

**THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE  
CONVENTION ON BIOLOGICAL DIVERSITY (CBD) AND THE  
PROTECTION OF TRADITIONAL KNOWLEDGE**

**TECHNICAL OBSERVATIONS ON ISSUES RAISED IN A COMMUNICATION  
BY THE UNITED STATES (IP/C/W/434)**

Submission from Brazil and India

The following submission, dated 4 March 2005, is being circulated at the request of the Delegations of Brazil and India. It was circulated as an advance copy for the Council's March 2005 meeting.

**I. INTRODUCTION**

1. By a communication dated 26 November 2004, the delegation of the United States submitted a proposal<sup>1</sup> on the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) mainly in response to the communications dated 2 March 2004 (IP/C/W/420 and Add. 1 submitted by the delegations of Bolivia, Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela) and 27 September 2004 (IP/C/W/429/Rev. 1 and Add. 1, 2 and 3 submitted by the same delegations plus the delegations of Colombia, Dominican Republic and Pakistan). The communication of 2 March proposed a Checklist of Issues on the relationship between the TRIPS Agreement and the CBD to facilitate more focused, structured and result-oriented discussions on this issue. The 27 September communication elaborated on the first of the three sets of issues identified in the Checklist i.e., the disclosure of source and country of origin of biological resources and/or traditional knowledge used in inventions. A further communication elaborating on the second set of issues in the Checklist i.e. elements of the obligation to provide evidence of prior informed consent under the relevant national regime was submitted to the December 2004 Council for TRIPS meeting.<sup>2</sup>

2. In its submission, the delegation of the United States indicated that it hoped that its paper would permit progress on this issue by identifying common ground where it exists and helping reduce differences among Members in order to resolve concerns expressed by various delegations. We welcome the submission of the United States and, in particular, the desire expressed by the United States to resolve the differences on this issue, as soon as possible, based on the Checklist of Issues as contained in document IP/C/W/420. We look forward to the continued engagement by the delegation of the United States and all other delegations in the TRIPS Council and hope that, working together, we can speedily come to a concrete solution and fulfil the Doha mandate in this regard.

<sup>1</sup> See WTO document IP/C/W/434.

<sup>2</sup> See WTO document IP/C/W/438 submitted by Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela dated 10 December 2004.

3. In its communication, the delegation of the United States expressed a number of concerns regarding the proposed new patent disclosure requirements and offered an alternative approach. While the communication raises some important issues, we consider that it has not made a case against the proposed disclosure requirement. If anything, the communication has provided evidence of why the proposed disclosure requirements would be the best way of achieving the objectives of ensuring that the implementation of the TRIPS Agreement does not undermine or otherwise run counter to the objectives of the CBD. This technical note is aimed at addressing the issues raised by the delegation of the United States and elaborating on why a patent disclosure requirement is the only effective means of addressing matters relating to patents and misappropriation of biological resources and/or associated traditional knowledge. Some of these concerns were already addressed in the submission contained in document IP/C/W/438, as well as in the new submission by a group of developing countries on disclosure of evidence of benefit-sharing. Where necessary, however, we will reiterate the explanations and justification for the various elements of the proposed regime.

## II. GENERAL OBSERVATIONS

4. The delegation of the United States indicates in its submission that it "views with utmost caution any proposals that would add uncertainties to patents rights that may undermine the role of the delicately balanced patent system".<sup>3</sup> There is no doubt that any system that introduces uncertainties and imbalances in the patent system may be detrimental to technological progress in general and protection of inventions in particular. However, the proposed disclosure requirement would in fact introduce much needed certainty and preserve the balance in the patent system in consonance with the objectives and principles of the TRIPS Agreements enshrined in Articles 7 and 8 and the conditions on patent applicants that have been established by other relevant Articles of TRIPS. In this regard, it is important to remember that facilitated access to biological resources and/or traditional knowledge, as acknowledged by the United States in its submission,<sup>4</sup> is of significant importance to researchers and bio-prospectors that use the patent system. By establishing clear internationally agreed rules on disclosure, prior informed consent and benefit-sharing, the proposed requirement would go a long way in establishing certainty in these matters and not uncertainty.

