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February 11, 2005

By electronic mail and courier

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Office of the United States Trade Representative
Washington, D.C.
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Dear Ms. Harrison:

I am writing on behalf the Biotechnology Industry Organization (BIO) in response to the notice, "Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment," published at Fed. Reg. 134 (January 3, 2005).

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 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 the patent system or the judicial structure for enforcing patent rights in a country are ineffective, a competitor can use an invention with impunity in that country – even though the invention is protected by patent rights in other countries – and deprive the patent owner of the economic value of the invention. Thus, BIO Members have a particular interest in encouraging uniform and robust intellectual property protection in all countries and regions of the world.

Our recommendations remain BIO encourages the USTR, pursuant to the "Special 301" provisions of the Trade Act of 1974 (codified at 19 U.S.C. § 2242), to designate **Israel** as a **"Priority Foreign Country"** in view of its egregious and systematic denial of adequate and effective protection of intellectual property rights in biotechnology products. It also requests that **India, Brazil, Argentina, China, and Egypt** be placed on the "Priority Watch List" due to their failure to provide adequate and effective protection for the intellectual property rights of BIO Members. Lastly, BIO has ongoing concerns regarding patent protection standards for biotechnology innovation in nine Member states of the European Union – **Austria, Belgium, France, Germany, Italy, Luxembourg, Netherlands, Portugal, and Sweden** – and continuing concerns for the status of patent and data package protection for life science products in **Canada.** BIO therefore requests that USTR place these countries on its "Watch List".

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PRIORITY FOREIGN COUNTRY

Israel

Israel supports some of the best industrial biotechnology research and some of the most capable commercial biotechnology enterprises in the world. Yet the Israeli patent system allows competitors to stall the grant of patent rights – sometimes indefinitely – through open-ended pre-grant opposition proceedings. As a result, a party entitled to a patent under the patentability standards set forth in the law can be effectively *and actually* denied adequate and effective legal rights to protect its invention.

Israel is also one of the few remaining countries that provides no exclusive period for the originator of a new drug to rely on the data it submits to support its application to market the drug, as required by at least TRIPS Article 39.3. Because Israel's laws and procedures are designed and structured to deny adequate and effective protection for intellectual property rights, BIO requests that USTR designate Israel a Priority Foreign Country under Sec. 1822(a)(2) of the Trade Act of 1974.

BIO Members are greatly encouraged by the willingness that the government of Israel has shown to discuss the shortcomings of its intellectual property regime. While many desirable reforms have been discussed, however, to date no corrective legislation has been enacted. Accordingly, BIO renews is recommendation that Israel be designated a Priority Foreign Country.

Problems Associated with Pre-Grant Opposition

Section 30 of the Israeli Patents Law provides that any person may file an opposition to any pending patent application within three months after the application is published. The opposition may be based on any grounds relating to patentability under the law, 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. In the late 1980s and early 1990s, diligent efforts by USTR and the U.S. Patent and Trademark Office (USPTO) led to the elimination of the pre-grant opposition authority from the Japanese Patent Law. The U.S. also has sought to preclude pre-grant opposition proceedings in its ongoing efforts to conclude Free Trade Agreements. Several recent agreement incorporate a prohibition on pre-grant oppositions, premised in part on the recognition that these types of proceedings can materially prejudice or even eliminate the ability of U.S. innovators to receive the patent protection for their patentable inventions. Just last fall, the U.S. Federal Trade Commission (FTC) considered possible options amending U.S. law to allow administrative challenges to granted patents as a means for promoting competition.[1] The FTC concluded that pre-grant oppositions would

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[1] U.S. Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy," October 2003; Chapter 5, Section III.B.

interfere unreasonably with the rights of patent holders. It therefore recommended implementing a post-grant opposition procedure, as also advocated by the USPTO.

We are aware of a specific instance that illustrates how Israel's pre-grant opposition practice allows a competitor to unreasonably interfere with the legitimate procurement of patent rights. One BIO Member company filed its patent application in Israel in 1980. After the application had been examined and published, an Israel-based competitor initiated an opposition proceeding in 1985. The opposition proceeding lasted longer than the entire term of the patent that would have been granted – nearly 20 years. The right to exclusivity associated with this particular patent expired before any enforceable rights were granted.

