

COMMUNICATION FROM THE UNITED STATES

During the meeting of the Council for TRIPS of 2 to 5 April 2001, the Secretariat received from the delegation of the United States a preliminary version of a paper prepared by this delegation on the relationship between the Convention on Biological Diversity and the TRIPS Agreement, which was made available by the Secretariat, on 3 April 2001, to delegations at that meeting, as requested by the United States, as advance copy of the paper. The present document reproduces the text of this paper received from the delegation of the United States on 24 April 2001, which differs in some respects from the preliminary version.

VIEWS OF THE UNITED STATES ON THE RELATIONSHIP BETWEEN THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE TRIPS AGREEMENT

Introduction

Article 27.1 of the TRIPS Agreement obliges WTO Members to make patents available for any inventions, whether products or processes, in all fields of technology if those inventions meet the criteria for patentability.¹ Article 27.3(b) creates an exception to the broad mandate of Article 27.1 by authorizing WTO Members to exclude from patentability plants and animals and essentially biological processes for the production of plants or animals. The subparagraph goes on to make clear, however, that the authorized exclusion does not apply to micro-organisms or to non-biological and microbiological processes. In addition, if a WTO Member chooses to exclude plant varieties from patentable subject-matter, the Member must provide an effective *sui generis* system for the protection of plant varieties. The subparagraph also establishes that WTO Members that do provide patents for plant varieties may also provide protection through a *sui generis* system.

The TRIPS Council is currently reviewing the provisions of Article 27.3(b), as provided for in the last sentence of the subparagraph. During that review, some Members have repeatedly referred to possible conflicts between the provisions of the TRIPS Agreement and the provisions of the Convention on Biological Diversity (the CBD). Although, in the view of the United States, the review called for under Article 27.3(b) should be limited to the provisions of the subparagraph, we nonetheless take this opportunity to address specifically the provisions of the CBD and the relationship, to the degree one exists, with provisions of Article 27.3(b) of the TRIPS Agreement.

¹ The criteria are that the invention be new, involve an inventive step (be non-obvious), and be capable of industrial application (be useful).

The Objectives on the Convention of Biological Diversity

The Preamble of the CBD states the intention of the Contracting Parties in entering into the Convention as a desire to enhance and complement existing international arrangements for the conservation of biological diversity and the sustainable use of its components, and expresses their determination to conserve and sustainably use biological diversity for the benefit of present and future generations. The objectives of the CBD, as stated in Article 1 of the Convention,² are threefold: (1) the conservation of biological diversity; (2) the sustainable use of its components; and (3) the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. The third objective, according to the text, relates to appropriate access to genetic resources, to appropriate transfer of relevant technologies and to appropriate funding. Determinations of what is "appropriate" in relation to access to genetic resources and transfer of technology are to be made, taking into account all rights over those resources and technologies.

The TRIPS Agreement's Preamble states WTO Members' intention as a desire to reduce distortions and impediments to international trade, and to establish a mutually supportive relationship between the WTO and the WIPO, as well as other relevant international organizations. The objectives of the TRIPS Agreement, as stated in Article 7,³ are the protection and enforcement of intellectual property rights in a way that contributes to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technology and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

The objectives of the two agreements, though disparate, do not conflict. Indeed, serious discussion of the provisions of both agreements, rather than negative rhetoric directed to the provisions of the TRIPS Agreement, could assist those WTO Members that are also Contracting Parties of the CBD, and that have not already done so, to implement their obligations under both agreements with an emphasis on the complementarity of the provisions of the two.

Knowledge, Innovations and Practices of Indigenous and Local Communities: Maintenance and Benefit Sharing

Article 8(j)⁴ of the CBD deals with some knowledge, innovations and practices of indigenous and local communities that embody traditional lifestyles. Article 8(j) appears to establish three obligations. First, Contracting Parties are to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity". Second, Contracting Parties are to promote the wider application of such knowledge, innovations and practices. Third, Contracting Parties are to encourage the equitable sharing of the benefits arising from the utilisation of such knowledge,

² Article 1, entitled "Objectives" states: "The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."

