

THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE PROTECTION OF TRADITIONAL KNOWLEDGE

By means of a communication dated 21 June 2002, the following text has been received from the Permanent Mission of Brazil on behalf of the delegations of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe with the request that it be circulated to TRIPS Council Members.

Summary

- We believe that the TRIPS Agreement and the Convention on Biological Diversity should be mutually supportive and promote the sustainable use of resources. Modifications in the TRIPS Agreement are necessary to ensure that it will not run counter to the objectives of the CBD.
- While the CBD recognizes Members' sovereign rights over their biological resources, the TRIPS Agreement allows Members to provide patents over biological resources (plants, animals and micro-organisms). Currently, the TRIPS Agreement contains no provisions preventing biopiracy acts, in which a person may claim patent rights in one country over genetic resources that are under the sovereignty of another country.
- In particular, the TRIPS Agreement contains no provisions ensuring the prior informed consent of the owners of the biological resources used in the invention. The Agreement also contains no provisions allowing a Member's claims to enforce its national regimes for fair and equitable sharing of benefits from the patenting of its own genetic resources in another country.
- In this connection, the TRIPS Agreement should be amended in order to provide that Members shall require that an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition to acquiring patent rights:
 - (i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention;
 - (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes; and
 - (iii) evidence of fair and equitable benefit sharing under the national regime of the country of origin.
- Failure to provide a solution to ensure a mutually supportive relationship between TRIPs and the CBD may turn out to be detrimental to the objectives of both instruments. With a view to avoiding conflicts in the implementation of TRIPS, an amendment of the

Agreement to accommodate some essential elements of the CBD will be a necessary outcome of the single undertaking of negotiations under the outstanding implementation issues, as part of the multilateral round of trade negotiations under the Doha Development Agenda.

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A. INTRODUCTION

1. The Doha Ministerial Declaration has taken a significant decision to examine the relationship between the Convention on Biological Diversity (CBD) and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The Declaration provides, in paragraphs 12 and 19, mandate for Members to introduce proposals for negotiations in the context of outstanding implementation issues, which “*shall be an integral part of the Work Programme*” (paragraph 12) established by the Ministerial Conference. In light of Paragraph 47 of the Doha Ministerial Declaration, “*the conduct, conclusion and entry into force of the negotiations shall be treated as part of a single undertaking*” of the multilateral round of trade negotiations under the Doha Development Agenda.

2. It should be recalled that, in the context of the review of Article 27.3(b) of the TRIPS Agreement, a number of Members, in particular developing countries, have presented their views on the relationship between the Agreement and the Convention on Biological Diversity, which include a number of proposals to ensure compatibility between the TRIPS Agreement and the CBD¹. Furthermore, in the Seminar on the Protection and Commercialization of Traditional Knowledge (New Delhi, 3-5 April, 2002)², several developing countries have expressed support for the need to develop an internationally agreed instrument that recognizes protection of traditional knowledge at the national level, as it would not only prevent misappropriation but also ensure that national level benefit sharing mechanisms and laws are respected worldwide.

3. Based on Paragraphs 12 and 19 of the Doha Ministerial Declaration, this submission addresses “the relationship between the TRIPS Agreement and the CBD and protection of Traditional Knowledge”. The elements addressed in this document in no way exhaust the issues to be raised in the context of the relationship between the TRIPS Agreement and the CBD in light of paragraphs 12 and 19. The co-sponsors of this proposal may bring further clarifications and complements to the issues contained in this document. This submission is without prejudice to positions that its co-sponsors might take subsequently.

B. RELEVANT PROVISIONS IN THE CONVENTION ON BIOLOGICAL DIVERSITY

4. The TRIPS Agreement and the Convention on Biological Diversity contain important elements in common. Among other relevant provisions in the CBD, its objectives, as stated in **Article 1**, 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 the genetic resources. **Article 3** of the Convention recognizes the principle of sovereign right of its Contracting Parties to

¹ See, for instance, documents WT/GC/W/282 of 6 July 1999 by Venezuela; WT/GC/W/25 of 13 July 1999 by the Least Developed Countries; WT/GC/W/362 12 October 1999 by Bolivia, Colombia, Ecuador, Nicaragua, and Peru; IP/C/W/166 of 5 November 1999 by Cuba, the Dominican Republic, Honduras and Nicaragua; IP/C/W/195 of 12 July 2000 by India; IP/C/W/206 of 20 September 2000 by the African Group; and IP/C/W/228 of 24 November 2000 by Brazil.