Israeli law does not provide for restoration of patent term due to administrative delay in granting the patent.[2] It does, however, permit a patentee to sue for acts after the date of publication that would have infringed the patent, had the patent been granted when it was published. Thus, the best that this Member company can hope for under current law is a declaration that it would have been entitled to a patent, had it not been opposed, and an award of damages for the "infringing" activities between the publication date and the 20-year anniversary of the filing date.[3] Money damages, however, are not adequate and effective compensation for the loss of the right to an exclusive market position in the domestic market and the right to preclude a competitor from using domestic manufacturing facilities to supply the world market for the patented product.

As this example illustrates, the Israeli patent system allows a competitor to suppress and evade the legitimate property rights due to the owner of a patent application that has been fully examined and found to comply with the requirements of the law. The ability of a third party to interfere with the procurement of a patent amounts to a denial of rights, in derogation of TRIPS Article 62.4, which incorporates the standards of Articles 41.2 ("Procedures ... shall not be unnecessarily complicated ... or entail ... unwarranted delays") and 41.3 ("Decisions on the merits of a case ... shall be made available ... without undue delay"). A regime structured to invite unlimited delay does not provide adequate and effective protection of intellectual property rights for U.S. commercial entities.

No Data Package Protection

As USTR has noted previously, Israel does not to comply with its obligations to provide data exclusivity for regulated products under Article 39.3 of the TRIPS Agreement. Such exclusivity is essential to the biotechnology industry, where even a TRIPS-compliant patent system can fail to provide effective market protection for an innovator. In the context of Israel's deficient patent

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[2] The Israel Patents Law does provide for an extension of patent term due to delay for regulatory review of an application to market a patented drug or medical device. *Id.* Sec. 64A *et seq.* Extension is limited to a maximum of 5 years and is conditioned on the patent being in force when the drug or device is approved. Because the term of this Member's patent has run before any patent has been granted, the Member cannot extend the term of the patent because the patent will never be enforceable.

[3] Israel Patents Law Sec. 179.

system, the absence of data exclusivity means that applying to market a new drug in Israel amounts to no more than an invitation to our industry's competitors – which include some of the most sophisticated generic pharmaceutical manufacturers in the world -- to misappropriate the massive investments our companies make to bring new products to market.

Israel is a modern, technologically advanced country. It enjoys preferential access to the U.S. market for pharmaceutical products made by its domestic industry. Even so, Israel claimed that, as a developing country, it could delay implementation of the TRIPS Agreement until 2000. In the more than nine years since the TRIPS obligations were established, Israel has done nothing to create a system for extending protection for test and other data provided by innovators of regulated products to obtain marketing authorization in Israel. The United States has repeatedly identified this absence of data protection for regulated products as a serious flaw of the Israeli intellectual property regime. Israel has ignored its obligations under TRIPS, ignored overtures from U.S. industry and the U.S. Government, and has refused to enact any form of data protection. By refusing to extend protection, Israel continues to confer on its domestic pharmaceutical industry an enormous commercial advantage that operates to the detriment of our Members.

Conclusion

The absence of adequate and effective intellectual property protection, such as is available to Israel-based entities that choose to compete in the U.S. market, significantly distorts the trade in biotechnology products between this country and Israel. Israel's deficient intellectual property system places the U.S. biotechnology industry at an unwarranted disadvantage in Israel. Notwithstanding public debate that our Members find encouraging, Israel has not yet addressed deficiencies that have been called to its attention repeatedly. For these reasons, BIO believes that Israel's intellectual property policies are egregious and warrant the strictest review and action by USTR under its authority under Special 301.

PRIORITY WATCH LIST

BIO's suggestions for countries to place on the Priority Watch List status are the same suggestions we made last year. With some marginal exceptions, there has been little progress of substance to address the inadequacies in these countries' protection of intellectual property rights. In India and Argentina, the level of protection has decreased significantly.

India

India has recently enacted substantial changes to its patent laws, adopting essentially TRIPS-compliant standards for many products, including conventional pharmaceutical products. BIO commends the government of India for taking these important steps, and we believe that the industry and ingenuity of India's scientific and industrial base will make the new patent law a success.

For the biotechnology industry, however, it is not clear that the recent reforms will have a significant impact. It appears that the patentability of biotechnology products has not been unambiguously determined, and new uses of old products, such as new therapeutic methods,

remain unpatentable. Moreover, the patent infrastructure in India – the capacity of the Indian Patents Office to review and grant patent application – remains unable to service the needs of the industries that depend on intellectual property. Accordingly, even in light of the significant improvement in the broader patent landscape in India, BIO believes that India should remain on the Priority Watch List.

