

United States of America

Q159

**The need and possible means of implementing
the Convention on Biodiversity into Patent Laws**

A) The National Situation

1. *Is the Rio Convention:*

- signed by your country?

Yes. Initially, the United States refused to sign the Convention, principally because of concerns that it contained broad, ambiguous language that could be construed to compromise intellectual property rights and require compulsory licensing of biotechnological inventions. However, on June 4, 1993, the last day that the Convention was open for signing, it was signed on behalf of the United States. Upon signing, the U.S. Ambassador to the U.N. issued an interpretative statement explaining the United States' understanding of the intellectual property provisions of the Convention.

- ratified by your country?

No. The President sent the Convention to the Senate for ratification, along with the interpretive statement referenced in the preceding paragraph, but the Senate has not ratified it.

2. *Is, in your opinion, the Rio Convention already applicable in your country?*

No. The Convention has not been ratified, nor has any implementing legislation been enacted. The United States has comprehensive environmental laws and regulations, and many aspects of the Convention are applicable through these laws and regulations and through executive orders.

3. *If the Rio Convention is not yet directly applicable in your country and if its application would require specific legislation, does said legislation already exist? In the negative, are there plans or actual debates for such legislation in your country?*

As noted in response to the preceding question, numerous laws, regulations and executive orders exist which are designed to protect the environment and preserve biodiversity, e.g., through laws protecting endangered species and wetlands laws. Sensitive habitats are protected through regulations and executive orders. However, no legislation implementing the Convention has been enacted, and no such legislation has been debated or even proposed.

4. *Apart from the Rio Convention or possible legislation for its enforcement, does there exist specific national legislation regulating the access to natural resources (genetic) of the country, the export provisions of such resources, the sharing of the results of their use or the transfer of technologies using them? If such legislation exists, does it contain different provisions, in particular more extensive ones, than those of the Rio Convention? Especially, does the access to genetic resources require the prior consent of the owner of said resources?*

The answer to Question No. 4 requires distinguishing between access to natural genetic resources on private lands and those on public lands. We are aware of no national legislation (outside of eminent domain powers of governmental authorities) that would compel an owner of private property to permit access to and taking of natural resources on the property. Nor are we aware of legislation that would require a private land owner to export genetic resources found on the land or to share technology or information derived from such resources. In the United States, a private owner of land also owns that which is attached to or produced by the land. Legislation mandating that a private land owner provide access to natural genetic resources on such land would

have Constitutional implications. The United States Constitution prohibits the taking of private property for public use without just compensation and due process.

The situation concerning public lands is more complicated. The federal government of the United States owns very large areas of land and closely controls their use. These public lands include national parks, national forests, wildlife reserves, seashores and the like. They are managed primarily by four federal agencies: The National Park Service, the Bureau of Land Management, the Forest Service and the Fish and Wildlife Service. Access to natural resources on public lands for research purposes has long been allowed. For example, National Park Service regulations permit investigators from reputable scientific or educational institutions or state or federal agencies to obtain permits to gather genetic resources in national parks.

Freely providing such access has led to some criticisms and controversies. For example, the heat-resistant enzyme, Taq polymerase, which is a component of the widely used polymerase chain reaction for amplification of DNA, was isolated from a thermophilic microorganism originally found in hot springs in Yellowstone National Park. Biomedical products containing this enzyme have been commercially successful, generating hundreds of millions of dollars in revenues; however, neither Yellowstone nor the National Park Service shared in these revenues.

To avoid such a result in the future, the Department of the Interior developed a strategy for sharing the biodiversity of the national parks with the private sector. During a ceremony commemorating the 125th anniversary of Yellowstone National Park, it was announced that the federal government had entered into a Cooperative Research and Development Agreement ("CRADA") with a private company, Diversa Corporation, by which Diversa would obtain a nonexclusive right to "bioprospect" microbial organisms in Yellowstone. In exchange for access to these genetic resources, Diversa agreed to share with Yellowstone a portion of any financial returns generated by commercial applications or products developed from these research materials. The ceremony was attended by top environmental policymakers, including then Vice President, Al Gore, the Secretary of the Interior, the National Park Service Director, and Yellowstone Park Superintendent. This was the first such agreement of its kind. The arrangement was challenged in federal court by a party who alleged that, by entering the CRADA without public notice and hearings, the government violated various federal statutes, including the Federal Technology Transfer Act of 1986, the National Park Service Organic Act of 1916, the Yellowstone National Park Organic Act, the National Environmental Policy Act, and the so-called public trust doctrine, as well as the Administrative Procedure Act. *Edmonds Institute, et al. v. Bruce Babbitt, Secretary of the Interior, et al.*, 93 F. Supp. 2d 63 (D.D.C. 2000).

