

**THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION  
ON BIOLOGICAL DIVERSITY (CBD) AND THE PROTECTION OF TRADITIONAL  
KNOWLEDGE – ELEMENTS OF THE OBLIGATION TO DISCLOSE EVIDENCE  
OF BENEFIT-SHARING UNDER THE RELEVANT NATIONAL REGIME**

Submission from Bolivia, Brazil, Colombia, Cuba, Dominican Republic  
Ecuador, India, Peru and Thailand

The following communication, dated 4 March 2005, is being circulated at the request of the delegations of Bolivia, Brazil, Colombia, Cuba, Dominican Republic, Ecuador, India, Peru and Thailand. It was circulated as an advance copy for the Council's March 2005 meeting.

**I. INTRODUCTION**

1. By a communication dated 2 March 2004 the delegations of Bolivia, Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela submitted a Checklist of Issues on the relation between the TRIPS Agreement and the Convention on Biological Diversity (CBD) with the aim of facilitating more focused, structured and result-oriented discussions on this issue.<sup>1</sup> Communications elaborating on the first and the second of the three sets of issues identified in the Checklist i.e. elements of the disclosure of source and country of origin of biological resources and/or traditional knowledge used in inventions, and elements of the obligation to disclose evidence of prior informed consent under the relevant regime, were circulated in the TRIPS Council as IP/C/W/429/Rev.1 and IP/C/W/438 respectively.

2. This communication elaborates on the third element of the checklist of issues as a basis for further discussion in the Council. It should be noted, however, that the elements relating to disclosure of origin and source of biological material used in inventions and the elements relating to prior informed consent and benefit-sharing are closely interlinked. This communication should therefore be read together with the earlier submissions.

A. WHAT SHOULD BE THE MEANING OF EVIDENCE OF BENEFIT-SHARING UNDER THE RELEVANT NATIONAL REGIME?

3. The disclosure of evidence of benefit-sharing arising out of the utilization of genetic resources and/or traditional knowledge in inventions, as contemplated, is aimed at not only ensuring that there is benefit-sharing *per se* but that sharing of benefits is fair and equitable among the parties, taking into account the circumstances of each particular case. The provision of evidence of benefit-sharing will therefore include evidence that there was sharing of the benefits arising out of the utilization of the genetic resources and/or traditional knowledge in the invention and that the shares of benefits that accrued to the source and country of origin and/or local/indigenous community, where applicable, was

<sup>1</sup> See IP/C/W/420 and IP/C/W/420/Add. 1.

equitable and fair in the circumstances. While it has been argued that there may be no straightforward way of determining the equitable and fair sharing of benefits, in the very least there are a number of factors that could be used to make this determination. These include, among others:

- assuming that there was sufficient prior informed consent, that the sharing of benefits or an arrangement for future sharing of benefits is premised upon mutually agreed terms in the context of Article 15(7) of the CBD. Mutually agreed terms generally cover elements relating to the conditions, obligations, procedures, types, timing, distribution and mechanisms of the benefits shared; and
- that there is a reporting obligation on issues relating to patenting or commercialisation especially where future benefit-sharing is contemplated.

4. In this regard, given that the CBD recognizes the rights of states to prescribe the conditions of access to the genetic resources that are under their sovereign jurisdiction, it is expected that the prevalent laws and practices of the countries of origin of the genetic resources and/or associated traditional knowledge should provide the framework within which to determine the terms of fair and equitable benefit-sharing.

5. Some have argued that requiring patent applicants to disclose evidence of benefit-sharing, as well as the origin of genetic resources and evidence of prior informed consent, cannot, *per se*, transfer benefits.<sup>2</sup> Mechanisms for benefit-sharing, it has been suggested, should be established at the national level. It should be pointed out, however, that a requirement for patent applicants to disclose evidence of benefit-sharing and prior informed consent would not be intended as a replacement for or alternative to national access and benefit-sharing regimes. On the contrary, it is intended that a requirement of disclosure of evidence of benefit-sharing would operate, in effect, as a vital supplementary measure and a necessary incentive for patent applicants to comply with the prevalent laws and practices of the countries of origin of the genetic resources and/or associated traditional knowledge, in accordance with the objectives and norms of the CBD.

6. In this regard, bio-prospectors, researchers and other prospective patent applicants who are committed to accessing biological resources and associated traditional knowledge in a fully lawful manner would have nothing to fear from disclosure requirements relating to benefit-sharing and prior informed consent. The disclosure requirement should not be found cumbersome in the least, given that such a requirement would do little other than ask of patent applicants that they supply information to the effect that the laws of the countries of origin of the genetic resources have been fully complied with.

7. On the other hand, as has been pointed out in previous submissions, bio-piracy is a global problem and, more often than not, involves the acquisition of material in one country and the seeking of a patent over that material, or over inventions deriving from or involving that material, in another country. Hence, while national level access and benefit-sharing regimes and/or *sui generis* systems for the protection of traditional knowledge associated with biological resources are currently being developed in several countries, such national regimes or systems by themselves could not be sufficient to protect and fully preserve biological materials and/or associated traditional knowledge. For example, the ability of patent offices and other authorities in a national jurisdiction to prevent bio-piracy, as well as to enforce prior informed consent and benefit-sharing mechanisms, does not *ipso facto* lead to similar actions in respect of patent applications in other countries.

