

**ARTICLE 27.3(B), RELATIONSHIP BETWEEN THE TRIPS AGREEMENT
AND THE CBD, AND THE PROTECTION OF TRADITIONAL
KNOWLEDGE AND FOLKLORE**

Communication from the United States

The following communication, dated 24 November 2004, is being circulated as the request of the Delegation of the United States.

I. INTRODUCTION

1. The purpose of this paper is to permit progress in current discussions under agenda items pursuant to paragraphs 12 and 19 of the Doha Ministerial Declaration. It attempts to identify common ground where it exists, to provide more focus and structure to the discussions, and to help reduce differences in order to resolve concerns that have been expressed by various delegations.

2. In conjunction with paragraph 12, paragraph 19 of the Doha Ministerial Mandate clearly directs the "TRIPS Council, in pursuing its work programme ... to examine the ...relationship between TRIPS Agreement and the CBD, protection of traditional knowledge, and folklore". Some Members have expressed concerns about the difficulty in implementing both agreements and that there may be a conflict between these agreements. Advancing various reasons, some delegations have proposed new disclosure requirements in patent applications regarding: (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.¹

3. On the other hand, the United States is one of a number of Members that see no conflict between the TRIPS Agreement and the CBD and that consider that these agreements can and should be implemented in a mutually supportive manner. As discussed in previous US submissions, while the objectives of these two agreements are distinct, they do not conflict.² Moreover, the United States views with the utmost caution any proposals that would add uncertainties in patent rights that may undermine the role of the delicately balanced patent system in its primary purpose of encouraging innovation, technological progress and economic development.

¹ See, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/403.

² See United States, IP/C/W/257.

4. In an effort to help achieve progress in the discussions in the TRIPS Council, this paper sets out the concerns of the United States with regard to proposed new patent disclosure requirements, as well as our view of what mechanisms may be effective for achieving objectives widely shared by Members. A closer study of these widely shared objectives suggests that implementation of effective national laws that directly address the relevant goals is the most effective way to proceed.

II. SHARED OBJECTIVES

5. Based on recent discussions in the TRIPS Council aimed at fulfilling the Doha Ministerial mandate, and written contributions submitted in that context, Members appear to share several broad policy objectives. These objectives include: (1) ensuring authorized access to genetic resources, i.e., that prior informed consent is obtained; (2) achieving equitable sharing of the benefits arising from the use of traditional knowledge and genetic resources; and (3) preventing the issuance of erroneously issued patents.

6. The United States supports these objectives and has consistently encouraged and supported the equitable sharing of benefits arising from the utilization of traditional knowledge and practices of indigenous and local communities. However, based on experience, our view is that the most effective means to achieve the stated objectives is through tailored, national solutions to meet practical concerns and actual needs. The introduction of new patent disclosure requirements will not achieve these important objectives and may have significant negative consequences.³

III. EXAMINING THE OBJECTIVES: NEW PATENT DISCLOSURE REQUIREMENTS ARE NOT THE ANSWER

A. PRIOR INFORMED CONSENT AND MISAPPROPRIATION

7. New patent disclosure requirements will not work to guarantee that prior informed consent was obtained. It must be recognized that it is the relevant prior consent agreement itself (usually constituting a contract between two entities), and not a disclosure in a patent application, that manifests prior informed consent. A researcher or collector needs to know where to go, who to contact and which persons are authorized to grant approval in order to receive prior informed consent. A completely separate, transparent mechanism needs to be established outside the patent system that implements these criteria regardless of any disclosure made in a patent application. If the goal is to ensure authorized access based on prior informed consent, only contractual obligations that establish the rights and obligations of the entities involved prior to any access to genetic resources can ensure prior informed consent is achieved.

8. In this light, a new disclosure requirement in the patent system also will not prevent misappropriation. Those with intent of acting in bad faith will not be deterred by disclosure requirements. Furthermore, a transparent prior informed consent regime is needed to ensure that the vast majority of researchers and/or collectors can conduct their research and activities in an appropriate manner. Some proponents of new patent disclosure requirements have suggested that "misappropriation has mainly taken the form of obtaining patents in, mostly, developed Members inconsistently with the will of the custodian communities".⁴ However, misappropriation, in the context of these discussions, relates to the improper collection and/or use of genetic resources or traditional knowledge. The act of patenting, *per se*, does not amount to misappropriation. Indeed,

³ By "new patent disclosure requirements," this paper refers to the proposed new requirements regarding source and/or origin, evidence of PIC, and evidence of equitable benefit-sharing that have been proposed by Members in the course of TRIPS Council sessions.