After initially concluding that environmental laws required the government to consider the environmental impact of the Diversa-Yellowstone CRADA, the court subsequently held that the arrangement was not illegal and was consistent with research goals of the Park Service. In reaching this conclusion, the court found that, "notwithstanding the novelty of the Diversa-Yellowstone CRADA itself, this agreement is not the first time that the National Park Service has permitted scientific research and collection of microbial specimens from Yellowstone's thermal features. To the contrary, the earliest research permit authorizing collection of microbial samples from Yellowstone was in 1898. Indeed, in recent years, the number of annual requests by researchers for access to Yellowstone has averaged 1,500, with some 250-300 research permits issued each year (between 40 and 50 of which are for microbial research projects)." The court noted that during the course of litigation of the *Edmonds Institute* case, Congress enacted the National Parks Omnibus Management Act of 1998. This Act specifically addresses needs of the National Park Service to manage its resources and provides for the sharing of profits in return for access to its natural resources.

The outcome of the *Edmonds Institute* case provides a framework for access to genetic resources on public lands, with revenue-sharing arrangements to benefit the provider of such access. This arrangement is similar in many respects to the often-cited INBio - Merck agreement, in which the pharmaceutical company, Merck, has been given access to genetic resources of Costa Rica in exchange for profit-sharing commitments.

While Yellowstone's policies and the Diversa-Yellowstone CRADA provide procedural vehicles for both public and private researchers to access the genetic resources of U.S. federal lands, they do not provide the type of access contemplated by the Convention on Biological Diversity. First, the arrangements are purely voluntary and contractual in nature -- they are not legislatively mandated. Second, there is no suggestion that Diversa was

required to share technology or transfer intellectual property rights (although CRADA's often do include government rights reservations and march-in rights). Third, CRADA's entered under the Federal Technology Transfer Act usually require domestic production, to the extent possible, of products developed as a result of the cooperative research. 35 U.S.C. § 204.

5. *Are the practitioners of your country aware of the impact on patent law of the Rio Convention? Do they consider that relevant provisions of the Convention are still too theoretical and vague to affect patents in practice? Or, on the contrary, do they believe that the Rio Convention is to be taken into consideration at the present time?*

It is not believed that most patent practitioners in the United States are aware of the impact on patent law of the Rio Convention. This is particularly so in view of the fact that the Convention has not been ratified, and there do not appear to be any serious efforts to secure its ratification in the U.S. at this time. To the extent that U.S. patent practitioners are aware of the potential impact of the Convention on patent law, they are wary of its possible interpretation requiring compromising of intellectual property rights and compulsory licensing. Patent practitioners in the biotechnology fields are very much aware of the claims that providers of genetic resources might make with respect to inventions and discoveries that result from access to those resources. For example, the exchange of biological materials often is made pursuant to material transfer agreements ("MTA's"). MTA's typically contain provisions delineating rights, if any, in downstream inventions and discoveries.

Although rare, some U.S. practitioners also have experience with bioprospecting agreements with governmental authorities both inside and outside the United States. These agreements, like those discussed in response to Question No. 4, typically address intellectual property rights, access to technologies and some form of profit sharing.

6. *Is the TRIPS Agreement:*

- signed in your country?

Yes.

- ratified by your country?

Yes.

7. *Is the TRIPS Agreement already applicable in your country? If not what is the deadline for its applicability?*

The TRIPS Agreement is applicable in the United States by virtue of the Uruguay Round Agreements Act of 1994.

8. *In your opinion, are the decisions of grant of biotechnology-related patents rendered by your national patent office, as well as the rulings of your national Courts consistent with the Rio Convention? (Whether the answer is positive or negative, groups shall illustrate their answer by quoting examples where possible.)*

It is not believed that the Rio Convention has had any influence on the grant of biotechnology-related patents by the United States Patent and Trademark Office, nor on the decisions of federal courts. The primary reason for this is that the Convention has not been ratified, and no implementing legislation has even been proposed; therefore, it would be improper for the Patent Office or the courts to apply the provisions of the Convention.

