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

(Submission by Brazil, Bolivia, Cuba, Dominican Republic, Ecuador, India, Thailand, Peru and Venezuela to the TRIPs Council on 28 May 2003)

INTRODUCTION

1. Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Peru, Thailand, Venezuela, Zambia and Zimbabwe had made a submission in the TRIPS Council on the relationship between the TRIPS Agreement and the CBD and the protection of Traditional Knowledge in June 2002[1]. The submission was made under paragraphs 12 and 19 of the Doha Ministerial Declaration. This submission was preceded by several papers and submissions from developing countries[2] to develop an effective and consistent framework so as to enable the WTO Members to meet their obligations under both the TRIPS and the CBD. The key issues raised in these papers was 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 regime; and

(iii) evidence of fair and equitable benefit sharing under the relevant national regime.

The Doha Ministerial Declaration provided a mandate to address the outstanding implementation issues on a priority basis by the end of year 2002. The deadline recommended by the Doha Ministerial Declaration has now passed, without any recommendation to the TNC. It is therefore incumbent on the TRIPS Council to treat this matter as one of great urgency, so as to arrive at some practical proposals for the TNC. The Doha Ministerial Declaration reaffirmed the objective of sustainable development. In order to achieve that objective and to fulfil the commitment to the interests of developing countries, it is incumbent upon the Members to arrive at an appropriate decision on this issue.

3. The purpose of this present submission is to highlight and strengthen the principal arguments for inserting a provision in the TRIPS Agreement that mandates patent applicants for inventions that use biological resources and traditional knowledge, to disclose the source of origin of such resource and knowledge, as well as provide evidence that they have obtained the necessary prior informed consent (PIC), and complied with national laws on benefit sharing. Such a provision in the TRIPS Agreement is critical for ensuring that the TRIPS Agreement and the CBD are implemented in a mutually supportive manner.

[1] Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Peru, Thailand, Venezuela, Zambia and Zimbabwe, IP/C/W/356

[2] See, for instance, Brazil, IP/C/W/228; India, IP/C/W/195; China, IP/C/M/36/Add.1, para 228.

EQUITY & PROTECTION AGAINST MISAPPROPRIATION

4. Disclosure of the source and the country of origin and evidence of PIC and fair and equitable benefit sharing in a patent application would play a significant role in preventing biopiracy and misappropriation[3] and in some cases, prevent the issue of 'bad patents' awarded without due regard to the prior use and knowledge with regard to the resource. There has been extensive documentation of patents being sought over resources and knowledge freely appropriated from biodiversity rich countries, as well as patents on the resources as they exist, without any further improvement or where the value addition does not appear to fully conform to the accepted benchmarks for inventiveness. Some of these examples include patents granted on quinoa and ayahusca, and on products based on plant material and knowledge developed and used by local communities such as the cases of turmeric, neem, kava, barbasco, endod and bitter gourd.

5. In the absence of norms of disclosure of source of origin of the biological resource and associated traditional knowledge, it can be said that a country of origin claiming that the 'invention' is not genuine, can pursue legal remedies under the patent laws of the country which has granted a patent; or its own laws on access to resources. However, pursuing a legal remedy under international laws and in multiple jurisdictions is complicated and expensive, and may not be economically feasible for many aggrieved countries. Moreover, the peculiar nature of the patent laws in countries which recognize prior art outside their country only in the form of written and published information, make legal challenges formidable and cumbersome.

6. It is our submission that in the case of inventions based on biological resources and/or traditional knowledge related to the same, the source of origin of the resources and details of the traditional knowledge, are critical for ascertaining inventorship, that is, whether the applicant has "invented" what s/he claims in the patent, or whether s/he has just found it in nature or obtained it from traditional cultures.[4] This is especially important when the traditional knowledge used in the invention is undocumented and exists in oral form, or is documented in a local language. Disclosure of origin of the resource and traditional knowledge would enable a better assessment by the patent examiner of the novelty and inventive step involved in the invention, as well as enable those having knowledge about the oral/undocumented knowledge to supply the necessary evidence of prior art to the patent examiners, at least in those patent regimes having pre-grant opposition procedures.

7. Disclosure of origin of the resource and associated traditional knowledge, and evidence of PIC and benefit sharing will therefore serve the purposes of: (a) reducing instances of bad patents; (b) enabling the patent office to ascertain more effectively the 'inventive step' claimed in a particular patent application; (c) enhancing the ability of countries to track bad patents in the instances where they are granted and challenge the same; (d) improving compliance with their national laws on PIC and fair and equitable benefit sharing prior to accessing a biological resource/associated traditional knowledge. This would also increase the credibility of the patent system, as well as contribute to achieving the principal objectives of the TRIPS Agreement. Placing the onus on a patent applicant to disclose the basis of its claims is a step that can pre-empt any misuse of patent laws and thereby prevent misappropriation of knowledge and resources.