It appears to be the case that 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 taken the stance 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. It is difficult to obtain any legal rights in India of any significant commercial value for a biotechnology product.

Additionally, India has now introduced substantive restrictions that disproportionately affect the biotechnology industry. As now amended, the 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. Special disclosure requirements such as those recently enacted in India are not permitted under Article 29 of the TRIPS Agreement. Because these disclosure requirements impose unreasonable burdens on biotechnology patent applicants, they constitute a failure to provide adequate and effective protection of intellectual property rights for life science innovators.

The Indian Patent Act also includes numerous restrictions on 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.

Compounding the problem concerning these inadequate standards is a marginally functional patent system. The Indian government has invested significantly in Patent Office infrastructure in recent years. Yet it appears that the Patent Office remains understaffed and has a huge backlog of unexamined applications.

Progress in the Patent Office has not been match by meaningful attempts to improve the judicial system. Patent litigation is virtually unknown in the Indian courts, and there is a crippling lack of adequately trained judiciary and enforcement officials. This is a general problem facing the patent system, and it raises daunting challenges for inventions in the field of biotechnology.

The dismal state of the Indian patent system appears anomalous in view of the country's public stance supporting the development of an indigenous biotechnology industry. It is our experience that India boasts a wealth of creative and talented scientists with education and

training well-suited to biotechnology innovation. Moreover, several large Indian pharmaceutical manufacturing concerns have expressed their intention to develop products for the global market. It is for precisely these reasons that many see Indian industry as a natural counterpart for trade and business development in the biotechnology sector. Yet without an effective intellectual property system, India cannot be an equal partner in the global enterprise.

The deficiencies in the Indian patent system are compounded by the absence of 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 or pioneer 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). In India, there is no protection of any kind provided to such data. The Indian regime is therefore deficient under TRIPS. Providing market exclusivity for regulated pharmaceutical and agricultural chemical products would dampen some of the huge barriers to realizing adequate and effective protection of intellectual property rights in India for our companies.

BIO urges USTR to place significant emphasis on the need for India to reform its domestic intellectual property regimes so that they comply fully with the obligations India has undertaken under the TRIPS Agreement. More specifically, BIO continues to believe that India should be encouraged by every available means to implement an intellectual property system that provides an effective level of protection for biotechnology inventions – not only through necessary changes to law and regulations, but in their application and practice.

Brazil

Patent protection for biotechnology in Brazil remains abysmal. The process of granting patents on pharmaceutical inventions is virtually paralyzed by the mandatory review in the health ministry of all such applications once the Brazilian patent office (INPI) has concluded the inventions that are the subject of such applications are entitled to be patented. Brazil thus continues to deny adequate and effective protection for intellectual property rights for the products of the biotechnology industry. BIO therefore urges that Brazil remain on the Priority Watch List.

USTR has previously identified the "local working" requirement of the Brazilian patent system as a major concern. Under this requirement, a patented invention must be manufactured within the territory of Brazil in order for the patentee to retain the exclusive rights associated with a Brazilian patent. Pharmaceutical biotechnology manufacturing facilities are multimillion dollar investments. It is simply not economically feasible for any company to build a factory in every country. Requiring a patent holder to construct such a facility as a condition of maintaining its patent rights effectively abrogates those rights.

The local working requirement is contrary to Brazil's express obligations under TRIPS Article 27.1. TRIPS requires member states to provide for the enjoyment of patent rights "without discrimination as to ... whether products are imported or locally produced." U.S. biotechnology companies are willing and able to supply the needs of the Brazilian market through importation of their patented goods on commercially reasonable terms. Yet, Brazil

refuses to remove the provisions from its law that allow it to grant compulsory licenses for any invention that is not locally worked.

Brazil also 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.

As a practical matter, the additional layer of drug patent review by ANVISA has had the effect of completely paralyzing a patent-issuing apparatus that is already hobbled by a chronic and dire lack of resources. INPI has consistently failed to adequately staff and run its operations to timely grant patent protection. Between delays due to the lack of capacity at INPI and delays due to dilatory review by ANVISA, there is a backlog of patent applications that now numbers in the tens of thousands. USTR has noted this problem in the past, yet no commitment by Brazil – let alone concrete actions – effectively addresses this critical issue.