5. Furthermore, since disclosure of source and country of origin, prior informed consent by providers of genetic resources and arrangements for fair and equitable benefit-sharing are issues of high importance for biodiversity rich countries as well as local and indigenous communities, the proposed system will not only ensure the legitimacy of the patent system but will in fact preserve and strengthen the balance in the system. The balance will be preserved by recognizing the contributions of Members as well as of traditional and local communities to innovation directly, or through the conservation of biological resources and/or traditional knowledge. Establishing an equitable and balanced system for the acquisition, maintenance and enforcement of patent rights, which rely upon or are otherwise based on biological resources and/or traditional knowledge, would also help fulfil the objectives of the TRIPS Agreement as expressed in Article 7.

6. The United States also suggests that the "implementation of effective national laws that directly address the relevant goals is the most effective way to proceed".<sup>5</sup> As with the grant and enjoyment of patent rights, the implementation of national access and benefit-sharing laws and policies is indeed very important if an effective system of protection is to be established. However, acknowledgement of the importance of establishing such national systems, a task which several countries have already undertaken or are currently undertaking, does not in anyway provide a basis for rejecting the establishment of an international system to support and facilitate the implementation of the national systems. Such an approach would be akin to arguing that in order to ensure the

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<sup>3</sup> See para 2 of the submission, *supra* note 1.

<sup>4</sup> See para 8 of the submission, *supra* note 1.

<sup>5</sup> See para 4 of the submission, *supra* note 1.

effective operation of the patent system, for example, only national patent laws are needed and not international agreements such as the TRIPS Agreement.

7. Clearly, both national and international mechanisms are critical in ensuring the mutual supportiveness of the implementation of the CBD and the TRIPS Agreement. Bio-piracy and the related issues being addressed in these discussions are issues with a significant international dimension needing international solutions and enforcement. As pointed out in document IP/C/W/438:

"The CBD also provides that States have the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.<sup>6</sup> In essence, these provisions are aimed at regulating, in particular, access by persons from outside the State that holds the genetic resources, a task that requires cooperation and enforcement in third countries. Indeed, Article 5 of the CBD recognizes cooperation of this nature, including through competent international organizations, for conservation and sustainable use of biological diversity."<sup>7</sup>

WTO is a competent organization on matters relating to bio-piracy and the issuance of patents with respect to inventions that have relied upon and/or used biological resources and/or associated traditional knowledge.

### III. SPECIFIC OBSERVATIONS

#### A. PRIOR INFORMED CONSENT AND MISAPPROPRIATION

8. On this issue, document IP/C/W/434 argues that "new<sup>8</sup> patent disclosure requirements will not work to guarantee that prior informed consent was obtained" and that "a completely separate, transparent mechanism needs to be established outside the patent system".<sup>9</sup> An international disclosure requirement alone will not work to guarantee prior informed consent just like a national regime alone will not work. The proposed mandatory, global disclosure requirement is not envisaged as a stand-alone system, but as a vital measure and incentive that would support and ensure the effective operation of national regimes for prior informed consent. Consequently, while contractual arrangements may have a role to play in implementing the requirements of prior informed consent, and could constitute the evidence of prior informed consent under the proposed system, clearly such arrangements alone cannot suffice to ensure the monitoring and enforcement of these requirements in third countries. Contractual arrangements or similar mechanisms in national laws can only suffice if they are obligatory and enforceable across borders.

