

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

**TECHNICAL OBSERVATIONS ON THE UNITED STATES SUBMISSION IP/C/W449  
BY BOLIVIA, BRAZIL, COLOMBIA, CUBA, INDIA AND PAKISTAN**

The following communication, dated 21 October 2005, is being circulated at the request of the Delegations of Bolivia, Brazil, Colombia, Cuba, India and Pakistan. Colombia has been added as a cosponsor in accordance with its request dated 2 November 2005.

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**I. GENERAL COMMENTS ON THE DOHA MANDATE TO EXAMINE THE  
RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CBD**

**A. CONFLICT BETWEEN TRIPS AND THE CBD**

1. The United States, in all its submissions, has argued that there is no conflict between TRIPS and the CBD. In its most recent submission, the United States in fact reiterates the same positions and arguments it put forward several years ago, in document IP/C/W/257. Comparing Article 1 of the CBD and Article 7 of the TRIPS, it argues that the objectives of the two documents do not run counter to each other and are mutually supportive. The United States, however, focuses its analysis on an excessively narrow interpretation of both treaties, which does not take into account their spirit and objectives. It is well accepted that the CBD does not address the resource depletion issue alone. Instead, it highlights this issue as a result of the extensive piracy of biological resources of the countries rich with genetic resources. It is an accepted fact that the gene and biochemical hunt over the components of biological diversity is largely driven by their use, value or the knowledge associated with those resources, without which bio prospecting loses much of its content. This knowledge associated with the biological resources is also a product of the human intellect, which is recognized under the CBD as deserving of protection. Hence, the protection of the components of biodiversity and associated traditional knowledge from bio piracy must be integrated within the framework of the TRIPS Agreement. The TRIPS Agreement as it stands today, whilst promoting the granting of patents to products based on genetic resources and associated traditional knowledge, contains no effective provisions to protect those resources and associated knowledge from misappropriation and theft. It is the absence of such provisions in the TRIPS Agreement that may generate conflicts between its implementation and that of the CBD. On the other hand, the inclusion of provisions in TRIPS to protect genetic resources and associated traditional knowledge from misappropriation would, in practice not only support fulfilment of the objectives of the CBD, but would also be in line with the fundamental objectives of TRIPS.

2. The United States opines that "the objectives of the TRIPS Agreement as stated in Article 7, are the protection and enforcement of intellectual property rights in a way that (and not should, as in the text) contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technology and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". Article 7 of TRIPS points to the need for a balance between the monopoly rights granted under the intellectual property (IP) regime and the public interest. It provides for the benefits that should accrue to the society at large in return for the grant of intellectual property rights, viz. promotion of technological innovation, transfer and dissemination of technology, social and economic welfare etc. What the CBD envisions is a different system, which claims benefit-sharing in respect of the use of genetic and biological resources and associated traditional knowledge for the countries of origin and providers of such resources or traditional knowledge which, regrettably, are not currently protected under TRIPS. The lack of safeguards against misappropriation in the TRIPS context has led to a situation where, under the existing IP regime, those genetic resources and associated traditional knowledge are often erroneously dealt with as if they formed part of the public domain, open to appropriation by anybody without any obligation to ask for permission and pay back the provider(s). No consideration is given to the fact that genetic resources and associated traditional knowledge constitute fundamental elements of several products and processes and represent both an economic and intellectual contribution to the attainment of the invention. The conflict thus largely relates to the issue of appropriation of benefits arising from the commercialization of products/processes that are based on biological material and/or traditional knowledge. The moot point is whether the patent holder appropriates all the benefits arising from the commercialization of a product based on biological material and/or traditional knowledge or whether he/she shares the benefits with the States and/or the traditional knowledge holders. This underlying conflict lifts the veil off the balance set by the US proposals by comparing the objectives of the Convention and the TRIPS.

**B. CBD DOES NOT REQUIRE OR MENTION PATENT DISCLOSURE REQUIREMENT**

3. The United States submits that there is no express obligation under the CBD regarding disclosure requirements in patent law.<sup>1</sup> This argument of the United States has already been responded to in previous TRIPS Council meetings. Not being an IP instrument, the CBD does not create patent disclosure requirements. But Article 16.5 of the CBD does oblige countries to cooperate to ensure that patents and other IP rights do not run counter to the objectives of the CBD. We submit that the Doha Development Agenda can make a crucial contribution in this regard.