⁴ African Group, IP/C/W/404.

patent rights can be an effective tool, in conjunction with a benefit-sharing agreement, to transfer benefits.

B. BENEFIT-SHARING

9. Nor will a new disclosure requirement in the patent system ensure that benefits are equitably shared with the provider of the traditional knowledge or genetic resources. The proposed new patent disclosure requirements, *per se*, cannot transfer benefits, as such a requirement would merely convey the information requested but would have no mechanism to transfer benefits between parties. If the country of origin of the relevant traditional knowledge or genetic resources has no benefit-sharing infrastructure in place for the use of the traditional knowledge and/or genetic resources, there still would not be any compensation to the custodians of the relevant knowledge or resource even if a patent relating to these materials were identified. A mechanism to transfer benefits must be established.

10. Indeed, if such a requirement were adopted and a non-compliant disclosure were discovered that would invalidate a patent, or prevent a patent application from grant, because of a new patent disclosure requirement, any benefits from that invention would be greatly diminished:

- for example, if a patent issued, but was later invalidated, or if an application were published, but never issued, the invention has been disclosed to the public and third parties can most likely use and commercialize the knowledge or resources disclosed without any obligation of sharing benefits;
- further, if a patent is never issued and the information never published, the patent applicant may still be able to commercialize the invention without disclosing the invention to the public and without any obligation to share benefits;
- a new disclosure requirement could also have further significant, unintended consequences where a patent applicant has entered into a valid benefit-sharing agreement with the custodians of the traditional knowledge or genetic resources but, due to uncertainties in the law, a disclosure may be found invalid. For example, if there were improper disclosure that resulted in revocation of a patent due to litigation by a third party not affiliated with a traditional knowledge or genetic resources holder, this could actually upset the pre-existing benefit-sharing agreement.

11. Moreover, a new patent disclosure requirement would fail to address benefit-sharing resulting from commercialization that occurs outside the patent system. New patent disclosure requirements will be meaningless when products derived from or based on traditional knowledge or genetic resources are commercialized, but not patented. There are many ways of protecting ideas that lead to commercialization, including trade secret and unfair competition laws. In such cases, benefits would likely not flow to the relevant communities unless a domestic access and benefit-sharing framework is first put in place to facilitate a contractual arrangement that would lead to benefit-sharing.

C. PREVENTING ERRONEOUSLY GRANTED PATENTS

12. Another objective raised by the proponents of disclosure requirements is that of preventing erroneously granted patents. Some have even suggested that they view a disclosure of source and/or origin as "critical for ascertaining inventorship" and capable of enabling a better assessment by patent examiners of novelty and inventive step.⁵ Indeed, these are laudable goals. The proposed new patent

⁵ IP/C/W/403.

disclosure requirements, however, will be ineffective in achieving this objective and will only complicate an already overburdened patent system.

13. First, none of the suggested new patent disclosure requirements aim to ensure compliance with patentability requirements such as proper inventorship, novelty or inventive step. Second, disclosure of source and/or origin can be expressed in wide variety of ways.⁶ Information indicating country of origin, *ex situ* collection sites, etc., would do little to ensure ascertainment of appropriate inventorship, novelty or inventive step, because such information does not generally address the considerations underlying these requirements, such as acts of invention or the state of the relevant art.

D. ADDITIONAL CONCERNS REGARDING NEW PATENT DISCLOSURE REQUIREMENTS

1. Adding uncertainty to the Patent System

14. Furthermore, new patent disclosure requirements would add new uncertainties in the patent system.⁷ Particularly where the sanctions for non-compliance include invalidation of a patent, this would create a "cloud" of uncertainty over the patent right by opening a new avenue for litigation and other uncertainties that would undermine the role of the patent system in promoting innovation and technological development. This could have negative effects on the economic development incentives that patents provide.⁸ These uncertainties would likely also undermine any potential benefit-sharing.

