,100 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.

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. If a country's patent system or the political structure for enforcing patent rights is ineffective, a competitor can use an invention with impunity, depriving the patent owner of the economic value of the invention. 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. In addition, we note with concern ongoing efforts in a number of countries, including members of the European Union, to unduly broaden research and breeder's exemptions in a manner that would undermine effective intellectual property protection for plant-related inventions.

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 **Brazil** and the **Philippines** on the Priority Watch List. BIO also requests that **Argentina**, **Chile**, **China**, **Egypt, India**, **Israel**, and **Ukraine** maintain their current status on the Priority Watch List.

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

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.

Throughout 2007, the Thai Government continued its support of compulsory licensing of patented pharmaceutical products as part of its trade policy. Last year's widely publicized compulsory licenses for SUSTIVA (efavirenz), KALETRA (lopinavir/retonavir) and PLAVIX (clopidogrel) continue to be a cause for alarm for BIO Members. Of even greater concern, just recently, the government has announced its intention to move ahead with at least three more 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 constitute an egregious and onerous policy that denies adequate and effective protection of intellectual property rights.

BIO remains concerned that these licenses go well beyond the letter and spirit of the Doha Declaration provisions relating to health emergencies. As noted in our previous comments to USTR, Thailand's policy appears to be driven in significant part by its own budget constraints. In particular, the Government's issuance of compulsory licenses for drugs that treat non-communicable diseases, such as cancer and stroke or myocardial infarction, is particularly alarming. The medical management of such non-communicable diseases may be complex and costly, but it does not rise to the level of a public health emergency. The Doha Declaration provides a mechanism for governments to deal with acute crises. It was not meant as an expedient to facilitate budgetary planning.

We note that the Thai Government has been more active in communications with the relevant intellectual property owners, and that this is a positive development. We also continue to 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. BIO continues to believe that the most effective global solutions will result from policies that respect and encourage innovation. The actions of the Thai government are in direct contravention of these goals.

The continued actions of the Government of Thailand seriously undermine the confidence of managers and investors in the ability of BIO Member companies to obtain and rely on patent rights in that country. The inevitable result of that approach to compulsory licensing is to provide a powerful disincentive to our Members to invest and do business in Thailand.

We strongly urge USTR to designate Thailand as a Priority Foreign Country. Thailand's continued pursuit of compulsory licensing as part of its trade policies denies U.S. industry

adequate and effective protection of its intellectual property rights. In light of the recent announcements of further compulsory licenses, it is clear that this disregard for the intellectual property rights that are critical to innovative biotechnology companies will continue unabated. More aggressive monitoring and engagement with Thailand on this issue is fully warranted.

PRIORITY WATCH LIST

Brazil

Brazil's recent grant of a compulsory license for a patented pharmaceutical product and persistent deficiencies in its patent system continues to deny adequate and effective intellectual property protection for the biotechnology sector. Therefore, BIO urges USTR to restore Brazil to the Priority Watch List.

In 2007, Brazil granted a compulsory license for SUSTIVA (efavirenz). This act raises significant concerns about the ability to adequately and effectively protect intellectual property rights in Brazil. Based on the information available, it appears that this action goes beyond the letter and the spirit of the Doha Declaration provisions relating to health emergencies and signals a policy that raises significant concerns about the ability of BIO Members to obtain intellectual property protection in Brazil. While BIO understands the challenges that countries face in providing effective and affordable healthcare systems, BIO Members continue to believe that the most effective solutions will result from policies that respect and encourage innovation. Instead, the granting of compulsory licenses in this manner will undermine incentives needed to develop new medicines. As further cause for alarm, press reports indicate that Brazil may be considering further compulsory licenses of pharmaceutical products. The inevitable result of this approach is to provide a strong disincentive to our Members to invest and do business in Brazil.

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. These higher standards are not consistent with Brazil's obligations under the TRIPS Agreement.

Article 27 of the TRIPS agreement provides that patents are to be available "for any inventions … provided they are new, involve an inventive step and are capable of industrial application." A member state may not impose additional requirements as a condition for establishing patentability. In addition, these patents are to 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 are inconsistent with the express provisions of the TRIPS agreement.

BIO urges USTR to restore Brazil to the Priority Watch List. 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.

The Philippines

In 2007, both houses of the Philippine legislature passed bills that would provide for amendments to the Intellectual Property Code of the Philippines. These amendments would weaken the protection of biopharmaceutical inventions in the Philippines and raise significant concerns for BIO Members.