8. Notions of equity and good faith mandate that the international community create an equitable system for the acquisition, maintenance, and enforcement of intellectual property rights,

[3] Brazil, IP/C/M/39, para 126
[4] *See*, India, IP/C/M/37/Add.1, para 253; India, IP/C/M/39, paras 122-123

which does not *a priori* exclude any section of the society.[5] It has been acknowledged that the principle of equity dictates that a person should not be able to benefit from exploiting IPRs based on genetic resources or associated knowledge acquired in contravention of any legislation governing access to the material.[6] This aspect has also been recognized under the CBD, Article 16 (5) of which states that countries should cooperate to ensure that patents and other intellectual property rights *are supportive of and do not run counter to the objectives of the CBD*. The CBD establishes the basic framework for access, PIC and fair and equitable benefit sharing, in recognition of a country's sovereign rights to its biological resources. Establishing a link between the framework of the CBD with the norms of disclosure of a patent application in the TRIPS Agreement is aimed at putting in place a mechanism for ensuring that patents are not granted, or are invalidated if granted in violation of the rights of the countries/ communities over their resources/knowledge. Such a provision, it is believed, will be in consonance with, and in pursuance of the CBD as well as the objectives articulated in Article 7 of the TRIPS Agreement, which emphasize that the '*protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation… 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'*.

9. It is therefore submitted that the disclosure norms should include evidence of PIC through approval of authorities under the relevant national regime in the country of origin of the resource and traditional knowledge, as well as evidence of fair and equitable benefit sharing under the relevant national regime.

ADDITIONAL CONDITIONS DO NOT VIOLATE PRINCIPLE OF NON-DISCRIMINATION

10. One of the arguments against the proposal of requiring the norms of disclosure to include source of origin of the biological resource and associated traditional knowledge, as well as evidence of PIC and benefit sharing, has been that the amendments would not be consistent with the TRIPS Agreement and would violate the principle of non-discrimination between fields of technology.[7] There would be discrimination only if the three criteria of patentability (novelty, inventiveness and usefulness) are applied differently to different fields of technology. For the reasons discussed below, it is submitted that different norms of disclosure for inventions based on biological resources and traditional knowledge, would not constitute discrimination between fields of technology.

11. The basis for the invention, claimed in the patent application, can often be the existing knowledge and use by a local or indigenous community pertaining to the biological resource, a fact that has been recognized.[8] Before a patent is granted, it would therefore be important to verify the extent of the prior existing knowledge that it utilizes and the 'inventiveness' involved in the invention. Procedures adopted for granting patents often have to be different depending on the 'field of technology'. For instance, in the case of micro-organisms, the nature of the invention demands that the micro-organisms that are used are deposited prior to grant of the patent. In a similar vein, where the field of technology involves bioresources, the special circumstances

[5] India, IP/C/M/28; Bolivia , Columbia, Ecuador, Nicaragua, Peru, IP/C/W/165; Cuba, Honduras, Paraguay, Venezuela, IP/C/W/166

[6] Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (September 2002), http://www.iprcommission.org/papers/text/final_report.

[7] United States, IP/C/W/257

[8] UNDP, *Human Development Report* (1999)

surrounding bioresources and associated knowledge, should require norms for disclosure of source of origin, and evidence of PIC and fair and equitable benefit sharing to enable, *inter alia*, adequate assessment of the tests of patentability. It is an established principle of interpretation that treating dissimilar fields of technologies differently will not be contrary to the non-discrimination principle.[9]

ADDITIONAL CONDITIONS DO NOT CONSTITUTE AN UNNECESSARY BURDEN

12. We emphasize that the logic behind placing the onus of disclosure of source of origin, evidence of PIC and fair and equitable benefit sharing on a patent applicant is that it is the patent applicant who is involved in the research and finding out of the products based on such research. The applicant would also have information on whether s/he complied with the national laws of the country of origin of the biological resource and associated traditional knowledge, with regard to PIC and fair and equitable benefit sharing. Requiring disclosure of origin of the resource and associated traditional knowledge, and evidence of PIC and fair and equitable benefit sharing, is a reasonable procedure based on knowledge readily available with a patent applicant.

13. Requiring the norms of disclosure would therefore not amount to a legal and administrative nightmare or an unnecessary burden on either the patent applicant or the patent office, contrary to what has been suggested.[10] Such a requirement would also pave the way for a comprehensive international solution, so that countries that are victims of biopiracy do not need to divert their precious national resources to expensive judicial procedures for the revocation of patents based on illegally obtained resources and associated knowledge.[11]

CONSEQUENCES TO BE ADDRESSED UNDER PATENT LAW

14. It is an established principle of patent law in most jurisdictions that a false representation of a material information could lead to revocation of a patent. Under the current Indian law governing patents, for instance, failure to disclose or wrongful disclosure of source of origin of a biological resource and evidence of traditional knowledge associated with the same, or a false suggestion or representation could result in revocation of the patent. Under U.S. law, when a patent is marked by a failure to disclose material information, or submission of false material information, with intent to mislead, the patent becomes unenforceable. This is also called the doctrine of inequitable conduct. The consequences of failure to disclose, or wrongful disclosure of origin of the biological resource and associated traditional knowledge, and evidence of PIC and fair and equitable benefit sharing should be addressed within the patent system, in the same manner as consequences of material information have been treated within the patent system.