9. The United States also argues that "a transparent prior informed consent regime is needed to ensure that... researchers and/or collectors can conduct their research activities in an appropriate manner" and that "those with intent of acting in bad faith will not be deterred by disclosure requirements".<sup>10</sup> It is further argued that "the act of patenting *per se*, does not amount to misappropriation". As already noted, the proposed disclosure requirements constitute a core component of international efforts to ensure a transparent regime that, while allowing for access by researchers and/or collectors to biological resources, ensures compliance with national regimes

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<sup>6</sup> See Article 3 of the CBD.

<sup>7</sup> See para 3 of the submission, *supra* note 2.

<sup>8</sup> It is presumed that by characterizing the proposed disclosure system as "new", the United States considers that existing provisions of the TRIPS Agreement permit Members to require of patent applicants the disclosure of the source and country of origin of biological resource and/or associated traditional knowledge used in an invention. However, what is needed for the effective prevention of bio-piracy and misappropriation are mandatory provisions, not permissive ones.

<sup>9</sup> See para 7 of the submission by the United States, *supra* note 1.

<sup>10</sup> Para 8 of the submission, *supra* note 1.

relating to prior informed consent and benefit-sharing. Such transparency and predictability cannot be established through a fragmented nation-to-nation system but only through an internationally established and enforced system. How can myriad separate and different national systems with no common denominator regulate the relationships between entities, persons and activities taking place in different countries?

10. Regarding the deterrence aspect of the disclosure proposal in respect of those actors intent on acting in bad faith, while it is true that the disclosure requirement by itself will not deter them, the legal consequences of the failure to comply with the disclosure requirements of the proposed international regime can, if properly calibrated, deter those bent on acting in bad faith. In this regard, documents IP/C/W/429/Rev.1 and IP/C/W/438 elaborate on several possible legal consequences for non-compliance, the nature of which will depend on whether one is dealing with a formal or substantive component of the disclosure and on whether it is at the level of pre- or post-grant. The legal effects proposed in the above-mentioned documents include non-processing of the patent application, revocation of the patent, full or partial transfer of the rights to the invention, narrowing of the scope of the claims, and imposition of criminal, civil and/or administrative penalties.

11. However, we recognize that these sanctions may be insufficient to have the full deterrence value that is desired. In this regard, we welcome additional proposals by any delegation aimed at strengthening the sanctions for failure to comply with the proposed disclosure requirement in order to ensure that such sanctions provide sufficient deterrence.

12. Finally, with respect to whether patenting *per se* could constitute misappropriation, it is important to note that no suggestion has been made that the act of patenting *per se* would constitute misappropriation under the proposed disclosure regime. It is the act of applying for a patent or patenting an invention where, biological resources and/or traditional knowledge is used, among others: to form part of the claimed invention; during the process of developing the claimed invention; as a necessary prerequisite for the development of the invention; to facilitate the development of the invention; and/or as necessary background material for the development of the invention, without obtaining the prior informed consent of the Member or relevant authorities of the Member in which the biological resources and/or traditional knowledge are obtained and without providing for equitable benefit-sharing, that constitutes a serious form of misappropriation. Moreover, it is clear that the system of patenting *per se* being followed in many cases today results in bad or questionable patents. The reason for that happening is insufficient disclosure of the details of the existing knowledge and the inadequacy of the existing patent system to check the relevant details. The proposed disclosure condition would surely contribute to preventing the issue of bad and questionable patents.

## B. BENEFIT-SHARING

13. Document IP/C/W/434 argues that the proposed disclosure requirement *per se* cannot transfer benefits, as such a requirement would merely convey the information required but would have no mechanism to transfer benefits between parties. As already noted, the proposed obligation to disclose evidence of prior informed consent and benefit-sharing under the TRIPS Agreement is not intended as a stand-alone system but as a system that would supplement and ensure the effective enforcement of national regimes. Consequently, it is not the international obligations *per se* that will transfer benefits but the proposed system coupled with the relevant national regimes. Moreover, given the enormous number of patents granted worldwide, the disclosure requirement will facilitate the monitoring of these patents by the owners of the biological material and/or associated traditional knowledge with a view to check whether prior informed consent and benefit-sharing arrangements are being adhered to by the patent owners upon commercialization. The United States also lists some examples to argue that benefits from an invention would be diminished if the patent was issued and later invalidated, or was never issued, and the invention is nevertheless commercialized.<sup>11</sup> However, the situation exists