The recently passed amendments would exclude from patentability 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 would appear to exclude from patentability many significant inventions in the pharmaceuticals area. For example, a new form of a known substance that may have improvements in heat stability for tropical climates, or other benefits that may not result in "enhanced efficacy," *per se*, would be denied patent protection even if it met all other patentability criteria. Such a requirement would thereby appear to be an additional patentability requirement 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, the amendments provide that this additional requirement is applied 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."

The recent amendments also contain provisions that expand the grounds on which compulsory licenses may be granted. This includes a new ground that permits a compulsory license "[i]n the case of drugs or medicines, [when] the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Department of Health." This provision 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.

BIO requests that USTR further engage the Philippines to revisit 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 in its current status on the Priority Watch List.

Argentina's patent system continues to suffer from a persistent 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, the National Institute of Industrial Property (INPI) in Argentina has issued highly restrictive patent examination guidelines in Resolution 243/2003 that provide for the denial of patent claims directed to transgenic plants and animals. This excludes protection for a wide class of biotechnological inventions, and also appears to be inconsistent with the Argentine patent law that provides an exclusion to patentability only for living material that is "pre-existing in nature." BIO members also continue to experience difficulties in 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 market pharmaceutical products in a particular market and is 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 inventions of BIO Members.

Chile

Chile does not provide adequate protection of data that is required for submission in support of marketing authorization for pharmaceuticals that is 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 providing onerous conditions on the ability to obtain this protection, and by providing that such protection, where available, may be revoked for broad grounds, including "reasons of public health, national security, public non-commercial use" and other circumstances that are not consistent with the obligations of Chile under either the FTA provisions or the obligations of Chile with respect to data protection set forth in 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 not grant marketing approval to a third party for a drug prior to expiration of the relevant patent term. This protection is highly important to prevent infringement of patents covering valuable inventions for BIO Members. The lack of such protections is particularly troubling in light of the clear obligations provided under the FTA.

In addition, Chile's patent laws do not provide for patent term extensions to compensate for unwarranted delays in the marketing approvals process. The patent law in Chile also excludes

transgenic plants and seeds 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 in a number of ways that deny protection for biotechnological inventions. In light of these deficiencies of the intellectual property regime in Chile, BIO requests that Chile remain on the Priority Watch List.

China

China's intellectual property system has made important improvements in recent years. Nonetheless, there are still many areas of concern relating 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 further poses a threat to public health, along with the consequent economic costs. Counterfeit medications place the public at unnecessary risk, and they divert the resources of industry and government agencies from productive uses. BIO urges USTR to promote more effective interdiction and enforcement directed toward traffickers and distributors of counterfeit biopharmaceuticals in China.

BIO Members remain concerned about some of the proposed changes to the patent law of China contained in the Draft Third Patent Law Amendments. In particular, the draft amendments to Article 25 of the Chinese Patent law would provide that claims in a patent application may be rejected if the completion of the invention depended on the acquisition and exploitation of genetic resources that is contrary to the "relevant laws and regulations of the state." Further, the amendments to Article 26 would require patent applicants to indicate the source of genetic resources if the completion of the claimed invention depended on genetic resources. BIO notes that these amendments appear to be intended to promote compliance with provisions of the Convention on Biological Diversity (CBD) related to access to genetic resources and equitable sharing of benefits from utilization of these resources. However, such a requirement would not help to further these goals, which can be accomplished more effectively by improved transparency in national access and benefit-sharing regimes. Pursuant to these draft amendments, each patent applicant would be responsible for tracing the "history" of all naturally-derived biological materials contributing to the invention, even if the applicant obtained the material from a commercial supplier and the material has been available from secondary sources for decades. The failure to identify the geographical source of a biological material used in the invention would apparently also be a basis for opposition or revocation proceedings. These special disclosure requirements impose unreasonable burdens on patent applicants, subjecting valuable patent rights to great uncertainty. Moreover, these amendments would not be consistent with China's obligations under the TRIPS Agreement.

Draft amendments to Articles 48 to 52 of China's patent law would provide changes with respect to compulsory licensing of inventions. While BIO applauds a number of changes in this area, including the elimination of compulsory licenses for failure to obtain a voluntary license (draft Article 48) and the introduction of limitation on the use of patented inventions under compulsory license in accordance with the TRIPS Agreement (Article 52), significant clarification regarding the events that would trigger compulsory licensing, as well as the scope and duration of the licenses granted, is needed.