³ Article 7, entitled "Objectives" states: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer of and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

⁴ Article 8(j) states: "Each Contracting Party shall, as far as possible and as appropriate; [...] Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices."

innovations and practices. Two phrases modify these obligations. Article 8's chapeau conditions "shall" with the phrase "as far as possible and as appropriate"⁵, and subsection (j) begins with the phrase, "Subject to its national legislation".

It should be noted that Article 8(j) does not encompass all knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles. Article 8(j) refers only to knowledge, innovations and practices "relevant for the conservation and sustainable use of biological diversity". Nothing in the Convention, however, would preclude countries from extending the application of the provision to other knowledge, innovations and practices of indigenous and local communities. If such knowledge, innovations and practices are to be respected, preserved and maintained and if their wider use is to be promoted, they must be identified. Seeking information on such knowledge, innovations and practices would necessarily involve seeking the approval and assistance of the indigenous and local communities in possession of the knowledge, innovations and practices. Seeking such information would also provide an opportunity to educate any communities that are unfamiliar with the basics of negotiations, contracting, various forms of intellectual property, etc., that might be relevant to them in marketing their knowledge, innovations, and practices for use by those outside their communities, and for obtaining an equitable share of the benefits arising from the utilisation of their knowledge, innovations and practices. The gathering of information would be directed toward achieving all three objectives of Article 8(j). Likewise, it also would provide an opportunity for indigenous and local communities to indicate that they did not want their knowledge, innovations and practices disclosed or shared with the larger community. That would be an appropriate time to provide information on the use of trade secret law as a tool for maintaining limitations on the circulation of the knowledge, innovations and practices.

Creating organized data bases of knowledge, innovations and practices relevant for the conservation and sustainable use of biological diversity, searchable over the Internet, would be valuable in a number of ways. It would create sources of information that could be used by potential licensees searching for knowledge, innovations and practices that might relate to their field of work and could indicate contact points, qualifications for licensees, conditions for licensing, etc. That would go toward the second and third objectives of Article 8(j), i.e., to promote the wider application of the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity with the approval and involvement of such communities, and would encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices. Suitable national or local legislation or regulations could establish the legal basis for such contractual arrangements between those seeking to develop knowledge, innovations and practices into commercial products and those providing the knowledge, innovations and practices.

Organized, searchable data bases of the knowledge, innovations and practices of indigenous and local communities also would provide a source of information that could be used by patent examiners worldwide when examining applications for patents relevant to conservation and sustainable use of biological diversity, in particular, and to other fields as well, if additional information is available on data bases. This would, therefore, aid in improving examination of patent applications in relevant fields to ensuring that inventions granted patents are new and do involve an inventive step.

The provisions of Article 8(j) of the CBD and the provisions of the TRIPS Agreement, when appropriately implemented, are, therefore, mutually supportive.

Access to Genetic Resources and Access to and Transfer of Technology

⁵ This same phrase is also included in Articles 5, 7, 9, 10, 11, 14.

Article 15 of the CBD is entitled "Access to Genetic Resources". The first paragraph in that Article states that, because States have sovereign rights over their natural resources, they are responsible for determining access to their genetic resources in accordance with their national law.⁶ Contracting Parties are charged with endeavouring to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of the Convention.⁷ Where access is granted, it is to be on mutually agreed terms as provided for in the Article.⁸ Access to genetic resources is subject to prior informed consent of the Contracting Party providing the resources, unless that Party decides otherwise.⁹ Contracting Parties are to endeavour to develop and carry out research on genetic resources acquired from other Parties with the full participation and, where possible, in the supplying Contracting Party.¹⁰ Finally, Contracting Parties are to take legislative, administrative or policy measures with the aim of sharing fairly and equitably with the Contracting Party supplying the resources, the results of research and development and any benefits arising from commercial or other use of those genetic resources.¹¹

Article 16 is entitled "Access to and Transfer of Technology." The first paragraph of the Article requires Contracting Parties, in accordance with the provisions of Article 16, to provide and /or facilitate access for and transfer to other Contracting Parties technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources while not causing significant damage to the environment.¹² Such access and transfer of technology to developing countries are to be provided or facilitated on fair and most favourable terms or, where mutually agreed, on concessional and preferential terms and, where necessary, using the financial mechanism established under Articles 20 and 21. Terms for technology protected by patents or other forms of intellectual property are to be consistent with adequate and effective protection of intellectual property rights.¹³ Paragraph 3 requires Contracting Parties to take appropriate legislative,

⁶ Article 15(1) states: "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation."