The question of whether the decisions of the U.S. Patent Office and the courts are consistent with the Convention is difficult to answer, because the provisions of the Convention dealing with patent rights are vague and subject to different interpretations. Patentable subject matter is defined very broadly in the United States and includes almost any nature of biotechnology-related invention or discovery (e.g., microorganisms, plants,

animals, nucleic acids (including EST's), novel biological processes, methods of treatment and diagnosis, etc.) Among the principal concerns that led initially to the United States' refusal to sign the Convention and then later to the refusal of the United States Senate to ratify it arose from ambiguous provisions concerning intellectual property rights - particularly those in Article 16. For example, the last section of Article 16 requires cooperation among Contracting Parties, "subject to national legislation and international law in order to ensure that [patent] rights are supportive of and do not run counter to [the Convention's] objectives." This provision and others could be construed to be inconsistent with the United States' policy of broadly defining patentable subject matter in biotechnology and medical fields. Because of these concerns, the President included an interpretative statement with regard to intellectual property rights when sending the Convention to the Senate for ratification. Based on this interpretive statement, certain biotechnology groups and pharmaceutical companies urged ratification of the Convention. See *The Convention May Not Be Used in Place of U.S. Law*, 103rd Congress, 2nd Sess. S14053 et seq. (October 4, 1994). Members of the Senate expressed concern, however, that there was no provision in the Convention for reservation of rights and that those parts of the Convention relating to patent rights and technology transfer were subject to differing interpretations. See *Opposing Consideration of the Convention on Bio-Diversity*, 103rd Congress, 2nd Sess. S13790-92 (September 30, 1994).

B) Possible Means of Implementing the Rio Convention into Patent Laws

9. *If your country is a member both of the Rio Convention and of the WTO, do you consider that contradiction may exist between the Rio Convention and the TRIPS Agreement? Further, if a subject liable to be contradictory does exist, could the Vienna Convention on the interpretation of international Treaties, particularly its Article 3(a), be invoked, if same is applicable in your country?*

The United States is member of the WTO, but not of the Rio Convention; therefore, there is no present contradiction. As discussed above, the potential conflict between intellectual property rights and certain provisions of the Convention has resulted in the refusal of the Senate to ratify the convention. This potential conflict stems from the ambiguities of the provisions of the Convention that concern intellectual property rights and the implication that such rights are subordinate to the goals of the Convention. The American Group does not believe that the main goals of the Convention -- preserving biodiversity and the sustainable use of its components -- are incompatible with strong intellectual property rights. Indeed, the role of the patent system in incentivizing innovation, requiring early disclosure and encouraging design-around activities will foster the goals of the convention. It must be kept in mind that patent rights are limited in duration, but the patented technology becomes part of the public domain of all peoples in perpetuity.

Some of these concerns about the Convention's impact on intellectual property rights were addressed in the following points of a proposed interpretive statement being considered during the Senate debate on ratification:

"(1) The Government of the United States of America understands that Article 3 references a principle to be taken into account in the implementation of the Convention.

(2) It is the understanding of the Government of the United States of America with respect to provisions addressing access to and transfer of technology that:

(a) 'fair and most favorable terms' in Article 16(2) means terms that are voluntarily agreed to by all parties to the transaction;

(b) with respect to technology subject to patents and other intellectual property rights, Parties must ensure that any access to or transfer of technology that occurs recognizes and is consistent with the adequate and effective protection of intellectual property rights, and that Article 16(5) does not alter this obligation.

(3) It is the understanding of the Government of the United States of America with respect to provisions addressing the conduct and location of research based on genetic resources that:

(a) Article 15(6) applies only to scientific research conducted by a Party, while

Article 19(1) addresses measures taken by Parties regarding scientific research conducted by either public or private entities;

(b) Article 19(1) cannot serve as a basis for any Party to unilaterally change the terms of existing agreements involving public or private U.S. entities.

(4) It is the understanding of the Government of the United States of America that, with respect to Article 20(2), the financial resources provided by developed country Parties are to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures that fulfill the obligations of the Convention and to benefit from its provisions and that are agreed between a developing country Party and the institutional structure referred to in Article 21.

(5) It is the understanding of the Government of the United States of America that, with respect to Article 21(1), the "authority" of the Conference of the Parties with respect to the financial mechanism relates to determining, for the purposes of the Convention, the policy, strategy, program priorities and eligibility criteria relating to the access to and utilization of such resources.

(6) The Government of the United States of America understands that the decision to be taken by the Conference of the Parties under Article 21, Paragraph 1, concerns 'the amount of resources needed' by the financial mechanism, and that nothing in Article 20 or 21 authorizes the Conference of the Parties to take decisions concerning the amount, nature, frequency or size of the contributions of the Parties to the institutional structure.

