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By electronic mail and courier

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Office of the United States Trade Representative
Washington, D.C.
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Re: *Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment*, 72 Fed. Reg. 1033 (January 9, 2007)

Dear Ms. Harrison:

The Biotechnology Industry Organization (BIO) provides this letter in response to USTR's request for comments involving the "Special 301" provisions of the Trade Act of 1974. BIO 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 health care, agricultural, industrial, and environmental biotechnology products and services.

Intellectual property rights are the foundation of the biotechnology industry. BIO Member companies depend on obtaining patents and related rights in a timely and predictable manner, and the ability to enforce those patents is critical. Biotechnology also is a uniquely global enterprise. If a country's patent system or the judicial structure for enforcing patent rights are 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.

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

Priority Watch List. BIO requests that USTR place **Thailand** on the Priority Watch List. Additionally, BIO requests that USTR maintain the current status of **China, India, Israel, and Brazil** on the Priority Watch List.

Watch List. BIO requests that USTR place **Switzerland** on the Watch List, and that **Egypt**, currently a Priority Watch List country, remain on at least the Watch List.

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PRIORITY WATCH LIST

Thailand

The Thai Government's recent and well-publicized issuance of compulsory licenses for SUSTIVA (efavirenz), KALETRA (lopinavir/retonavir), and PLAVIX (clopidogrel) are of great concern to BIO Members. Based on the information available to the public, it appears that this action goes well beyond both the letter and the spirit of the Doha Declaration relating to provisions for public health emergencies.

Thailand's policy appears to be driven in significant part by constraints it has placed on its own budget. In connection with the compulsory licensing of efavirenz, the Health Ministry announced that "the budget allocated from the Thai Government can only cover some patients with Efavirenz, whereas the rest has to use other non-patented more toxic anti-retrovirals." Cast in these terms, the problem is one of economics, not of a public health emergency. The Thai Government's issuance of a compulsory license for clopidogrel is particularly telling. Clopidogrel is not indicated to treat any infectious or communicable disease. Instead, it is indicated for the prevention of stroke or myocardial infarction. The medical management of such non-communicable conditions whose medical management can 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 never meant as an expedient to facilitate budgetary planning.

BIO appreciates that the diseases that can be treated with drugs such as these affect a great many people and are matters of national concern for many governments. Moreover, BIO Members strongly support initiatives to make effective treatments for all diseases readily available around the world. At the same time, BIO Members continue to believe that the most effective global solutions will result from policies that respect and encourage innovation. Thailand's recent actions do neither.

Thailand's abrupt and unilateral action directly harms a range of interests than goes well beyond the companies that manufacture and market the involuntarily licensed drugs. The failure to respect legitimate intellectual property rights harms the interests of the biotechnology and pharmaceutical industries at large. Moreover, the Thai government's decision to base its action on the limitations of its budget, rather than on public health considerations directly, means that the uncertainty relating to intellectual property protection extends to all industry sectors in which BIO Members are active, and not only the health care sector.

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

BIO strongly urges USTR to engage the Government of Thailand to cooperate with governments and industry to seek practical solutions to its economic challenges. USTR should remain vigilant to all aspects of Thailand's trade policy, and in particular to its compliance with its obligations under the TRIPS Agreement. Thailand's use of compulsory licensing denies U.S.

industry adequate and effective protection of its intellectual property rights. If Thailand imposes additional compulsory licenses in similar circumstances, a more aggressive review will be warranted.

China

BIO Members have noted an increase in the trafficking of counterfeit pharmaceuticals and biopharmaceuticals in China. Such counterfeits are troubling to our industry for several reasons. Of course, counterfeiting improperly deprives the owners of intellectual property of the value of their assets. However, the threat to public health, together with the economic costs of responding to clinical emergencies associated with the use of impure or ineffective pharmaceuticals, are of greater concern. Counterfeit medications place the public at unnecessary risk, and they divert the resources of industry and government agencies from productive uses. In this regard, BIO also notes that Chinese Government agencies and municipalities lack the coordination and cooperation necessary to address enforcement issues. BIO urges USTR to promote more effective interdiction and enforcement directed toward traffickers and distributors of counterfeit biopharmaceuticals in China.