**C. COLLECTION OF GENETIC RESOURCES BY THE UNITED STATES GOVERNMENTAL AGENCIES CONSISTENT WITH THE CBD PRINCIPLES OF PRIOR INFORMED CONSENT AND BENEFIT SHARING ON MUTUALLY AGREED TERMS**

4. The United States argues that its governmental agencies and US-based companies have been undertaking bioprospecting activities in a manner consistent with the principles of prior informed consent (PIC) and benefit sharing; it also affirms that its efforts have been in line with the Bonn Guidelines.<sup>2</sup> Though it may be true that the United States may be taking steps internally, these steps are not sufficient to solve the concern of misappropriation caused by the issue of bad patents and the trans-boundary nature of the problems of illegitimate bioprospecting. In this regard, contractual agreements alone cannot ensure compliance with the principles of PIC and benefit sharing, as it is difficult to enforce a foreign obligation for an act that is not prohibited in the country in which it is to be enforced. It is an established fact that in enforcement of laws involving multiple jurisdictions, the binding nature and enforceability of foreign judgements/obligations are always moot points. The Yahoo! – Nazi case illustrates this point very well. The French Jewish and anti-racist groups initiated legal action against the California-based Yahoo! web portal when the latter allowed Nazi memorabilia

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<sup>1</sup> IP/C/W/449 paragraph 4.

<sup>2</sup> IP/C/W/449 paragraph 6.

(items such as SS daggers, swastikas, photos of death camp victims, replicas of Zyklon B poison gas canisters etc.) to be sold on its US auction pages.<sup>3</sup> As the French laws bar the display or sale of racist materials, the French court ordered that French internet surfers should be denied access to US pages hosting the auction. Though Yahoo! banned the sale of hate-related items from all the sites, it challenged the decision on the ground that the offending sites were aimed primarily at the American market and were therefore protected by the US freedom of speech laws. Subsequently, the US Federal Court ruled that Yahoo! was not bound to tailor its non-French sites to French laws. This clearly demonstrates the difficulty of enforcing foreign judgements based on contractual obligations in the United States that are not expressly regulated in the United States through legislation. There is no law enacted by the United States to date to ensure that non-compliance with the CBD obligations by US nationals in other countries can be remedied under US jurisdiction. The existing system allows patents to be claimed at the USPTO for inventions relating to genetic resources and associated traditional knowledge without any concern for access and bio prospection rules in the countries of origin of those resources and knowledge.

## II. GENERAL COMMENTS ON PROPOSALS FOR NEW PATENT DISCLOSURE REQUIREMENTS

5. The United States argues that the proposed disclosure of origin requirement would lead to uncertainty.<sup>4</sup> It cites examples where 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 resources or traditional knowledge; and whether the national courts or national IP offices would have to interpret other nations' laws etc. This cloud of uncertainty, in the view of the United States, would be potentially detrimental to innovation and technological development, the economic incentives of the patent system and benefit sharing under the ABS regime. Such arguments, however, are based on a misreading of the proposed disclosure of origin requirement. There are three types of disclosure requirements proposed. They are: (1) disclosure of source and country of origin of the genetic materials and associated traditional knowledge used in developing the invention claimed in the patent application; (2) disclosure of the evidence of prior informed consent; and (3) disclosure of the evidence of a benefit-sharing agreement. As is evident, these disclosure requirements are intended to achieve different yet interrelated objectives of the CBD. The US submission tries to read these requirements together, which creates confusion. Such unnecessary confusion cannot be a basis to avoid internationally binding solutions to the very real problems of misappropriation and bio piracy.

6. It is clear from the proposals that the disclosure of source and country of origin is primarily aimed at preventing the grant of bad patents that do not fulfil the patentability criteria of novelty and/or inventive step. Introducing such a requirement in the TRIPS Agreement would not lead to uncertainty but to greater legal certainty, as it would ensure that the patent system does not issue bad patents. This is evident from the number of cases that have come up before the USPTO and the EPO.<sup>5</sup> It is much better for the patent system to prevent the issue of bad patents rather than to take a laissez-faire attitude that would shift on to society and aggrieved third-parties the burden of revoking such bad patents after they have been issued. The procedure for revocation of patents is more expensive and burdensome than merely requiring patent applicants to disclose the source and country of origin of the genetic resources and associated traditional knowledge. The frequent revocation of patents would surely create more uncertainty for the patent system and prevent technological innovation and the facilitated flow of information that may be of great importance to bioprospecting

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<sup>3</sup>See <http://www.guardian.co.uk/international/story/0,3604,893642,00.html>; also see <http://www.theinquirer.net/?article=21207>, [http://www.cyber-rights.org/documents/yahoo\\_ya.pdf](http://www.cyber-rights.org/documents/yahoo_ya.pdf); <http://www.vnunet.com/personal-computer-world/news/2042963/yahoo-backs-nazi-case>,

<sup>4</sup> IP/C/W/449 paragraph 8 and IP/C/W/434 footnote 7.