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<sup>11</sup> See para. 10 of the US Submission, IP/C/W/434.

for all kinds of patents, and is not limited to patents involving disclosure of the country and source of origin of biological materials and/or associated traditional knowledge. In such cases, as in the case with any other type of patents, other legal means would have to be resorted to by the owners of the biological material and/or associated traditional knowledge to rectify the damage, for example by commercializing the product themselves (in case of invalidation) or competing in the market place with those who commercialize it (in cases of commercialization without patent rights). What changes with the grant of a patent is the grant of a legally enforceable monopoly to the exclusion of everyone else without any feasible recourse, particularly for developing countries and impoverished traditional and local communities, for a long period of time, and it is this damage that will be prevented by the proposed disclosure requirement.

14. 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 or local/indigenous community was 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 determinations. 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 commercialization especially where future benefit-sharing is contemplated.

15. Where there is no national regime, 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 regime in the country of origin, but that there was benefit-sharing or an arrangement for future benefit-sharing, at least, with the authority or community in charge of the location where the biological resources and/or traditional knowledge were accessed.

16. The United States in its submission also raises the question of what would happen where there is no patent but there is in any case commercialization, that is, commercialization that occurs outside the patent system or commercialization by others where the patent is, for example, revoked. These are all important questions and valid concerns. However, these are concerns and issues that will be dealt with outside the patent system and is not a subject that the TRIPS Council can satisfactorily address. The proposed disclosure requirements are aimed at addressing situations where biological resources and/or traditional knowledge is utilized for purposes of obtaining or otherwise exploiting patents. In other words, the system is aimed at addressing patent related issues and therefore only constitutes one element, albeit a crucial one, of a larger national and international benefit-sharing regime. Situations falling outside the patent system would have to be addressed within the national regimes in conjunction with other international rules outside the patent system including, where applicable, by addressing issues relating to trade secret laws or competition laws.

### C. PREVENTING ERRONEOUSLY GRANTED PATENTS

17. Document IP/C/W/434 also submits that the proposed disclosure requirements will be ineffective in preventing erroneously granted patents and that such a requirement would do little to

ensure ascertainment of appropriate inventorship, novelty or inventive step. Indeed, the mere disclosure of source and country of origin may not help ascertain inventorship etc. However, to the extent that the disclosed information will help determine whether the biological resources and/or traditional knowledge was used: to form part of the claimed invention; during the process of developing the claimed invention; as a necessary prerequisite for the development of the invention; to facilitate the development of the invention; and/or as necessary background material and/or information for the development of the invention, such information would be relevant in determining the existence of prior art and the non-obviousness of the claimed invention, determining inventorship or entitlement to the patent, the scope of the claim and/or for understanding or carrying out the invention. Indeed, the United States accepts this premise and argues in its submission, in paragraph 29, that "patent examiners worldwide could use organized searchable databases of genetic resources and traditional knowledge when examining patent applications. This could aid in the discovery of relevant prior art and thereby improve the examination of patent applications in the relevant field".<sup>12</sup> The disclosure of the country and source of origin will enable the patent examiner to do this job more effectively and prevent issue of bad patents.