An essential component of an effective mechanism for enforcing intellectual property rights is a functional and efficient judicial system. Unfortunately, China's progress in this respect continues to lag. Such a system is necessary not only to deter counterfeiters, but also to resolve commercial disputes involving intellectual property rights. Litigation to enforce patent rights remains inefficient and unpredictable. The lack of an effective civil judicial system is a significant hindrance to the adequate and effective protection of intellectual property rights in the biopharmaceutical and biotechnology sectors in China.

China has continued its progress toward establishing a comprehensive statutory scheme of intellectual property protection. BIO commends China in this regard. However, significant gaps in existing law remain. Additionally, as BIO has previously noted, ambiguities in China's intellectual property laws hinder patent procurement and enforcement. In the experience of BIO Members, such deficiencies in the legal framework contribute to a failure of the Chinese system to provide adequate and effective protection for intellectual property rights.

We note with particular concern that amendments to Articles 25 and 26 of the Chinese patent law 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. The amendments would require patent applicants to indicate the source of genetic resources if the completion of the claimed invention depended on the acquisition of genetic resources. 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 the equitable sharing of benefits. BIO believes that such provisions would not significantly enhance fulfillment of the objectives of the Convention, and they will place a significant burden on innovation. Moreover, it is not clear that these amendments would be consistent with China's obligations under the TRIPS Agreement.

Articles 48 and 49 of China's new patent law amendments provide for compulsory licensing. Significant clarification regarding the events that would trigger compulsory licensing, as well as the scope and duration of the licenses granted, is needed.

BIO also notes that new Article 63(5) provides a "Bolar exemption" to patent infringement for pharmaceutical products. However, unlike the law of most countries, this exemption is not balanced by any provision for extending the terms of pharmaceutical patents to compensate patent owners for delays encountered in the regulatory approval process. In the absence of such a provision, the Chinese patent law fails to provide adequate and equitable treatment to the owners of intellectual property relating to pharmaceutical inventions.

Finally, BIO notes that shortcomings of patent and plant variety protection also continue to deny BIO members adequate and effective protection of their intellectual property rights for broad categories of inventions. In particular, BIO members whose businesses focus on transgenic plants and animals are unable to protect their inventions in China because their inventions are ineligible for protection under the Chinese patent law.

India

In recent years, India has taken several encouraging steps toward enhancing both its intellectual property laws and the capacity of its Patents 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.

The Indian patent system still excludes from protection most biotechnology inventions. Thus, it is not clear that polypeptides, nucleic acids, and other biomolecules, are eligible for patents under the Act. The Patents Office has also determined that the Indian Patents Act also excludes from eligibility living organisms, ranging from microorganisms, such as bacteria or yeast, to stable cells lines, to transgenic plants and animals. Thus, it is difficult to obtain any legal rights in India of any significant commercial value for a biotechnology product.

We do note a somewhat positive development in the form of a report by an expert advisory group chaired by Dr. R.A. Mashelkar. The report concludes correctly that excluding certain kinds of pharmaceutical inventions and microorganisms from patent-eligibility would be inconsistent with India's obligations under the TRIPS Agreement. BIO urges USTR to encourage India to act in conformance with the minimal conclusions set forth in the report as to such inventions.

India's Patents Act requires applicants to disclose the source and geographical origin of biological materials used to make an invention that is the subject of a patent application. This means that 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 such 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. These special disclosure

requirements are inconsistent with Article 29 of the TRIPS Agreement, and they impose unreasonable burdens on biotechnology patent applicants.

The Indian Patent Act also 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.

The patent infrastructure in India – the capacity of the Indian Patents Office to review and grant patent application – is not yet able to fully support the industries that depend on intellectual property. Moreover, patent litigation remains rare in the Indian courts, and there is a lack of experienced judiciary and enforcement officials.

India has yet to implement any meaningful protection for 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 producers 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). 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.

BIO continues to urge USTR to place significant emphasis on the need for India to reform its intellectual property laws to achieve full compliance with its obligations under the TRIPS Agreement. In particular, India should be encouraged by every available means to implement an intellectual property system that provides an effective level of protection for biotechnology inventions. Thus, notwithstanding recent indications of progress, BIO believes that India should remain on the Priority Watch List.