⁷ Article 15(2) states: "Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention."

⁸ Article 15(4) states: "Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article."

⁹ Article 15(5) states: "Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party."

¹⁰ Article 15(6) states: "Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties."

¹¹ Article 15(7) states: "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."

¹² Article 16(1) states: "Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment."

¹³ Article 16(2) states: "Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below."

administrative or policy measures aimed at providing, on mutually agreed terms, access to and transfer of technology making use of genetic resources, including technology protected by patents or other intellectual property rights, to Contracting Parties that supplied the genetic resources, particularly those that are developing countries.¹⁴ Contracting Parties also are to take appropriate legislative, administrative or policy measures with the aim of having the private sector facilitate access to, joint development and transfer of technology covered by paragraph 1 for the benefit of governmental institutions and the private sector of developing countries. These measures also are to impose the obligations of paragraphs 1, 2 and 3 on the private sector.¹⁵ Finally, Contracting Parties are to cooperate, subject to national legislation and international law, to ensure that patents and other intellectual property rights support and do not run counter to the objectives of the Convention.¹⁶

Articles 15 and 16 are best discussed together because the most effective means for providing access to genetic resources, and for ensuring that any benefits that arise from their use are shared fairly and equitably, would be through contracts between those granting access to the resources and those to whom access is granted. CBD Contracting Parties can provide, through legislation or regulations, systems that permit parties seeking access to genetic resources to enter into contracts with the sovereign entity or private party responsible for granting access. To be effective, such contracts should spell out in detail the terms and conditions under which access is granted, including such things as any requirements for joint research and development or for transfer of technology that might result from the use of the genetic resources to which access was to be granted. Obviously, questions of jurisdiction of courts and conditions required to be included in contracts with any third parties licensed to make use of the genetic resources obtained would also have to be spelled out. A contract granting access also should define expressly terms that are not clear on their face, such as the definition of the term genetic resources.

Those seeking access to genetic resources likely would welcome such a regime, because it would clarify rights and obligations on both sides at the outset. Such clear rules would help to avoid misunderstanding and confusion. By making transparent the requirements for being granted access to genetic resources, CBD Contracting Parties could encourage greater use of their genetic resources in a sustainable way. Where genetic resources can be obtained from a number of sources, of course, the party seeking access likely would seek the resources from the territory that provides more favorable terms, so that an incentive would exist for balance between the access to genetic resources granted and the terms and conditions on which access is based. Such a contract system also might include a requirement that a party to which access is to be given identify the contract in the specification of any patent application it files claiming an invention developed through use of the genetic resources obtained. Obtaining patents around the world for commercial products that serve to conserve biological diversity would provide benefits that could be shared in accordance with the terms of the contract. Absent patent protection, others who were not bound by contract, would be free to use the technology without any obligation to share the benefits with the Contracting Party that provided the

¹⁴ Article 16(3) states: "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, or mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below."

¹⁵ Article 16(4) states: "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above."

¹⁶ Article 16(5) states: "The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."

genetic resources on which the invention was based. Finally, in the event of a breach of obligations on either side, contracts can be litigated in the specified jurisdiction and judgements enforced around the world under international agreements regarding the recognition of judgements.