The draft amendments also seek to add a "Bolar exemption" to patent infringement for pharmaceutical products in Article 74(5). However, unlike the law of many countries that provide this exemption, the exemption proposed in the patent law amendments does not balance this provision by providing extensions of patent terms for patent owners to compensate for delays encountered in the regulatory approval process. Without this balancing provision, the amendment, standing alone, does not provide equitable treatment to owners of intellectual property rights relating to pharmaceutical inventions.

The Third Patent Law Amendment is an opportunity for China to implement changes to its law that better reflect international standards and provide for improved protection for intellectual property rights holders and the consequent improved enabling environment for innovation in that country. BIO urges USTR to engage with China to improve these amendments prior to enactment in order to achieve a patent law that is fully TRIPS-compliant and that adequately and effectively protects intellectual property rights.

Egypt

Egypt's patent laws continue to lack adequate and effective protection for a wide range of technologies that are important to BIO Members. In that light, BIO requests that Egypt be maintained in its current status on the Priority Watch List.

The Egyptian patent law prohibits patent protection for many valuable 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 areas in the Egyptian patent laws do not fall within those permissible exclusions. In addition, Egypt precludes the patenting of genetically engineered plants and animals. In sum, the Egyptian law precludes patenting of most basic commercial products and processes in the biotechnology industry.

Further, Egypt still does not provide for adequate and effective protection of data supplied to regulatory agencies in support of product marketing authorizations. Data protection is critical for biopharmaceutical companies that want to market products in a particular country. This lack of protection is not consistent with Egypt's obligations under the TRIPS Agreement Article 39.3.

BIO requests that USTR continue to engage Egyptian counterparts in order to make improvements to the protection of intellectual property rights in Egypt and to provide for the eventual adoption of a fully TRIPS-compliant regime in that country.

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. While BIO welcomes this trend, 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, and parts thereof. Further, inventions of tissues, cells, viruses, and the processes of preparing them are not eligible for patent protection, even though protection is mandated by the TRIPS Agreement for inventions in these areas, provided the invention is new, has an inventive step and has industrial applicability. Additionally, it remains unclear whether polypeptides, nucleic acids, and other biomolecules are eligible for patents under the Act. Thus, it remains difficult to obtain legal rights in India of any significant commercial value for a biotechnology product.

Further, the 2005 amendment to the Indian Patents Act introduced 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 would appear to exclude from patentability many significant inventions in the pharmaceuticals area, e.g., new forms of known substances that may have improvements in heat stability for tropical climates, or safety or other benefits that may not result in "enhanced efficacy," *per se*. In addition, such a requirement would appear to be inconsistent with the obligations of India 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 of patentability beyond novelty, inventive step and industrial application. Furthermore, this additional hurdle is applied only to certain chemical compounds and therefore appears to be violative of 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 requirements appear intended to promote compliance with goals of the CBD relating to appropriate access to genetic resources by patent applicants and equitable benefit-sharing from utilization of such resources. However, such a requirement would not help to further these goals, which can be accomplished by improved transparency in access and benefit-sharing regimes. Instead, these special disclosure requirements impose unreasonable burdens on patent applicants, subjecting valuable patent rights to great uncertainty. Each patent applicant is responsible for

tracing the "history" of all naturally-derived biological materials contributing to the invention, even if the applicant obtained the material from a commercial supplier and the material has been available from secondary sources for decades. The failure to identify the geographical source of a biological material used in the invention may be the basis for opposition or revocation proceedings. Such requirements pose unacceptable risks for patent applicants and would undermine the incentives of the patent system to promote innovation in biotechnological inventions. Further, such requirements would not be consistent with India's obligations under the TRIPS Agreement.

The Indian Patents Act places many restrictions on the use of patent rights. These include broad exceptions for use of patented technology by the Indian Government or third parties, and an extensive authority for the grant of compulsory licenses, including upon the sole justification that the products falling under the patent are not manufactured in India.

Further, 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 does not yet implement 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 notes the May 2007 release of the "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.". BIO views the report 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 that, in the "post-transition period," 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, the transition period is not defined and is apparently indefinite. In that light, 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 these "safeguards" would appear to undermine the proposed protection almost entirely.[1] 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 Members.

[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). 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."

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 so that these laws 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 fall far short of providing 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. Data exclusivity is essential to the biotechnology industry and is mandated by TRIPS Article 39.3. In recent years, changes to Israeli laws have weakened data protection and patent protection for pharmaceutical products in that country. 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. Further, growing delays in the registration process for innovative products further erodes the exclusivity period that is necessary for effective protection. In addition, the current laws relating to patent term extension are burdensome and severely restrict the ability to obtain these extensions, which are 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 the reference countries. These deficiencies in the intellectual property rights regime have been raised for years by the United States, yet Israel has not corrected these matters and 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 certain actions have been taken in recent years to 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 to 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 significant potential to harm U.S. applicants, and 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 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.