² The International Seminar was convened by the Government of India and UNCTAD, with the participation of representatives from Brazil, Cambodia, Chile, China, Colombia, Cuba, Egypt, Kenya, Peru, Philippines, Sri Lanka, Thailand, Venezuela and India.

exploit such resources. **Article 15** specifically obliges the Parties to take necessary measures to share in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Party providing such resources, on mutually agreed terms. Article 15 unambiguously states that the authority to determine access to genetic resources rests with national governments and is subject to national legislation and that access, where granted, shall be on mutually agreed terms and shall be subject to the prior informed consent of the Contracting Party providing such resources. **Article 16(5)** of the CBD further states that 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. Finally, **Article 8(j)** of the CBD enjoins Contracting Parties to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities and encourages the equitable sharing of benefits arising from their utilization.

5. Moreover, the VI Conference of the Parties of the CBD recently adopted (in the Hague, Netherlands, 7 - 19 April 2002) under Decision VI/24 ("Access and benefit-sharing as related to genetic resources") the **Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization**, which serves as inputs when developing and drafting legislative, administrative or policy measures on access and benefit-sharing with particular reference to provisions under Articles 8(j), 10 (c), 15, 16 and 19; and contracts and other arrangements under mutually agreed terms for access and benefit-sharing. Among other important provisions, the Bonn Guidelines define, under the Chapter "Roles and Responsibilities in Access and Benefit-Sharing Pursuant to Article 15 of the Convention on Biological Diversity", that "Contracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted. These countries could consider, *inter alia*, the following measures: (...) (ii) Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights; (iii) Measures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources." Under the provisions on "National monitoring and reporting", the Bonn Guidelines further defines that "depending on the terms of access and benefit-sharing, national monitoring may include (...) (c) applications for intellectual property rights relating to the material supplied".

6. Regarding the "Role of Intellectual Property Rights in the Implementation of Access and Benefit-Sharing Arrangements" under the Bonn Guidelines, the Conference of the Parties to the CBD "invites Parties and Governments to encourage the disclosure of the country of origin of genetic resources in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted". The COP "also invites Parties and Governments to encourage the disclosure of the origin of relevant traditional knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity in applications for intellectual".

C. THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY

7. We believe that the TRIPS Agreement and the CBD should be mutually supportive and promote the sustainable use of resources. At the implementation level, conflicts between the two

Agreements could arise, for instance, in the case of patents claimed over genetic resources (sometimes even in naturally occurring genetic resources), which are protected by the CBD. Some examples are already well known to the general public. In its paper on "*Protection of Biodiversity and Traditional Knowledge*" (IP/C/W/198), for instance, India reports its experience with cases of patents claimed over turmeric, karela, basmati and the neem tree; another example is the case of the ayahuasca vine (a native plant of the Amazonian rainforest used by thousands of indigenous peoples of the Amazon for sacred religious and healing ceremonies).

8. Unauthorized patents on a Member's genetic resources, granted outside its territory raises the issue of potential conflicts with the principle of the sovereignty of the Contracting Parties of the CBD over their genetic resources. Currently, the TRIPS Agreement allows Members to provide for patents – which are private rights – over genetic resources (plants, animals and micro-organisms). The Agreement, however, contains no provisions preventing a person to claim patent rights in one country over genetic resources that are under the sovereignty of another country. In particular, TRIPS contains no provisions allowing a Member's claims to enforce fair and equitable sharing of benefits from the patenting of its own genetic resources abroad. In the absence of clear provisions in TRIPS providing for a mutually supportive relationship of that Agreement with Members' obligations under the CBD, implementation of the TRIPS Agreement may allow for acts of biopiracy and thus result in systemic conflicts with the Convention. With a view to avoiding conflicts in the implementation of TRIPS, an amendment of the Agreement to accommodate some essential elements of the CBD will be a necessary outcome of negotiations related to the mandate in Paragraphs 12 and 19 of the Doha Ministerial Declaration. Failure to provide a solution to this relationship may turn out to be detrimental to the objectives of both instruments.

9. In order to provide a mutually supportive relationship between the TRIPS Agreement and the Convention on Biological Diversity, one important step would be to ensure that patenting of biological resources – plants, animals or micro-organisms – shall not run counter to the provisions of the CBD, in particular those provisions recognizing the sovereignty of the Contracting Parties of the CBD over their genetic resources; the objectives of benefit sharing and of prior informed consent; and the protection of traditional knowledge.