As it stands, many drug innovators face the very real prospect of not receiving a final decision on their Brazilian patent applications before the potential patent will expire by operation of law. A system that can only determine the patent rights that *would have been* available, had the applications been acted on in a timely manner, does not constitute adequate and effective protection.

BIO also remains concerned that the ability of our Members to obtain and enforce rights in plant biotechnology. We note that while Brazil is a member of the UPOV, and has adopted a plant variety protection regime, Brazil continues to preclude our companies from obtaining meaningful patent rights that cover plant innovation. Moreover, rights that are obtained are difficult to enforce, and do not confer the type of market protection that such rights were designed to confer. Reforms to the enforcement system for such rights in Brazil are needed.

Accordingly, BIO urges the USTR to work constructively with Brazil to institute workable patent grant and enforcement mechanisms. BIO also encourages the USTR to more actively engage with the Government of Brazil to make the necessary amendments to the Brazilian patent law to eliminate provisions that are inconsistent with Brazilian obligations under the TRIPS Agreement. Until these legal and practical impediments are removed, biotechnology companies will not be able to obtain or effectively enforce patent rights in Brazil. Finally, BIO

firmly believes it is in the long term interests of Brazil to adopt stronger intellectual property standards and practices including to encourage development of its indigenous biotechnology industry.

Argentina

Argentina has taken no steps to remedy the serious deficiencies in its intellectual property regime. It is a major producer and exporter of agricultural biotechnology products, yet its intellectual property laws are egregiously deficient. USTR has noted that Argentina had engaged in discussions to clarify its obligations under TRIPS and other agreements. While we welcome such engagement, Argentina's legal system continues to deny adequate and effective protection for the intellectual property of agricultural and other biotechnology concerns.

We discern no evidence that Argentina has made any significant progress in any negotiations to remedy the deficiencies in its laws. Accordingly, BIO urges that Argentina remain a "Priority Watch List" country.

The Argentine legal system fails to provide adequate and effective protection of intellectual property rights in new plant varieties and in plant-related technology. Transgenic crops are not eligible for patent protection. The absence of *any* effective mechanism to enforce property rights in proprietary plants and plant varieties has led to the substantial – if not rampant – piracy in the sales and use of protected seed. One agency has estimated that black market sales of proprietary seeds in Argentina account for up to 50% of the total market.[4]

Argentina competes unfairly with licensed agricultural producers in the United States in two ways. First, by growing of crops for domestic consumption in derogation of US companies' intellectual property rights, producers in Argentina reduce their need to import those crops from the United States. Second, by producing additional quantities for export into international markets, those same producers also rob US producers of significant additional exports. BIO Members conservatively estimate their losses in the millions of dollars.

The most significant problem in Argentina is the absence of an effective enforcement regime for any form of intellectual property rights in plant technology and protected plant varieties. Penalties for unauthorized use of protected seed varieties are negligible. They provide no measure of deterrence against unauthorized use of seed. Judicial enforcement procedures in Argentina likewise are ineffective as a mechanism to prevent the unauthorized commercial use of protected varieties.

Additionally, Argentina is not in compliance with the standards defined in the 1991 Act of the International Union for the Protection of New Varieties of Plants (known by its French acronym, UPOV) regarding the protection of plant varieties. The 1991 Act requires countries to provide that the rights in a protected plant variety will extend to "essentially derived varieties" of such plant varieties. Argentina has not taken steps to implement this obligation. This provision

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[4] General Accounting Office Report 00-55, "Information on Prices of Genetically Modified Seeds in the United States and Argentina" (January 2000), at 14-16.

of the UPOV Act is particularly important in the modern plant biotechnology setting, where nearly all transgenic varieties are "essentially derived" from other protected varieties. Further problems are created by the absence of patent protection for plant inventions in Argentina.

Even when technology is eligible to be patented, many inventors are blocked from obtaining patents under Argentine law. The Argentine patent law excludes plant inventions from eligibility, regardless of the merits of the technology.

The lack of effective enforcement options for plant variety rights, combined with the absence of patent protection for a significant range of biotechnology inventions, renders Argentina's intellectual property system grossly inadequate from the perspective of the biotechnology industry. According to a State Department analysis,[5] even the enactment of a new patent law in 1995 and new patent regulations in 1996 fell "far short of the [Argentine] Administration's commitments to the United States," perpetuating a "flawed regime." Argentina has yet to effectively address the deficiencies in its legal system for providing adequate and effective protection of intellectual property rights.