8. What is needed is the establishment of an international framework of protection. Such a system would provide, *inter alia*, a procedure whereby the use of biological material and/or associated traditional knowledge from one country is allowed, particularly for commercialisation and/or the

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<sup>2</sup> See United States, IP/C/W/434.

taking out of intellectual property rights, only after the competent authority in the country of origin certifies that the source of origin has been disclosed, and that prior informed consent and benefit-sharing conditions have been accepted. The patent system should be supportive of, and not run counter to, the objectives of such a framework. The TRIPS Agreement, in effect, has a role to play in supporting its operation. As in the case of disclosure of evidence of prior informed consent, requiring patent applicants to provide evidence of fair and equitable benefit-sharing will enhance the credibility of the patent system by contributing to the realization of the stated objectives and principles of TRIPS itself, as enshrined in Articles 7 and 8 of this WTO Agreement.<sup>3</sup>

**B. WHEN IS THIS EVIDENCE TO BE INTRODUCED BY THE PATENT APPLICANT?**

9. There have been questions raised about the point when evidence of benefit-sharing should be introduced by the patent applicant since, it is argued, that the benefit-sharing could only take place after the grant of a patent and the commercialisation of the relevant technology. While this may be true, it does not necessarily raise a problem with respect to furnishing evidence of benefit-sharing at the time of applying for the grant of a patent. In the first instance, the very fact of gaining access may trigger a certain level of benefit-sharing. To juxtapose with patent law, it is common practice that companies or individuals who require access to background intellectual property to undertake further research and development may pay for the benefit of having access to such background information.

10. More importantly, however, where the real benefits can only arise from the patenting and commercialisation of the invention which utilised genetic resources and/or traditional knowledge, the applicant will still have to provide evidence at the time of the application. The nature of the evidence contemplated here is evidence of the existence of an arrangement for the fair and equitable sharing of any benefit that may arise out of the utilization of the resources, in accordance with the terms of the country of origin's national laws, regulations and practices. It could also be contemplated that the applicant would, in providing evidence of the existence of an arrangement to ensure future sharing of benefits, have to indicate how the national authority (and community, where applicable) would enforce such an arrangement without having to resort to expensive litigation. This is an important consideration because it can not always be assumed that the two parties, especially where local or indigenous communities are involved, would be able to negotiate and enforce the arrangement on equal terms.

**C. WHAT SHOULD BE THE OBLIGATION IF THERE IS NO RELEVANT NATIONAL REGIME IN THE COUNTRY OF ORIGIN?**

11. Where there is no national regime a similar approach to that taken for prior informed consent discussed in Document IP/C/W/438 would apply. In particular, it is foreseen that the applicant will be deemed to have complied with the obligation by indicating in the relevant declaration that there was no national access and benefit-sharing regime in the country of origin, but that there was, in any case, benefit-sharing or an arrangement for future benefit-sharing with the authority or community in charge of the location where the genetic resources and/or traditional knowledge were accessed, in a manner that fully respects the prevalent laws, regulations and practices of the country of origin.

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<sup>3</sup> See IP/C/W/438.

D. WHAT SHOULD BE THE LEGAL EFFECT OF NOT PROVIDING EVIDENCE OF FAIR AND EQUITABLE BENEFIT-SHARING UNDER THE RELEVANT NATIONAL REGIME?

12. To fulfil the requirement of furnishing evidence of benefit-sharing, the applicant will have to discharge a positive obligation. As with the disclosure of source and country of origin and evidence of prior informed consent, it is foreseen that the requirement for furnishing evidence of benefit-sharing would be provided for by obligating Members to require, as a condition for acquiring patent rights, that applicants furnish evidence of fair and equitable benefit-sharing with respect to genetic resources and/or traditional knowledge used in the invention. The nature of the legal effect of not providing evidence of benefit-sharing will also depend on whether it is at the pre or post-grant stage.

13. Where it is determined that genetic resources and/or traditional knowledge was used in an invention but no evidence of benefit-sharing or an arrangement for future benefit-sharing has been furnished as required before the examination or grant of a patent, the legal effect could be that the application would not be processed any further until the submission of the necessary declaration and evidence. As with disclosure of source and country of origin and prior informed consent, this could be accompanied with penalties, including criminal penalties where appropriate, and time-limits within which the proper declaration and evidence must be provided. Otherwise the application could be deemed withdrawn. The failure to provide evidence of benefit-sharing should justify the non-processing of the application.

14. Where the failure to provide evidence of benefit-sharing is discovered after the grant of a patent, the legal effect could include:

- Revocation of the patent where it is determined that there is fraudulent intention behind the failure to provide evidence of benefit-sharing. In addition to, or as an alternative to revocation, criminal and/or administrative sanctions may also be imposed, in particular, to ensure adequate compensation where it is eventually determined that no benefits were shared or are intended to be shared;
  - Full or partial transfer of the rights to the invention, also as an alternative to revocation, as a means of promoting fair and equitable benefit-sharing;
  - Criminal and/or civil sanctions, outside the patent system, including the possibility of punitive damages, where it is determined that the patent holder in fact provided benefits but did not provide the evidence in the application.
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