Ukraine

BIO has significant concerns about the requirements being imposed under the new Ukrainian Plant Variety Protection (PVP) regime. The regulations implementing the Law on Protection of Rights in Plant Varieties require that the parental inbred lines and pedigrees of hybrids must be submitted to the government in order to obtain protection and registration for the hybrids themselves. This appears to a new requirement beyond the scope of the 1991 UPOV Convention. Further, such a requirement subjects highly valuable, proprietary lines to public availability, including potential availability to competing plant breeders, without adequate protection from unauthorized use.

The UPOV convention requires that the variety being protected be examined for novelty, distinctness, uniformity and stability. These can all be evaluated with respect to the seed of the hybrid itself, without access to the parental lines or the pedigree. In addition, since uniformity is a function of cultural practices such as detasseling and rogueing, the uniformity of the hybrid cannot be assessed by examination of the parent inbreds. There are clear alternatives that would permit the authorities to obtain equivalent information about the novelty, identity, distinctness and stability of the parental lines, such as submission of DNA either directly or in leaf material or devitalized seed, without exposing viable seed to misuse.

Ukraine's plant variety protection laws contain provisions that subject the valuable proprietary rights of BIO members to unwarranted risks. In this light, BIO requests that USTR retain Ukraine 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 in Switzerland.

New 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. It should also be noted that the typical market for many of the products of the biotechnology industry is the research community. These include, for example, products such as reagents that are useful in biochemical assays. Article 40b seems to categorically exempt the users of such products 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 of the recent amendments requires that patent applicants disclose the source of a genetic resource, "insofar as the invention depends directly" on the resource. The Swiss law does attempt to minimize 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 has nothing to do with the requirements for patentability of the invention set forth in TRIPS Article 27.1 or the disclosure of invention requirements of TRIPS Article 29.

Other provisions in the law, such as Article 1b and Article 8c, also contain language that could be construed as limiting the patent-eligibility of DNA or gene fragments. However, this language is not clear, and we must look to the manner in which these provisions are applied in the Swiss Patent Office and courts. We urge that USTR engage with Swiss officials to ensure that these provisions are implemented in an appropriate manner.

The situation in Switzerland merits close 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.

Canada

BIO Members recognize that Canada has recently implemented positive regulatory changes, namely the new 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, recent judicial decisions and judge-made-law now undermine the adequate and effective protection of intellectual property of BIO members operating in Canada. In that light, BIO requests that USTR maintain Canada on the Watch List.

Enforcement

Canada is required under the TRIPS Agreement and NAFTA to ensure effective enforcement of intellectual property rights. TRIPS Article 41 and related articles and NAFTA Article 1714 require Canada to "ensure that enforcement procedures are available under its law so as to permit effective action against any act of infringement of intellectual property rights … including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements." Recent judicial precedent has undermined effective patent enforcement such that Canada now stands in violation of its obligations.

(a) Patented Medicines (Notice of Compliance) Regulations (PM NOC Regulations)

In 1993, Canada implemented its version of the U.S. Hatch-Waxman Act. Simply summarized, patent owners are required to list their patents in the Patent Register established under the PM NOC Regulations. 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, recent jurisprudence from the Canadian courts has undermined intellectual property rights in Canada by biasing such proceedings against the patent holder.

For example:

- The generic drug company is not required to address patents listed after the generic Abbreviated New Drug Submission (ANDS) is filed. Given that 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, if the requirement that a submission to the list must precede the generic ANDS date is maintained, the effective date of the listing of a patent in the Register should be 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, in sharp contrast, 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. The Canadian courts have held that upon issuing the NOC, the judicial proceedings are rendered moot and any appeals are dismissed. Moreover, it is considered an abuse of process to bring an action against subsequent generic drug companies alleging the grounds upon which the first generic company obtained an NOC, even if the formulation, doses, or drug form differ from the first approved generic drug. 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. An adverse decision cannot be appealed and is available to every other generic who wishes to leverage that decision. This raises questions of the availability of equitable procedures required by TRIPS Article 42 and NAFTA Article 1715.1(d).