Argentina also fails to comply with its obligations under TRIPS Article 39.3 to provide data exclusivity for regulated products. In fact, Argentina has managed to establish a regime that affirmatively denies any protection for test data, to yield significant commercial advantages for its domestic pharmaceutical industry. Data exclusivity is essential to providing adequate and effective protection for biotechnology companies attempting to bring new drugs and agricultural chemical products to market. The absence of any degree of data protection in Argentina contributes to the systematic denial of adequate and effective protection for intellectual property rights in Argentina.

For these reasons, BIO urges that Argentina remain on the Priority Watch List.

Egypt

According to the express provisions of the Egyptian patent law, Egypt fails to provide adequate and effective protection for a wide range of technologies that are of critical commercial interest to BIO Members.

Among the several express exclusions from patent eligibility in the new 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. For example, the exclusion of "viable cells" conflicts with the obligations of Article 27.3(b), which expressly require countries to extend patents on microorganisms, which encompass "viable" human or animal cell lines, yeast, bacteria and other types of "viable" cells. "DNA" is a chemical compound that must be extended protection under patents pursuant to

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[5] See "FY 1997 Country Commercial Guide: Argentina," Report prepared by U.S. Embassy Buenos Aires, released by the Bureau of Economic and Business Affairs, August 1996, available by Internet at www.state.gov/www/about_state/business/com_guides/1997/latin_america/argentina97.html.

Article 27.1 of the TRIPS Agreement. Purified or cultured "natural or biological materials" similarly must be granted patents, if the materials are new, useful and non-obvious. The Law makes no distinction between these classes of materials on the basis of whether they are in the form found in nature (*i.e.*, are naturally occurring) or are the result of human inventive activity. Permitting this exclusion to stand will exclude patents on most of basic commercial embodiments of the intellectual property of the biotechnology industry.

Additionally, Egypt's patent law does not provide for protection of genetically engineered plants and animals. This is a significant concern to the biotechnology industry since it includes many commercial products, including genetically modified crops. Without adequate and effective protection for the intellectual property rights that are relevant to their products, BIO Member companies will be reluctant to enter the Egyptian market or enter into joint ventures with Egyptian companies. While Egypt has suggested they will provide some protection for plant varieties under a new section of their laws, this protection appears inadequate on its face to protect the intellectual property of BIO's Members.

There are provisions to protect test and other data submitted to the Egyptian Government as well as to provide exclusive marketing rights as a transition measure. Unfortunately, there have been attempts to implement these provisions in a manner that would be inconsistent with the obligations in the TRIPS Agreement. Without protection at the level required by the TRIPS Agreement for these forms of protection, BIO Members would be increasingly reluctant to enter the Egyptian market. Consequently, the effectiveness of these two forms of protection in Egypt needs to be monitored closely.

We continue to support efforts by USTR to encourage Egypt to modify its law to conform its intellectual property to its obligations under the TRIPS Agreement.

China

In its 2004 "Special 301" submission, BIO noted a favorable trend in the development of China's patent infrastructure. We continue to observe indications that China is genuinely committed to providing a robust and responsive patent regime. This commitment is particularly evident in the case of the Chinese Patent Office, which is on its way to becoming a world-class agency. The development in recent years of the statutory law governing patent rights in China is also laudable.

Regrettably, however, the development of China's judicial system has not kept pace with the progress of its administrative institutions. Litigation to enforce patent rights remains inefficient and unpredictable. Such rights are hollow without an effective means to enforce them. Thus, as we observed last year, the effective level of protection for intellectual property rights in China remains marginal. Shortcomings of the patent and plant variety protection systems also continue to deny BIO Members adequate and effective protection of their intellectual property rights.

In recent years, China has taken significant steps toward creating the legislative and regulatory environment to protect innovation. China also has made specific intellectual property reform commitments pursuant to its accession to the WTO. China is a contracting party of the

Patent Cooperation Treaty (PCT) and has undertaken significant responsibilities under the PCT as an International Search and Examining Office. Its patent statute generally corresponds to international norms, and the Chinese Intellectual Property Office appears increasingly willing to give applicants a full and even-handed hearing.

As we noted, BIO Members face continuing and significant problems in enforcing their intellectual property rights in China. In addition, under Chinese law, transgenic plant and animal inventions remain ineligible for protection. This denies BIO Members adequate and effective protection for the full range of their innovations.