2. Administrative Burdens

15. Moreover, new patent disclosure requirements may also lead to significant administrative burdens for the patent offices of Members that would in turn create additional costs, particularly with respect to those requirements that would demand compliance with foreign laws. A patent office is not positioned to examine documentation, unilaterally provided by applicants, in response to requirements such as those proposed regarding source and/or origin, prior informed consent, or evidence of benefit-sharing. To implement an appropriate standard of review within the patent system for these matters would create significant new administrative burdens and substantial new costs, including training and system development, for the patent offices of all Members. Furthermore, even with the added resources and costs, it does not seem possible that patent examiners could make such determinations with any degree of legal certainty, particularly decisions involving interpretations of foreign laws to determine the validity of prior informed consent or adequate benefit-sharing according to the custodian country's legal regime, thereby compounding the uncertainties both in granted patent rights and in the process of granting patents. Courts and other authorities of those jurisdictions providing

⁶ See Switzerland, IP/C/W/400/Rev.1.

⁷ These new patent disclosure requirements would generally be requirements untested to a great extent at the national level, leading to significant legal uncertainty, for which at least one proposed sanction is the revocation of the patent right. Concerns include, *inter alia*, situations in which the resource is indigenous to one country, but freely available in several other countries, the degree of relationship between the claimed invention and the relevant genetic resource or traditional knowledge, and whether national courts or national intellectual property offices would have to interpret other nation's laws. This would also lead to undue burdens on those applicants seeking to comply with such requirements, which, in turn, may discourage applicants from seeking protection and may thereby act as a disincentive to innovation and investment.

⁸ The patent system is designed to promote innovation and provides significant economic development incentives. See e.g., Kamil Idris "Intellectual Property: A Power Tool for Economic Growth," describing a number of ways in which patents can stimulate economic development, including: (1) patent information facilitates technology transfer and investments, (2) patents encourage R&D at universities and research centres, (3) patents are catalysts of new technologies and businesses, and (4) businesses use patents in licensing, joint ventures and other revenue generating transactions.

the genetic resources or traditional knowledge would be more appropriately situated to examine these matters.

3. Ineffectual Monitoring System

16. Proponents of a new patent disclosure requirement also appear to wrongly assume it to be an effective monitoring system. Indeed, the proposal by Switzerland for a disclosure of source requirement in the context of the Patent Cooperation Treaty (PCT) appears to recognize the shortcomings of such a disclosure of source requirement in noting the difficulties posed by the various ways that information could potentially be disclosed, such as through databases, publications or *ex situ* collections.⁹ Thus, the Swiss, apparently aware of the shortcomings of a disclosure of source requirement, *per se*, go so far as to suggest that it be implemented in conjunction with an apparently multilateral system of notification, in which national patent offices would identify and notify points of contact designated to receive such information in other governments. This would be coordinated through an office at WIPO that would create a list of notified contact points for each government.¹⁰ Notwithstanding the complexity of issues surrounding the creation of such a system, including its associated costs and effectiveness, such an apparently multilateral notification system still does not address legal uncertainties in the patent system and consequent negative effects created by a disclosure of source and/or origin requirement nor does it address the fact that an access and benefit-sharing infrastructure in a country is necessary to enable the sharing of such benefits.

17. In light of these concerns, the United States is not convinced that new disclosure requirements in patent applications are an appropriate solution. However, the United States shares many of the objectives raised by various Members. The real challenge is how most effectively to achieve these objectives. As more fully described below, this challenge can best be met if countries establish separate legal and other frameworks that will directly and effectively address these issues.

IV. EXAMINING THE OBJECTIVES: OPTIONS TO ACHIEVE APPROPRIATE ACCESS AND EQUITABLE BENEFIT-SHARING

18. Experience shows that the most effective means to achieve the shared objectives of obtaining appropriate access and benefit-sharing is through development of national laws outside the patent system that can more directly and effectively regulate conduct relevant to these issues.

A. ACHIEVING PRIOR INFORMED CONSENT

19. It is imperative that governments implement laws that require prior informed consent from clearly delineated points of contact, such as the government and/or indigenous representatives before a party seeks to use or collect traditional knowledge or genetic resources. Points of contact should include the persons authorized to provide access to materials. For example, countries could establish permit systems that impose civil and/or criminal penalties for extracting genetic resources without a permit, where the permit would serve as evidence of prior informed consent.