D. PROPOSAL

10. In this connection, it is proposed that the TRIPS Council recommends to the Trade Negotiations Committee that it takes a decision to the effect that the TRIPS Agreement should be amended in order to provide that Members shall require that an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition to acquiring patent rights:

- (i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention;
- (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes;
- (iii) evidence of fair and equitable benefit sharing under the relevant national regimes.

11. Such measures are fully in line with the provisions of the Convention on Biological Diversity and the recommendations of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation. An amendment of the TRIPS

Agreement to include such provisions would prevent systemic conflicts with the CBD arising from the implementation of TRIPS.

12. From a practical standpoint, it would be more cost-effective to establish an internationally accepted solution as suggested above to prevent biopiracy than to divert national resources to expensive judicial processes for the revocation of patents that include illegal genetic resources (as experienced, for instance, by the Government of India and Amazonian countries in challenging patents abroad over its genetic resources). Developing countries, in particular, do not have the resources to follow each and every patent issued outside their territories on the use of their resources.

13. Besides addressing a crucial problem of coherence between two binding international agreements, fulfilling such requirements would not be any more burdensome than any other regular requirement in the already existing patent application procedures. Certainly, law-compliant, *bona fide* companies and individuals would not have difficulties in fulfilling the requirements mentioned in paragraph 14 above – and many of which already engage in bilateral contracts that include the elements of such requirements. Consequently, the proposed amendment would have the clear benefit of providing a predictable environment for Governments, investors, traditional communities and researchers. Research and development in biotechnology in developing countries would thus be encouraged, which would be in line with the objectives of the TRIPS Agreement to promote technological innovation and the transfer and dissemination of technology.

14. In line with Article 16 of the CBD, several countries³ today are putting in place legislation to regulate access to genetic resources, many of which contain intellectual property-related provisions. In many cases, such countries include requirements to disclose the origin of the source of the genetic material used in biotechnological inventions and the related traditional knowledge used in the invention, as well as requirements of evidence of benefit sharing and prior informed consent from the relevant national authorities.

15. The proposed requirements in paragraph 14 would also represent an important step towards ensuring, although only to a limited extent, protection of traditional knowledge from unauthorised patenting by third persons without the prior informed consent of the traditional communities that hold the involved knowledge. Traditional communities have faced threat of misappropriation of their knowledge arising from increasing evidence of biopiracy and the grant of bad patents. One of the major concerns in the global community today refers to the patenting of new biotechnological inventions based on the biological resources and associated traditional knowledge, without any share of the benefits arising out of commercial use to the communities who conserved and developed such resources and knowledge.

16. The incorporation of the proposed requirements in the TRIPS Agreement, however, would only provide defensive protection for traditional communities from misappropriation of their knowledge – associated or not to genetic resources – through unauthorized patenting. Consequently, it might be necessary for the TRIPS Council to give further consideration to proposals regarding an international framework to provide positive protection of traditional knowledge, which would recognize protection of traditional knowledge at the national and regional levels. As reflected in the Communiqué issued by the Seminar on the Protection and Commercialization of Traditional Knowledge (New Delhi, 3-5 April, 2002) regarding the process of identifying essential components of a framework for international recognition of various *sui generis* systems, customary law and others for protection of TK, “some of the possible components identified include: (i) local protection to the rights of TK holders through national level *sui generis* regimes including customary laws as well as others and its effective enforcement *inter alia* through systems such as positive comity of protection systems for TK (ii) protection of traditional knowledge through registers of TK databases in order to

³ The Andean Community, Brazil, Costa Rica, India, the Philippines, Sweden, among others.

avoid misappropriation (iii) a procedure whereby the use of TK from one country is allowed, particularly for seeking IPR protection or commercialization, only after the competent national authority of the country of origin gives a certificate that source of origin is disclosed and prior informed consent, including acceptance of benefit sharing conditions, obtained (iv) an internationally agreed instrument that recognizes such national level protection. This would not only prevent misappropriation but also ensure that national level benefit sharing mechanisms and laws are respected worldwide.”

17. In light of the above, Members reserve the right to bring further proposals in the context of negotiations under paragraphs 12 and 19 of the Doha Ministerial Declaration regarding other issues regarding the relationship between the TRIPs Agreement and the Convention on Biological Diversity, such as the development of an international framework for positive protection of traditional knowledge.