A significant ongoing problem is the inability of Chinese courts to provide a viable means for investigating infringing activities, and for enforcing judgements based on infringement of patents or plant variety rights. As a consequence, the *effective* level of protection for biotechnology innovation in China is woefully inadequate. Because China does not now have an effective legal infrastructure to allow patent and plant variety rights to be fully enjoyed, pursuant to Article 41 of the TRIPS Agreement, it fails to provide adequate and effective protection of such rights. China also has yet to implement any meaningful data protection provisions for pharmaceutical products, as required by TRIPS Article 39.1 and by China's accession agreement obligations. Accordingly, BIO submits that China should be placed on the Priority Watch List.

China has acceded to the UPOV and enacted legislation to provide protection for new plant varieties. China's plant variety protection laws are, however, insufficient to provide adequate and effective protection for intellectual property rights in the plant varieties that are important to the biotechnology industry. China acceded to the 1978 Act of UPOV, rather than the 1991 Act, and its laws conform to the former. The 1978 Act requires protection for registered plant varieties *per se*, but, unlike the 1991 Act, it does not require member states to protect "essentially derived varieties" of plants. Because most of the recombinantly produced plants developed by the agricultural biotechnology industry are "essentially derived" from registered varieties, the limited scope of protection effectively denies the industry's commercial products of enforceable protection. As a result of this deficiency, China's law fails to provide adequate and effective protection for the intellectual property rights in the U.S. biotechnology industry's products.

USTR has appropriately undertaken an out-of-cycle review to focus on the deficiencies of China's intellectual property regime. As for many other industries in this country, China is an important market for biotechnology, and China has actively encouraged a domestic biotechnology industry. In view of China's outlook – and the tremendous potential for China to be an effective player in the global biotechnology industry – BIO urges USTR to encourage China to implement a truly capable civil judicial system so that rights conferred by its patent and plant variety protection laws can have their full and intended effect.

WATCH LIST

Austria, Belgium, France, Germany, Italy, Luxembourg, Netherlands, Portugal, and Sweden

As we noted a year ago, several Members of the European Union (EU) have not implemented the EU Biotechnology Directive in their national patent regimes. The nine countries listed have either failed to enact any legislation to comply with the Directive or have implemented laws that do not fully conform. The Directive is of particular importance to our industry because it ensures that the European market will be a viable one.

The Biotechnology Directive (98/44/EC) obligates EU Member States to enact reforms to their national laws and practices to affirmatively provide patent protection for a broad range of biotechnology inventions, including isolated nucleic acid and polypeptide inventions, transgenic plants and animals, and cell lines. The reforms mandated by the Directive will create a comparable level of protection for biotechnology innovations within and throughout the European Union as is found in other developed countries.

The patent laws of many of the noted European countries do not now explicitly provide that patents must be made available for inventions as specified in the Directive. A number of these countries have stated publicly that they oppose implementation of the Directive. We note, however, that under the practices of the European Patent Organization (EPO), patents are currently being granted on inventions consistent with the scope of eligibility specified in the EU Biotechnology Directive.[6] The absence of an explicit confirmation of patent eligibility by these Members relative to that mandated by the Directive and followed by the EPO raises serious concerns as to whether patent rights in these countries will remain available to our companies, and in particular that such rights, if obtained, can be enforced. Without legally assured patent rights, there can be no adequate and effective protection for the intellectual property existing in most of the products of the biotechnology industry.

We note in particular that in 2004, the lower house of the German Parliament approved amendments to the German patent law to implement the EU Biotechnology Directive. Unfortunately, these amendments provide that the patents on man-made human DNA sequences will only protect the sequences used in connection with the functions described in the patent application. Non-human sequences will be protected when used in connection with the functions described in the patent application as well as later discovered functions and non-biological inventions are protected when used in connection later discovered functions as well as described functions. Thus, by describing trivial differences in function, competitors will be able to use the breakthrough inventions of BIO Members.

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[6] The EPO is governed by the European Patent Convention (EPC). A patent issued by the EPO has legal effect as a "bundle" of national patents enforceable in the courts of the various EPC contracting states under the respective national patent laws. All of the EU Member States are contracting states of the EPC. However, the EPC is not an instrument of the EU, and several non-EU countries are EPC contracting states. Thus, an EPO patent is not "automatically" enforceable under the standards prescribed by EU law.