Israel

Israel's legal framework continues to fall far short of providing adequate and effective legal protection for biotechnology and pharmaceutical inventions. Accordingly, BIO requests that USTR maintain Israel as a Priority Watch List country.

Israel has weakened the protection it provides regarding the use of data submitted by the originator of a new drug to support its application to market the drug. Data exclusivity is essential to the biotechnology industry. Indeed, such protection is required by at least TRIPS Article 39.3. Israel's laws and procedures governing the use of proprietary data are designed and structured to deny adequate and effective protection for intellectual property rights. The United States has repeatedly identified the absence of data protection for regulated products as a serious flaw of the Israeli intellectual property regime, yet Israel has not acted to correct this glaring deficiency.

Israel's pre-grant opposition remains a matter of serious concern to BIO Members. We understand that the Patent Office has attempted to reform its internal procedures to modulate the

most egregious abuses of its opposition procedure. However, the patent statute continues to provide that any person may file an opposition to any pending patent application within three months after the application is published. An opposition may be based not only on grounds relating to patentability under the law, but also on compliance with formalities by the patent applicant, or a question of the ownership of the invention. The U.S. Government has long recognized that pre-grant patent opposition proceedings have an immense potential to harm the interests of U.S. patent owners, and domestic entities in Israel have a long history of using pre-grant oppositions to deny adequate and effective protection to the intellectual property rights of foreign interests.

Israel is a modern, technologically advanced country. It enjoys preferential access to the U.S. market for pharmaceutical products made by its domestic industry. Israeli companies and research institutions regularly 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 the intellectual property rights of U.S. biotechnology companies significantly distorts the trade in biotechnology products between this country and Israel. BIO believes that Israel's intellectual property policies warrant continued close scrutiny by USTR and that it should remain on the Priority Watch List.

Brazil

Patent protection in Brazil remains effectively unavailable for large parts of the biotechnology sector. Thus, BIO urges that Brazil remain on the Priority Watch List.

Brazil denies adequate and effective protection of the intellectual property rights of pharmaceutical innovators by requiring all drug patents to be approved not only by its patent office (the National Institute for Industrial Property, "INPI"), but also by the Minister of Health (through the drug regulatory agency, ANVISA). Brazil has thus effectively imposed a special, higher and discriminatory standard for obtaining a patent on pharmaceutical technology. Such higher standards are contrary to Brazil's obligations under two distinct provisions of Article 27.1 of the TRIPS Agreement.

First, Article 27.1 provides that patents are to be available "for *any* inventions ... provided they are new, involve an inventive step and a re capable of industrial application" (emphasis added). A member state may not impose arbitrary additional requirements as a condition for establishing patentability. Second, "patents shall be available ... without discrimination as to ... the field of technology." Technology-specific conditions on the availability of patent grants, 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 TRIPS.

BIO also remains concerned that the ability of our Members to obtain and enforce rights in plant biotechnology. Although Brazil has implemented a plant variety protection system, it continues not to provide meaningful patent rights for plant innovations. Moreover, even plant

variety rights that are obtained are difficult to enforce. Reforms to the enforcement system for such rights in Brazil are needed.

BIO urges USTR to continue to work constructively with Brazil to institute workable patent grant and enforcement mechanisms. Until such mechanisms are in place and supported by a TRIPS-compliant legal regime, however, Brazil should remain on the Priority Watch List.

WATCH LIST

Switzerland

In December, the Swiss National Council approved revisions to the Patent Law that have the potential to undermine the availability of adequate and effective patent protection for certain biotechnology inventions in Switzerland. Some of the changes clearly take away from the property rights associated with a patent. In many other cases, whether or not the potential for harm is realized will depend on the interpretation of specific language by the Swiss patent authorities. Because an assessment of the practical effect of these will require ongoing vigilance, BIO requests that USTR place Switzerland on the Watch List for the coming year.

In the main, it appears that Switzerland's amendments to its patent law are motivated by a desire to advance protection for the dignity of living beings. BIO supports this objective. However, we believe the amendments are overbroad in some respects.