Some have said that contractual systems would not work in ensuring that benefit sharing results from access to genetic resources, because some individuals might not respect a requirement that parties seeking access to genetic resources enter into a contract with the sovereign entity or private individual as provided under the laws of a country. It is possible that a few individuals could ignore the legal requirements and simply put an herb in their pocket, in the same way that some individuals counterfeit trademarks or pirate copyrighted works, but this does not negate the value of a contractual system that would apply to the vast majority of those seeking access, just as trademark and copyright laws apply in their spheres. Just as is done in the case of trademark counterfeiting and pirated copyrighted works, criminal provisions and/or civil liability for failure to comply can be included in the country's laws for those few who might take genetic resources without entering into an access agreement with the appropriate party.

The provisions of the TRIPS Agreement would not preclude countries from providing that those seeking access to genetic resources for research and development enter into arm's-length contracts providing, *inter alia*, for a sharing of the benefits of any patents that might be granted for inventions developed from those genetic resources, including by providing access to the technology. The provisions of Articles 15 and 16 of the CBD and the provisions of the TRIPS Agreement are, therefore, mutually supportive, not conflicting.

Handling of Biotechnology and Distribution of its Benefits

Article 19 is entitled "Handling of Biotechnology and Distribution of its Benefits." Paragraph 1 requires Contracting Parties to take appropriate legislative, administrative or policy measures to permit participation in biotechnological research by the Contracting Parties providing the genetic resources for the research and, where feasible, in those Contracting Parties' territories.¹⁷ Paragraph 2 requires Contracting Parties to take "all practicable measures" to "promote and advance" priority access, on a fair and equitable basis and on mutually agreed terms, to Contracting Parties that provided genetic resources to results and benefits arising from biotechnologies based on those resources.¹⁸ Paragraph 3 requires Parties to consider whether a protocol is needed establishing procedures for safe transfer, handling and use of genetically modified organisms that might adversely affect biological diversity.¹⁹ Paragraph 4 requires Contracting Parties themselves, or through natural or legal persons within their jurisdictions, to provide any available information on safety, handling and use of genetically altered organisms to Contracting Parties into the territory of which such organism is being introduced.²⁰

¹⁷ Article 19(1) states: "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties."

¹⁸ Article 19(2) states: "Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms."

¹⁹ Article 19(3) states: "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."

²⁰ Article 19(4) states: "Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms,

These obligations also are better met through contractual arrangements between the Contracting Party giving access to genetic resources from which a modified genetic organism is developed and the party to which access to those genetic resources is given. The party creating the genetically modified organism from genetic resources provided by the Contracting Party would be most likely to have the relevant information. If another Contracting Party created the genetically modified organism from genetic resources provided by a Contracting Party, there would be no need for a separate agreement, since the provisions of Article 19 would apply. If the creator of the organism is a private party, the requirement to provide the relevant information regarding any genetically modified organism, including information regarding any adverse effects the organism might have on the conservation and sustainable use of biological material, should be included in the contract between the party and the Contracting Party or private party giving access to the genetic resources. The existence of a patent would help to ensure that the genetically modified organism was within the control of the patent owner or its licensee, thereby minimizing the likelihood that the organism would be widely distributed or mishandled in ways that could have undesirable effects. Such control also would ensure that liability could be established should an accident occur with the organism. As mentioned before, such arm's-length contracts ensure that both the party receiving access and the Contracting Party or private party granting access clearly understand their rights and obligations at the outset of the relationship and such contracts can be enforced in courts in the jurisdiction agreed upon, with judgements enforceable in courts in other jurisdictions as provided in international agreements.

The provisions of the TRIPS Agreement would impose a requirement to protect, from unauthorized disclosure to, acquisition by, or use by other parties in a manner contrary to honest commercial practices, undisclosed information that might be provided in order to fulfill the disclosure obligation of the contract. Article 19 of the CBD and the provisions of the TRIPS Agreement, therefore, are mutually supportive.

Conclusion

A close look at the obligations of the provisions of the CBD most frequently cited as related to the provisions of the TRIPS Agreement reveals that, rather than conflicting, the provisions of the TRIPS Agreement are supportive of measures that would implement the obligations of the CBD most effectively. As before, we recommend that WTO Members that are also Contracting Parties to the CBD and that are concerned about consistency of particular measures bring those measures to the attention of the TRIPS Council so that they can be discussed.