D. ADDITIONAL CONCERNS RAISED IN THE SUBMISSION BY THE UNITED STATES: UNCERTAINTY, ADMINISTRATIVE BURDEN AND EFFECTIVENESS

18. The submission by the United States raises a number of additional concerns in its communication including that the proposed disclosure requirement would "create a 'cloud' of uncertainty over the patent right", that the requirement would lead to significant administrative burdens and costs, that patent examiners would be unable to determine the validity of prior informed consent or adequate benefit-sharing and that the system would not be an effective monitoring system. First, with respect to uncertainty, as already explained:

"[T]he proposed disclosure requirement would in fact introduce much needed certainty and preserve the balance in the patent system in consonance with the objectives and principles of the TRIPS Agreements enshrined in Articles 7 and 8 and the conditions on patent applicants that have been established by other relevant Articles of TRIPS. In this regard, it is important to remember that facilitated access to biological resources and/or traditional knowledge, as acknowledged by the United States in its submission, is of significant importance to researchers and bioprospectors that use the patent system. By establishing clear internationally agreed rules on disclosure, prior informed consent and benefit-sharing, the proposed requirement would go a long way in establishing certainty in these matters, not uncertainty."<sup>13</sup>

19. The question of administrative burden and costs has already been addressed in an earlier communication.<sup>14</sup> However, it is worth repeating here that while we consider that there will be administrative implications and there may be cost implications for applicants as they are expected to at least employ all reasonable measures to determine the country of origin and source of the material to meet this obligation, it is not foreseen that administrative procedures and costs related to meeting the obligation would be in any way burdensome. In any case, such a burden would generally be subsumed in, or at least not be more burdensome than, the usual burden befalling the patent applicant to make out a case for his claims under current patent procedures and practices.

20. As a matter of patent law practice, there are a number of other disclosure requirements, including disclosure of best mode, and in other jurisdictions, such as the United States, a requirement to disclose all information material to patentability. The proposed requirement is no different from

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<sup>12</sup> See the United States Submission, *supra* note 1.

<sup>13</sup> See para. 4 above.

<sup>14</sup> See the communication of 27 September 2004, *supra* note 10, paras. 9 and 10.

these obligations the fulfilment of which has not been shown to impose any unnecessary burden on applicants. In fact, for the US patent system, the proposed disclosure requirement should not be burdensome at all, as it could most likely be covered under the 'information material to patentability' requirement. The US system would only have to put in place an additional requirement to cover prior informed consent and benefit-sharing. The collection and recording of the information necessary to meet the obligation should not require applicants to undertake significant additional recording and documentation outside what would be done in the process of developing an invention even where there is no disclosure obligation. The disclosure obligation as envisaged, taking into account existing practice, would therefore not impose any burdensome administrative or other costs on applicants.

21. With respect to determining the validity of prior informed consent and adequacy of benefit-sharing, it is important to note, firstly, that no suggestion has been made that patent examiners would be required to determine the validity of prior informed consent or the adequacy of benefit-sharing. Secondly, as explained in the communications of 27 September and 10 December 2004,<sup>15</sup> the obligation of patent applicants would be clearly defined under the proposed mandatory disclosure system and all the patent examiner would be required to determine is that the patent applicant has met the defined disclosure obligation. As noted, in the communication of 10 December, in particular:

"It is foreseen that the applicant will be deemed to comply with the requirement of furnishing evidence of prior informed consent if the patent application contains and/or is accompanied by a declaration, in the prescribed form, indicating that prior informed consent was obtained from the relevant national authorities (and local and indigenous communities, where applicable). Further, the declaration would be accompanied, where relevant, by the actual evidence of prior informed consent, for example, in the form of a certificate or duly certified contract between the applicant and the national authorities of the country of origin. In this regard, it should be noted that it may be possible that a single declaration with the necessary evidence could be furnished to cover the requirements on disclosure of source and country of origin, evidence of prior informed consent as well as evidence of equitable benefit-sharing."<sup>16</sup>

22. Consequently, the role of the patent examiner will be limited to confirming that the patent application contains a declaration in the prescribed form indicating that prior informed consent was obtained and that benefits were shared and/or that there exists an arrangement for future benefit-sharing in accordance with the relevant national law. The patent office will need to take decisions based on these documents only when the validity of a patent is challenged in the pre- or post-grant opposition or revocation proceedings. In such cases the patent office will have evidence from both the parties to the proceedings and could take a decision like any other ground on which the grant of a patent is opposed or revocation of a patent is requested.