We are concerned with two restrictions placed on the patent-eligibility of DNA or gene fragments.

First, Article Ib provides that DNA fragments are patentable only if "their function" is clearly disclosed. Of course, a requirement for disclosure of properties that make a claimed invention useful is a bedrock principle of patent law. The "function" could be understood to require an identification of their "natural" functions. Such a reading of the law would amount to an additional technology-specific disclosure requirement in violation of TRIPS Article 27.1.

Second, Article 8c provides that for a DNA molecule claimed with reference to its sequence, patent protection shall extend only to the part of the sequence that is responsible for its described function. BIO sees the potential for considerable uncertainly in enforcing patents according to this standard. For example, only part of a large protein may be involved directly in a particular biological activity, but it is the structure of the protein as a whole that accounts for its biological properties. We must look to the Swiss Patent Office and courts, to apply this provision in a manner that adequately takes account of the real-world nature of the patentable products of the biotechnology industry.

Article 40b provides that any user of a patented invention used "as an instrument or tool for research" shall be entitled to a non-exclusive compulsory license under the patent. The intent of this provision appears to be to prevent the improper use of patent rights from stifling research,

a goal that BIO supports. However, as the legislation is drafted, it is not limited to non-commercial research. Moreover, the natural market for many of the products of the biotechnology industry is the research community – as is the case, for example, for reagents that are useful in biochemical assays. Article 40b categorically exempts the users of such products from liability for infringement, without regard to the commercial or noncommercial nature of their activity. This provision goes beyond the legitimate policy objectives of the amendments to the Swiss law. BIO urges USTR to encourage the Swiss Government to revisit this provision.

Finally, new Article 49a requires patent applicants to disclose the source of a genetic resource, "insofar as the invention depends directly" on the resource. The Swiss law minimizes the potential burden on patent applicants by expressly providing that if the source of a genetic resource is not known to the applicant or the inventors, they may so state. Nevertheless, the requirement for a disclosure of the sources of genetic resources is set forth among the substantive disclosure requirements for patent applications. As such, we believe this requirement amounts to an additional technology-specific requirement in violation of TRIPS Article 27.1. Of greater concern to our Members, it raises a new potential ground of invalidity that will be asserted in litigation, notwithstanding that the information that is the subject of the requirement has nothing to do with the patentability requirements enumerated at Article 27.1 or the disclosure requirements specified at Article 29 of the TRIPS Agreement.

Egypt

Egypt's capacity to process and review patent applications in a timely manner remains deficient. In particular, the Patent Office has an enormous backlog of "mailbox" applications – filings submitted years ago, when the Egyptian Patent Office was not examining pharmaceutical product patents, and held for examination at a later date. Egypt has now undertaken to process these applications, but its progress has been extremely slow. The patentable products covered by the claims of these applications do not have adequate and effective intellectual property protection, since patent rights attach only after the patents are granted. BIO encourages USTR to support every effort to reduce this backlog.

Additionally, Egypt's legal framework for granting patents fails to provide adequate and effective protection for a wide range of technologies that are critical to the commercial interests of BIO Members. Among several express exclusions from patent eligibility in the law are "organs, tissues, viable cells, DNA, genome and natural and biological matters." Each of these classes of inventions must be extended protection under patents pursuant to the TRIPS Agreement, provided the material in question is new, involves an inventive step, and is industrially applicable. Similarly, Egypt's patent law does not provide for protection of genetically engineered plants and animals. The broad exclusions from patent-eligible subject matter preclude patents on most basic commercial products and processes in the biotechnology industry. We continue to support efforts by USTR to encourage Egypt to modify its law to conform its intellectual property laws to its obligations under the TRIPS Agreement.

Finally, Egyptian law still fails to provide for the protection of data supplied to regulatory agencies in support of product marketing authorizations. Such protection is mandated by Article

39.3 of the TRIPS Agreement, and it is a practical necessity for any biopharmaceutical company that wishes to market products in a country. This deficiency in Egypt's law constitutes a failure to provide adequate and effective protection for BIO Members' intellectual property.

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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Biotechnology Industry Organization