(7) The Government of the United States of America understands that although the provisions of this Convention do not apply to any warship, naval auxiliary, or other vessels or aircraft owned or operated by a State and used, for the time being, only on government non-commercial service, each State shall ensure, by the adoption of appropriate measures not impairing operations or operation capabilities of such vessels or aircraft owned or operated by it, that such vessels or aircraft act in a manner consistent, so far as is reasonable and practicable, with this Convention."

See Executive Reports of Committee, 103rd Congress, 2nd Sess., 140 Cong. Rec. S8484 (July 11, 1994).

The United States is a party to the Vienna Convention on the Law of Treaties; however, it is not believed that reliance on the rules of construction contained in Article 3.A. of that Convention would be sufficient to overcome current opposition to ratification of the Rio Convention.

10. *What is your opinion on the reservations of Article 27(2) of the TRIPS Agreement which make it possible to "exclude from patent protection inventions whose commercial exploitation would be detrimental to 'ordre public' or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.?" In this respect, do you consider that AIPPI should confirm the Resolutions adopted in Montreal in 1995 (see hereinabove)?*

As explained in our earlier report on Q150, the American Group does not believe that the patent laws are appropriate for regulating health, public safety or morality. To the extent that such legislation is needed in connection with biotechnology-related inventions, it should be in the form of enabling legislation for regulatory agencies, not restrictions on patentability.

11. *Some problems exist on the patentability of biological material such as DNA, living tissues etc. Do you think that AIPPI can confirm the Resolution adopted in Montreal on Q 114? Attention should also be paid to the position expressed by AIPPI on Q150 studied during the Executive Committee held in Sorrento in April 2000. Do you think that, if national legislation excludes from patentability such inventions, this exclusion would be such as to facilitate the application of the Rio Convention or, on the contrary, that this exclusion would have no influence for putting in practice the provisions of the Rio Convention on the access and use of genetic resources of a country?*

The American Group believes that the patentability of biotechnology-related inventions should be strongly endorsed by the AIPPI and that patentability issues should not be confused with issues more appropriately reserved for regulatory agencies having expertise in health, safety and social matters. It is not believed that excluding biotechnological inventions from patentability would facilitate the Rio Convention, because such exclusions would (1) discourage investment in these important technologies - investments that in the long run benefit all mankind, (2) would discourage disclosure of technologies and encourage reliance on trade secrets and (3) would discourage productive relationships between research-based entities and resource providers. Thus, it is believed that restrictions on patentability would impair, rather than facilitate, the goals of the Rio Convention.

12. *What do you think of the reservations of Article 27(3) of the TRIPS Agreement which make it possible to exclude plants and animals from patent protection? Do you think that this exclusion by national legislation would be such as to facilitate the application of the Rio Convention or, on the contrary, that this exclusion would have no influence on putting I practice the provisions of the Rio Convention on the access and use of genetic resources of the country?*

As explained in the answer to the preceding question, it is not felt that restrictions on patentability of biotechnological inventions will facilitate achievement of the goals of the Rio Convention. Contrary to what is often reported in the press, patents cannot claim products as they exist in nature - they only can claim novel, nonobvious products resulting from human ingenuity and intervention. Concerns that patent owners will restrict the use of established local practices and materials, such as seeds and germplasm, are not well-founded. Access to genetic resources on mutually agreeable terms (not necessarily involving technology transfer, compulsory licensing or dedication) will be best facilitated by ensuring strong intellectual property protection. This will maximize returns both to resource providers and technology providers, as evidenced by the INBio-Merck and Diversa-Yellowstone CRADA described above.

13. *The Rio Convention challenges neither the existence of patents nor the importance of patent rights. Articles 15 and 16 (see hereinabove) are however designed to determine the conditions of access to a technology making use of genetic resources. Groups are invited to provide their comments regarding the possible practical solutions which are to be considered for the allocation of ownership of patent rights where the subject inventions are achieved due to information concerning genetic resources or by means of genetic resources themselves (for example: a plant or a microorganism). Is the signature of research and/or development agreements an appropriate path to explore with a view to solving the patent rights ownership allocation issue? Examples for such agreements have been given during the workshop N· V of the Rio Congress, as mentioned in the Introduction. Groups of countries already having experience in this respect are welcome to illustrate their answer with relevant examples.*

The premise of Question No. 13 is not as clear as the first sentence suggests. As discussed above, the reluctance of the President to sign the Convention and the refusal of the Senate to ratify it were based in large part on a concern that the vague language of the Convention could be interpreted to restrict the protectability of biotechnological inventions and to require compulsory licensing. As further noted above, certain biotechnology industry groups and research-based pharmaceutical companies in the United States ultimately endorsed ratification of the Rio Convention on the understanding that strong intellectual property rights would be observed and technology transfer would be the result of arms-length negotiations rather than compulsory licensing. It is the view of the United States Group that voluntary agreements, like the INBio-Merck agreement and the Diversa-Yellowstone CRADA, described above in response to Question No. 4, are the preferred means for governing access to genetic resources and allocating resources and potential revenues.