B. ACHIEVING EQUITABLE SHARING OF BENEFITS

20. A contract-based system can be used to effectively control the collection of resources and ensure the sharing of benefits from their use. Contracts can provide a great deal of flexibility in determining benefit-sharing, both monetary and non-monetary. Within the contract, a party can require the researcher to report regularly to the point of contact regarding progress of his research. This informs the authorities of how the relevant traditional knowledge or genetic resource is being

⁹ IP/C/W/400/Rev.1.

¹⁰ IP/C/W/400/Rev.1.

used and keeps communication channels open. The contract can also require mandatory disclosure to appropriate authorities of any future commercial application utilizing the relevant traditional knowledge or genetic resource, whether patented or not. This type of mandatory disclosure requirement can provide for an effective monitoring system by ensuring a specific type of disclosure of the particular commercial application involved. The contract can also specify choice of law provisions, so that all parties are aware of the law that will apply should disputes arise. Contracts can be specifically enforced, requiring adherence to its terms; damages for breach of contract can also be specified, including punitive damages.

21. It is also our understanding that many Members have not yet implemented access and benefit-sharing regimes. As described in previous US submissions to TRIPS Council, the United States has developed contract-based systems to ensure appropriate access and benefit-sharing.

22. In June of 2001, the United States introduced a paper¹¹ that described in detail the provisions of the CBD that might have some implications for the TRIPS Agreement,¹² and explained how those obligations might be implemented through the use of a contract-based regime for access to genetic resources. The paper suggested that, *inter alia*, contracts authorizing collection of genetic materials include provisions requiring reporting and benefit-sharing and that parties to such access agreements be obliged to notify the appropriate authorities in the event an invention was developed using genetic materials collected under the contract.

23. In March of 2002, the United States submitted another paper¹³ describing in considerable detail the procedures used by the US National Cancer Institute in collecting genetic materials for screening for potential therapeutic uses related to cancer. Many US government agencies have established policies that embody the principles of appropriate access and equitable benefit-sharing. Further, in November of 2002, the United States submitted a paper describing the regime for access to genetic materials in US National Parks.¹⁴ That paper includes a detailed description of the regime, including the use of Scientific Research and Collecting Permits as well as Cooperative Research and Development Agreements. This experience might be helpful to other Members, particularly those Members that have not yet implemented such a regime in their respective territories.

24. The access systems described in these papers are easily adaptable to other legal systems, and can provide countries the flexibility to protect their traditional knowledge or genetic resources without the risks mentioned earlier of undermining the economic development incentives of strong intellectual property protection and without the risk of undermining benefit-sharing, as discussed earlier.

C. COMPLIANCE WITH ACCESS AND BENEFIT-SHARING REGIMES

25. Many of the proponents of disclosure requirements do not challenge the necessity of effective, contract-based, access and benefit-sharing regimes.¹⁵ However, some argue that patent disclosure requirements are necessary, in addition to such regimes, to improve compliance with such mechanisms.¹⁶ The United States disagrees with such a policy approach as unnecessarily burdensome to the patent system. Such a legal regime, if in force, can be adequately enforced without resort to

¹¹ United States, IP/C/W/257.

¹² Specifically, Articles 8(j), 15, 16 and 19.

¹³ United States, IP/C/W/341.

¹⁴ United States, IP/C/W/393.

¹⁵ See Bolivia et al., IP/C/W/403, paragraph 18 states that "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." Further, see paragraph 16 of Switzerland, IP/C/W/400, which notes that Article 15.7 of the CBD requires that sharing of benefits arising from utilization of genetic resources shall be on mutually agreed terms and that "generally, the mutually agreed terms will be laid down in a contract."

¹⁶ IP/C/W/403.

patent law requirements. Effective enforcement regimes for access and benefit-sharing should be part of civil and criminal codes specifically designed to enforce access and benefit-sharing laws. Such enforcement mechanisms can be appropriately tailored so as not have unintended, negative consequences on the intellectual property system. Patent law was not designed to regulate or enforce misconduct issues, such as misappropriation of traditional knowledge or genetic resources, but to promote the progress of the useful arts. Patent rights permit an inventor to exclude others from certain acts,¹⁷ but do not permit an inventor to use the invention without restriction. Restrictions can and are placed on the use of certain inventions to ensure safety and efficacy (e.g. health regulations governing pharmaceutical products), to protect the environment (e.g., regulations governing emissions from automotive engines) or to protect domestic or national security (e.g., regulating firearms), for example. These restrictions, notably, are enforced outside the patent system by separate regulatory mechanisms.