23. Finally, on the question of effectiveness of the system. As already pointed out, the proposed regime is not intended as a stand-alone mechanism.<sup>17</sup> However, the proposed international obligation for disclosure coupled with national regimes and other international rules such as those developed under the CBD or elsewhere would constitute an effective system.

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<sup>15</sup> *Supra* notes 10 and 2 respectively.

<sup>16</sup> See para.11 of the submission.

<sup>17</sup> See paras. 6 and 7 above.

#### **IV. OBSERVATIONS ON THE PROPOSED OPTIONS FOR ACHIEVING APPROPRIATE ACCESS AND EQUITABLE BENEFIT-SHARING AND PREVENTING BAD PATENTS**

24. In light of the concerns expressed in its submission, all of which we have addressed in this communication, the United States in its submission also proposed an alternative mechanism outside the patent system as the most effective way of addressing issues related to misappropriation and bio-piracy. Before commenting on the proposed alternative approach, we wish to reiterate that a fragmented nation-to-nation system cannot achieve our objectives. Such a system would entail very high transaction costs and would hence be difficult to implement. Only through an internationally established and enforced system can the problems of misappropriation and bio-piracy, which have a significant international dimension, be effectively addressed.

##### **A. ACHIEVING PRIOR INFORMED CONSENT**

25. While delineated national points of contact and the establishment of permit or other national systems are important elements of a national regime and may be a necessary prerequisite for ensuring prior informed consent, such national requirements can do little to address the transnational character of the problem of misappropriation and bio-piracy.

##### **B. ACHIEVING EQUITABLE BENEFIT-SHARING**

26. The limitations of a contractual system in addressing the international dimension of the issues under discussion have been amply demonstrated in earlier communications and repeated here in paragraphs 8 to 16 above.

##### **C. ORGANIZED DATABASES AND INFORMATION MATERIAL TO PATENTABILITY**

27. While organized searchable databases may play, in some cases, an important role in helping ensure that prior art information is available to patent examiners, we do not see how such databases can be a substitute for the disclosure requirement. Just like organized databases cannot achieve the purposes such as the one served by the requirement under United States law for patent applicants to disclose information material to patentability, or requirements such as for disclosing best mode, it cannot serve the purpose of the disclosure requirement. More importantly, a voluntary system of searchable databases or provision of information material to patentability will provide no guarantee that in fact patent examiners in different countries will consider this information in the prior art search.

28. One should also recall, furthermore, that, as has been pointed out in previous submissions,<sup>18</sup> databases in themselves have other important limitations as a possible tool to facilitate the protection of traditional knowledge. Given the vast breadth and depth of such knowledge, no documentation effort can be completely comprehensive and exhaustive of all the traditional knowledge available in a country. This is particularly true when traditional knowledge used in a particular invention is undocumented, based on oral traditions or documented in a local language. Moreover, in many developing countries there are serious 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. Given these limitations, it is clear that, while databases can, in some cases, complement the purpose of expanded disclosure norms, they cannot substitute them.

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<sup>18</sup> See WTO document IP/C/W/403, submitted by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand and Venezuela.

D. POST-GRANT OPPOSITION AND RE-EXAMINATION

29. While pre-grant and post-grant opposition or re-examination proceedings can rectify the situations of erroneously granted patents, such proceedings cannot replace the need for a disclosure requirement. If anything, the effectiveness of such proceedings with respect to cases involving biological resources and/or traditional knowledge will be significantly improved or may depend on the disclosure obligation. In this regard, the disclosure requirement as envisaged will also be useful in cases relating to challenges to patent grants or disputes on inventorship or entitlement to a claimed invention as well as infringement cases.

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