<sup>5</sup> A sample list of cases attached at Annex.

and the biotechnological industry. The disclosure of origin obligation, on the other hand, would only require reasonable efforts on the part of patent applicants to obtain the relevant information. Since such information would normally be part of a larger batch of information collected by the patent applicant for filing an application, it is not correct to argue that disclosure of origin would constitute an additional and/or burdensome obligation.

7. The United States puts forward that erroneously granted patents are rare exceptions rather than the rule,<sup>6</sup> but the high rate of erroneously granted patents on inventions involving biological resources and associated traditional knowledge tells the other side of the story. In any case, there is no case for doing nothing to prevent issuance of bad patents when our international obligations demand it and the adverse effect is primarily on developing country stakeholders. In all the above situations, we can see that the new disclosure requirement, being crucial in the determination of novelty and inventive step, can effectively remedy the problem of issuance of such bad patents involving genetic resources and associated traditional knowledge. In other words, it would act as a crucial factor in the determination of the patentability of biotechnological inventions. As has also been pointed out previously,<sup>7</sup> disclosure of origin will be relevant in helping patent examiners to determine whether the claimed invention constitutes an invention that is excluded from patentability under Article 27, paragraphs 2 and 3 of TRIPS; would serve as part of a process to systematize available information of biological resources and traditional knowledge that will continuously build the prior art information available to patent examiners and the general public; and will 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.

8. The mandatory requirement of disclosure of source and country of origin would solve the problem raised by the United States regarding genetic resources that may be indigenous to one country but freely available in different countries. In such cases, the source would be the country from where the applicant received the genetic material and the country of origin is the country to which the genetic resource is indigenous. It is not clear how the patent office would be forced to interpret the law of other countries in such cases.

9. It is also not correct to argue that the other two disclosure requirements would create uncertainties and additional burdens for the patent office. The obligation is only to produce evidence issued by the legally recognized authority of the country where access to the relevant material and information takes place. The same applies to the case of the benefit-sharing agreement. Disputes would not arise if this is obtained based on the requirements of the law of the country. Only in cases where the applicant committed fraud could there be a dispute. The raising of disputes during the opposition proceeding for failure to satisfy the requirements of the patent law is not new to the patent office. In such cases, parties would provide adequate and convincing evidence to the patent office to establish their claims. The job of the patent office is only to evaluate such evidence and decide the claim. The patent office is not expected to interpret the content of these documents but only to ascertain, through the claims and counterclaims, whether such evidence has been provided where a national regime requires such evidence. It is difficult to appreciate how interpretation of foreign law is involved in such cases.

### **III. PROPOSED OPTIONS FOR ACHIEVING APPROPRIATE ACCESS, BENEFIT SHARING, AND PREVENTING ERRONEOUSLY GRANTED PATENTS.**

10. The United States proposes many options to achieve the objectives of the CBD<sup>8</sup> and provides that a contract-based national regime with an international outlook, supplemented by the guidelines of international instruments would be an ideal one. The CBD system, as it exists now, is in line with the

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<sup>6</sup> IP/C/W/449 paragraph 9.

<sup>7</sup> IP/C/W429/Rev.1.