14. *In your opinion, what means could empower a State or an institutional owner of genetic resources to work or allow the working in the host country of patents filed by third parties which make use at least partially of such resources? Do you consider, for example, that a State should be entitled to constrain a patent owner to grant a compulsory licence, or even to sell the subject patent? The reply thereto should take into account the TRIPS Agreement, whose Article 31 in particular provides for the possible working of a patented invention without the owner's consent, subject to the fulfilment of*

several conditions. Groups are invited to report detailed comments as to how States could be theoretically empowered to regulate the utilisation of their natural biological resources, attention being paid to the practical conditions imposed by the TRIPS Agreement for such regulations. As for previous question 13, groups of countries having experience on this subject are warmly invited to illustrate their comments by concrete examples.

TRIPs Article 31 permits compulsory licensing only upon a showing of extraordinary circumstances and only under limited conditions. Requiring compulsory licensing under less rigorous circumstances or on broader terms, even with respect to inventions derived from genetic resources of a country, would not be consistent with TRIPs. As discussed above in connection with Question No. 13, a preference to compulsory licenses or forced assignment of intellectual property rights would be voluntary agreements in which the resource provider and the technology provider resolve conditions for access to genetic resources in advance. The terms and conditions will then depend on the importance and uniqueness of the genetic resources being provided and the potential downstream value of products and intellectual property rights.

15. *The Rio Convention distinguishes between the resources which have been acquired prior to its entry into force (in which case the Convention does not apply to their working) and the resources acquired later. For instance, data obtained from collections or data bases established before the date of entry into force of the Convention do not fall within its scope. Groups are invited to report their possible experience regarding the working of resources acquired earlier than the date of entry into force of the Convention so that lessons may be drawn with a view to its application to future resources, as same will be subjected to the Rio Convention.*

The American Group does not have experience with this issue.

16. *As indicated hereinabove, in particular as concerns article 15 and 16 of the Rio Convention, the latter contains provisions which can be implemented only upon mutually agreed terms. Negotiations between the party providing resources and the candidate desiring access and use will therefore become necessary. Groups are invited to express their opinion as well as their comments on such negotiations. In this respect, it should be noted that article 31(b) of the TRIPS Agreement also provides that the party seeking access to or the transfer of technology must have endeavoured to obtain consent from the patent rights owner before a compulsory licence is granted. Generally speaking, do groups agree that amicable and free negotiations should prevail between contracting parties, including States, without any constraining schedule so that attention could be paid to the specificity of the host country as well to that of the subject resources? On the contrary, should pre-negotiated agreement forms be considered? On this particular subject, as well as for the previous ones, groups are invited to report their experience gained in their country, where Conventions were negotiated regarding the utilization of natural resources in the sense of the Rio Convention.*

As discussed above in response to several questions, it is believed that access to genetic resources should be on terms voluntarily entered by the resource provider and the technology provider in advance. While certain patterns of agreements almost certainly will be developed, there should be sufficient flexibility that the parties can tailor the arrangement to the specific facts, particularly the scope and value of the resources to which access is being provided. This is similar to the practice in the United States involving CRADA's between private entities and federal agencies or laboratories. The basic framework of the CRADA is established, but specific terms and conditions, including licensing rights, compensation, term and the like are subject to negotiation.

Summary

Because the United States has not ratified the Rio Convention and no immediate prospect of such ratification exists, the American Group does not have significant experience with this Convention. There has, however, been a great deal of debate and commentary in the United States concerning the Convention. It is believed that broad, ambiguous provisions of the Convention that potentially could be interpreted to limit patentability of biotechnological inventions and require compulsory licensing were principal factors in the refusal of the United States Senate to ratify the Convention. The American Group believes that voluntary agreements between

resource providers and research-based entities, which define terms for access and reasonable consideration in advance, are the preferred vehicles for achieving the goals of the convention. The INBio-Merck agreement and the Diversa-Yellowstone CRADA are examples of arrangements that have the potential of providing substantial benefits to both providers and users.