Germany's amendments appear inconsistent the requirements to protect inventions in TRIPS Article 28, are discriminatory within the meaning of TRIPS Article 27.1, and are inconsistent with the EU Biotechnology Directive. Worse, recent press accounts report that the German Ministry of Justice will attempt to convince other Member States to adopt the German model.[7]

Laws ensuring uniform, reliable and comprehensive protection for biotechnology innovation are an important concern for BIO Members, with tangible economic impact. Uniform patent laws are essential for this industry (or any industry) to operate efficiently in a global market. The transactional costs associated with maintaining an effective commercial position in various countries amid a patchwork of legal deficiencies have the effect of discriminating against the biotechnology industry. The difficulties are especially problematic in a single market such as the EU, since goods made or imported into any one EU Member State may be freely transported to and marketed in any other. The failure of any major market, such as Europe, to provide adequate and effective protection of the intellectual property rights of an entire industry will give rise to economic activity that improperly distorts the U.S. market.

We are mindful that the European Commission adopted the Biotechnology Directive only after long and arduous negotiations within the EU. The Directive is supported by the biotechnology industry. It also has the full backing of the Commission, which recognizes the importance of secure and uniform intellectual property protection to promote the efficient operation of its internal market. Timely implementation of the Directive – an obligation binding on the Member States under EU law – is critical. The failure of the noted Member States to do so merits the attention of USTR.

The European Commission is pursuing formal proceedings before the European Court of Justice against the Member States that have yet to transpose the Biotechnology Directive into their national laws. In this regard, we commend the efforts of the Commission, and we emphasize that our complaint regarding the Directive focuses on the particular Member States that have failed to implement it as they are required to do under European law. We encourage USTR to support the Commission's efforts to persuade the noted countries to reform their laws to create a secure and explicit guarantee of intellectual property protection for the biotechnology industry across the whole of the European Union.

Canada

BIO Members remain troubled by regressive policies toward adequate and effective protection for biotechnology products that coalesced in 2002. We remain troubled that very little progress has been made in the interim to address the situation. Canada is an important trading partner for the United States. It is also both an important market and a significant agricultural production and manufacturing area for the biotechnology industry. Fully effective intellectual property protection is absolutely essential to our industry's ability to continue to do business in Canada.

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[7] "German Biopatent Law Passed," *The Scientist*, 10 December 2004.

In 2002, the Canadian Supreme Court decided that Canadian law excludes from eligibility any invention that is a "higher life form." Thus, pursuant to this decision, Canadian law apparently precludes a new, useful, and non-obvious genetically modified plant, animal, or multicellular organism from being the subject of a patent. The decision raises questions regarding the patent-eligibility of a wide variety of commercially important biotechnology products, ranging from genetically engineered crops to transgenic animals that produce therapeutic proteins in large quantities.

The Supreme Court decision is especially troubling because it is not limited to patents on inventions whose commercial exploitation must be prohibited to address moral or ethical concerns, or to prevent significant harm to the environment. Thus, the decision suggests that a broad range of commercially important technology and products will be excluded under the Canadian patent system. Even though the Supreme Court's ruling was handed down more than a year ago, no significant efforts to amend the law to provide adequate and effective patent rights in plant and animal inventions have been undertaken. We encourage USTR to impress upon Canada's government the importance of this issue to our industry.

BIO Members also remain concerned with an increasing level of public discussion in Canada that calls for further limits on exclusions from patent protection for gene-related inventions. The biotechnology industry is critically dependent on patents to nucleic acids, polypeptides and other biomolecules produced using the genetic discoveries made by our companies. For many of our companies, patent rights are the only significant assets they can use to attract capital to fund their product development activities. Even the *prospect* of restricting the patent-eligibility of the industry's inventions in the future raises serious concerns that affect investment and business decisions *now*.

The developments on patent eligibility compound an ongoing problem of erosion in protection of intellectual property in pharmaceutical and medical technology in Canada. For example, the ability of companies to realize the full value of their intellectual property rights is limited by restrictive practices governing pricing of new, patented pharmaceuticals. In addition, health authorities in Canada interpreted regulations promulgated to implement the NAFTA provisions on undisclosed test and other data in a manner that essentially removes any protection for these data associated with pharmaceutical products and that is inconsistent with that Agreement and the TRIPS Agreement.

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
Director for Intellectual Property
Biotechnology Industry Organization