15. Leaving the consequences of disclosure of source of origin, and evidence of PIC and fair and equitable benefit sharing outside the realm of patent law would render these requirements ineffective. There should therefore be provisions in the patent law to ensure that these requirements are not reduced to just a formality.[12]

LIMITATIONS OF RELYING ONLY ON DATABASES

[9] India, IP/C/M/37 Add.1, para 224.
[10] United States, IP/C/W/257.
[11] Brazil, IP/C/M/39, para 126.
[12] India, IP/C/M/39, para 232

16. Compiling databases of traditional knowledge at the national level is an important aspect being addressed at the national level in several countries, including India, through efforts at compiling a Traditional Knowledge Digital Library. Such databases would play a key role in facilitating a patent examiner's check against patent requests relating to the existing documented knowledge of traditional communities.[13] However, given the vast breadth and depth of such knowledge, the inherent limitation of such documentation is that this cannot be completely comprehensive and exhaustive of all the traditional knowledge available in a country.[14] This would be particularly true when traditional knowledge used in a particular invention was undocumented, based on oral traditions or documented in the local language.[15] In such cases, reliance on the documented source itself may not be sufficient. Moreover there are concerns about the appropriateness of use of databases for reasons of loss of confidentiality of the traditional knowledge, which is not in the public domain. Disclosure of the source and nature of the knowledge and location of the material, however, would play a significant role in determining inventorship, that is, whether the applicant has "invented" what he claims in the patent, or whether he has just found it in nature or obtained it from traditional cultures.

17. It has been suggested that the use of databases documenting the knowledge, innovations and practices of traditional communities which can be made widely accessible over the internet, to enable their use by patent examiners, will be an adequate solution to redress the problem of biopiracy.[16] For the reasons discussed above, use of databases is fraught with certain limitations. While use of databases can complement the purpose of expanded disclosure norms, they cannot substitute the same.

LIMITATIONS OF NATIONAL LAWS OR CONTRACTS

18. It has been suggested that there should be a separate law for governing aspects of biopiracy, and that PIC and fair and equitable benefit sharing can be done through contracts as well.[17] The CBD mandates its member states to enact national laws that would facilitate PIC and benefit sharing in a fair and equitable manner, prior to access and use of biological resources and traditional knowledge. It is acknowledged that these mechanisms can and should be used, and several countries have already enacted laws to put in place an Access and Benefit Sharing (ABS) regime. However, this in itself, is insufficient to arrest biopiracy and misappropriation of resources. It also does not achieve the central objective of disclosure norms- that is to stall the reward of a patent for knowledge or information misappropriated from another country.

19. For the same reasons, relying on contracts will be insufficient as well. Contracts being voluntary in nature, would be ineffective if the parties to the contract are of vastly unequal bargaining strengths, as would be the case involving traditional communities and the commercial interests.

20. National systems by themselves would not be adequate to fully protect and preserve traditional knowledge. For example, the ability of patent offices in national jurisdictions to prevent biopiracy as well as to establish informed consent mechanisms to ensure reward to TK holders, does not *ipso facto* lead to a similar action on the patent applications in other countries.

[13] Brazil, IP/C/M/37/Add.1, para 255.
[14] India, IP/C/M/37/Add.1, para 253
[15] India, IP/C/M/37/Add.1, para 253; India, IP/C/M/39, para 123.
[16] United States, IP/C/W/257
[17] United States, IP/C/W/257

Similarly, benefit sharing mechanisms established through national legislations would need to be recognized in user countries.[18] The remedies that can be sought under national laws for access and benefit sharing will also inevitably have only territorial application within the country whose laws are violated. It is not our submission that patent law should be the mechanism to ensure compliance with other international obligations, or that patent law should fill in where other national laws prove ineffective. It is also not our submission that patent laws should facilitate 'benefit sharing' with country/community of origin of the biological resource and knowledge. What is being sought is a simple mechanism whereby patent laws in different countries through the world make an effective determination of 'inventorship' and 'prior art', and further, do not reward a patent applicant for violating the source countries laws on access and benefit sharing.

CONCLUSION

21. Amendments to the TRIPS Agreement to include an obligation to disclose the origin of genetic resources and associated traditional knowledge and to provide evidence of PIC and fair and equitable benefit sharing are imperative to implement the TRIPS Agreement and the CBD in a mutually supportive and complementary way.[19] This obligation would ensure transparency as regards the origin of biological materials that are used in the patent claim, as well as make the CBD provisions on PIC and fair and equitable benefit sharing more effective.[20]

22. It is therefore submitted that adequate amendments be introduced into the TRIPS Agreement to ensure harmonious and mutually supportive implementation of the provisions of the TRIPS Agreement and the Convention on Biological Diversity.

[18] UNCTAD, IP/C/350, summarizing the views and discussions of an international seminar convened with the participation of Brazil, Cambodia, Chile, China, Cambodia, Cuba, Egypt, Kenya, Peru, Philippines, Sri Lanka, Thailand, Venezuela and India at New Delhi, 305 April, 2002.
[19] Brazil, IP/C/W/228; India, IP/C/W/195; Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe, IP/C/W/356; China, IP/C/M/38, para 238.
[20] Norway, IP/C/W/293.