26. While a few individuals could ignore the legal requirements of an access and benefit-sharing system, in the same way that individuals currently may violate health or safety regulations, the case has not been made for why a contractual system that would apply to the vast majority of those seeking access would not serve effectively, just as health and safety codes apply in their spheres. As is done in the case of these other distinct regulatory systems, 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 required party.

27. In order for the TRIPS Council to more fully consider the concerns raised by the proponents of disclosure requirements, Members may want to more fully examine national experiences with respect to access and benefit-sharing systems currently in place in order to better understand the perceived shortcomings of such existing systems. In this light, the Council may also want to consider the extensive work that continues in the Intergovernmental Committee on Intellectual Property, Genetic Resources and Folklore of the WIPO, which was specifically created to deal with many of these, and related, matters.

V. EXAMINING THE OBJECTIVES: OPTIONS TO PREVENT THE ISSUANCE OF ERRONEOUSLY GRANTED PATENTS

28. Several tools can and are being used to address concerns regarding the issuance of erroneously granted patents. The TRIPS Council may want to consider these more fully.

A. ORGANIZED DATABASES

29. First, patent examiners world-wide 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 examination of patent applications in the relevant fields.¹⁸

B. INFORMATION MATERIAL TO PATENTABILITY

30. Furthermore, Members may wish to consider a requirement such as that used in the United States for patent applicants to disclose any information known by the applicant to be material to

¹⁷ See, e.g. TRIPS Article 28.

¹⁸ A number of initiatives are exemplary of this approach, including the China Traditional Chinese Medicines Database and the India Traditional Knowledge Digital Library (TKDL) of Ayurveda. See, e.g., the relevant web site of the World Intellectual Property Organization (WIPO) at <http://www.wipo.int/tk/en/databases/tkportal/index.html>.

patentability.¹⁹ If the objectives are to truly to determine prior art, to ascertain inventorship and to prevent mistakenly granted patents, this type of requirement is directly related to achieving these goals, to the extent that the applicant may have such information. Inventorship is included here because US law clearly requires that inventorship be a requirement for entitlement to a patent.²⁰ This type of information is directly related to the questions of patentability and can aid examination of patent applications in a manner that disclosure of source and/or origin of genetic resources or traditional knowledge cannot.

C. POST-GRANT OPPOSITION OR RE-EXAMINATION

31. Implementation of post-grant opposition or re-examination proceedings can rectify the situations in which patents are issued erroneously. These procedures are far less costly than litigation and can alert national patent authorities when new information is discovered that is relevant to the patentability of the invention. These procedures can directly bring information to the attention of patent authorities, as appropriate, in order to address questions of patentability with regard to issued patents. Indeed, a number of granted patents have been successfully challenged when it was demonstrated through existing opposition processes that these patents should not have been granted. This has included patents relevant to turmeric and neem in the United States and in the European Patent Office.²¹

32. We are unaware that any of the perceived instances of misappropriation have involved a wrongful determination of inventorship or prior art that could not be satisfactorily addressed by the above means, or that a patent disclosure requirement for source and/or origin would have corrected this.

VI. CONCLUSION

33. The patent system has been and continues to be a highly effective tool for technological and economic development. The WTO should be wary of upsetting the delicately balanced patent system, particularly when it is doubtful that any suggested changes will actually achieve their stated objectives.

34. Further, it would be wrong to assume that a new disclosure requirement within the patent system will accomplish the objectives of ensuring access and equitable benefit-sharing, preventing misappropriation and preventing erroneously issued patents. Rather than focusing on proposed new patent disclosure requirements, the TRIPS Council should focus with more precision on what Members are trying to achieve in this area, review the past experiences and situations that have prompted various concerns and consider any appropriately tailored solutions. As many of the broad objectives are widely shared, we are confident that appropriate solutions can surely be reached to address the concerns of all Members.

¹⁹ 37 CFR 1.56(a): Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [United States Patent and Trademark] Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.

²⁰ See 35 USC 102(f): "A person shall be entitled to a patent unless he did not himself invent the subject matter sought to be patented".

²¹ See Carlos Correa, "Traditional Knowledge and Intellectual Property: Issues and Options Surrounding the Protection of Traditional Knowledge", QUNO, November 2001.