(b) Full Patent Infringement Actions

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, is practically unattainable under Canadian judge-made-law. The standard for such interlocutory relief is extremely high, even when there is compelling evidence of infringement and validity. Canadian courts have held that there is no

"irreparable harm" when a generic drug is launched and sold because money damages can fully compensate the patent holder. Furthermore, patent infringement actions, and particularly damages claims, in Canada are exceedingly slow . BIO members have experienced pendency of such actions for more than a decade. In many instances, the patent is expired before a decision by the court is rendered, which reduces the action to money damages only and is tantamount to a compulsory license. These experiences call into question Canada's compliance with Article 50 of TRIPS and Article 1716 of NAFTA, both of which call for "prompt and effective" measures, including interlocutory relief.

Patents

Two decisions, one of which is pending before the Supreme Court of Canada, cause serious doubt as to whether "selection patents" continue to be valid patents in Canada. Selection patents are important for the adequate protection of inventions in the pharmaceutical and biotechnology arts where the inherent unpredictability of biological systems lead to subsequent advancements building on prior discoveries. One decision, *Eli Lilly Canada Inc. v. Novopharm Ltd.,* 2007 FC 596, subsequently dismissed on appeal, articulates a "super-sufficiency" requirement that the patent description of the invention must provide sufficient evidence *to prove* the existence of any properties upon which patentability is predicated. This development in the law in Canada potentially undermines hundreds of patents held by pharmaceutical and biotechnology companies. Further, it is not consistent with the obligations of Canada under TRIPS Article 29 which states that Members shall require only disclosure of the invention in a manner "sufficiently clear and complete for the invention to be carried out by a person skilled in the art" and that Members may require the "best mode" for carrying out the invention. While evidence supporting the asserted beneficial properties of the claimed invention may be required to be submitted during the patent application or litigation process, applying this standard for sufficiency of disclosure of an invention is not consistent with international norms. Another decision, pending before the Canadian Supreme Court, is *Apotex v. Sanofi-Synthelabo Canada Inc.,* (FC) (Civil) (By Leave) 31881,concerns whether selection patents are valid patents generally. BIO members believe the Canadian government should clarify the law of sufficiency through legislative action to overrule *Lilly* and closely monitor the *Apotex* case and similarly intervene by legislative action if this important category of patents is eliminated under Canadian law.

In addition, 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 biotechology inventions.

Data Protection

Canada is also required to provide effective data protection to prevent unfair commercial use of regulatory data as required by TRIPS Article 39.3 and NAFT Article 1711(5) and (6). The October 18, 2006 regulations implementing eight years of data protection represent a profound step forward in improving Canada's intellectual property regime. However, these regulations are now subject to two legal challenges, one by a generic drug manufacturer and one by the generic drug trade organization, 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 contains a number of matters of concern to BIO Members that warrant further monitoring. In light of these deficiencies, BIO requests that Colombia be placed on the Watch List.

Andean Community Decision 486, which is applicable 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 appears to exclude a wide array of biotechnological inventions. 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 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 processing of patent applications for commercially valuable pharmaceutical inventions, essentially denying protection for these valuable inventions.

Mexico

Mexico continues to deny adequate and effective intellectual property protection to BIO Members by failing to appropriately implement its obligations relating to test data required to be submitted for marketing approval of pharmaceuticals. Mexico has obligations under TRIPS Article 39.3 to provide protection for pharmaceutical test data against "unfair commercial use" and obligations 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. Nonetheless, Mexico still does not provide protection consistent with these obligations. The industrial property states that law will implement requirements under various international obligations of Mexico, 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 about the lack of adequate enforcement procedures in Mexico that undermine the ability to enforce patents on pharmaceutical products. In addition, we 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 Mexico be retained on the Watch List.

Saudi Arabia

BIO appreciates the positive steps taken by Saudi Arabia in recent years in establishing a new patent regime. However, the implementation of the new patent regime in 2004 has effectively denied protection for inventions contained in applications that were filed prior to 2004. Prior to the enactment of the new law, Saudi Arabia had a type of "confirmation" system permitting filing for protection of inventions that had been patented in other countries. However, the adoption of the new law eliminated the "confirmation patents" process without providing a conversion mechanism for applications under the prior system. This has led to a situation in which protection for many valuable inventions is unavailable under the current system.

In addition to this, the new Saudi patent law excludes plants and animals from patent protection, further exacerbating the denial of important intellectual property rights with respect to an important class of biotechnological inventions.

BIO requests that USTR engage Saudi Arabian officials to establish a transitional mechanism to ensure meaningful protection is available for valuable inventions filed prior to the change of laws in 2004 and to encourage a fully developed patent regime that can provide an enabling environment for the biotechnology industry in Saudi Arabia. In that light, BIO requests that Saudi Arabia remain on the Watch List.

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
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