<sup>8</sup> IP/C/W/434.

proposition of the United States i.e. "CBD supplemented by the Bonn Guidelines."<sup>9</sup> Despite this, the number of bad patents and instances of misappropriation are increasing and the objectives of PIC and benefit sharing are not often met. Since the problem is the issue of bad patents and failure to respect the rights and obligations of holders of the traditional knowledge on the basis of which the patent is issued, as well as the rights of the countries of origin of the genetic resources, the solution must also be based on patent law and, in particular, the TRIPS Agreement. Since the contribution of the custodians and holders of the genetic resources and associated traditional knowledge is not recognized and is clearly manifested in the misappropriation of the knowledge, a TRIPS-based solution is only just and reasonable. The new disclosure requirement can bring to a great extent uniformity and certainty in relation to these concerns. A contract-based system, howsoever perfect it may be, cannot ensure the effectiveness and mandatory enforcement at the international level. There is, therefore, a need for a binding international disclosure requirement regarding the source and country of origin (to deal with bad patents) and evidence of PIC and benefit sharing (to promote PIC and benefit sharing) under the TRIPS Agreement to enforce national norms. There is no need for opting for a multiple-forum solution or international arbitration when there can be a "one-stop shop" at the WTO. In any case, we are committed to resolve this problem in the Doha Development Agenda as part of our mandate, and we are obliged to do so to the extent that the TRIPS Agreement requires any interpretation to fulfil this mandate. Arguing otherwise would tantamount to shifting a component of the Doha mandate to outside the WTO, a proposition that may not be acceptable in other areas of negotiations.

#### **IV. SPECIFIC OBJECTIVES ON ACHIEVING WIDELY SHARED OBJECTIVES**

##### **A. PIC AND MISAPPROPRIATION**

11. The United States argues that the submissions of India and Brazil that the new disclosure requirement would not be a stand-alone system, makes it clear that, in the absence of a national regime, the new disclosure requirement would be of little or no utility and so the primacy is to establish national regimes.<sup>10</sup> It is submitted that this line of argument does not take into account the aim of the proposed requirement of disclosing the source and country of origin. This requirement is to ensure that misappropriation of genetic resources and associated traditional knowledge is not encouraged through grant of patents on inventions relating to genetic resources without recognizing the contributions of the holders of traditional knowledge. Given the different nature of the prior art and inventive step involved in cases of genetic resources and traditional knowledge associated with them, disclosure of source and country of origin can surely help the patent office to request more information from the patent applicant during examination of the application to ensure that bad patents are not issued. This can surely prevent bio piracy and misappropriation of traditional knowledge by the patent applicant. This is clearly one of the objectives of the CBD and this can be achieved only if changes are introduced in the global regime governing the patent law and not through national access legislation alone. This also adds to the certainty and legitimacy of the patent system. The disclosure requirement is also not as costly as the contract-based system envisaged by the United States.

12. Disclosure of source and country of origin also facilitates realization of the CBD objectives of PIC and benefit sharing. Production of the evidence of PIC and benefit sharing along with the patent application are proposed specifically to achieve this. It is in this context that the proposal from India and Brazil emphasized the need for national systems to support the international obligation in this regard. Thus, it is incorrect to state that the object of the new disclosure requirement of source and country of origin is of "little or no utility" if national regimes on PIC and benefit sharing are not in place. Even in the absence of a national ABS regime, disclosure of source and country of origin could surely help prevent bio piracy and misappropriation of traditional knowledge associated with genetic resources by preventing the issue of bad patents. Additionally, in the cases where national ABS

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<sup>9</sup> There exists no recommendation from the WIPO IGC on the matter.

<sup>10</sup> IP/C/W/449 paragraph 14.

regimes have been established, disclosure ensures that the requirements of these national regimes are met by bio-prospectors.

13. The options contained in a contract-based system as proposed by the United States, viz. choice of forum, choice of law, international arbitration provisions governing transboundary issues, enforcement issues etc., are concerns of private international law. Since the problem of misappropriation of genetic resources and associated traditional knowledge is a truly global one, requiring international intergovernmental norms, solutions-based on private international law are inadequate. It is submitted by the United States that a contract-based system "can be international in its outlook" with "provisions relevant to cross-boundary dispute or enforcement issues". The United States is thus admitting to the limitations of relying solely on national systems, and is agreeing that additional steps need to be taken to rectify the limitations of the existing regime. Clearly, the best and most effective way to address the shortcomings of the existing system is through the establishment of an internationally binding obligation rather than the simple use of private international law principles within the national regime. This binding international obligation can easily be achieved by integrating it within TRIPS obligations. It is this aspect that India and Brazil emphasize when arguing for a binding requirement of disclosure of evidence of PIC and benefit sharing in the patent application.

## **1. Monitoring System**

14. The United States also opines that a contract-based ABS regime can be an effective monitoring system by mandating disclosure of any commercial application utilizing the resources or traditional knowledge.<sup>11</sup> It is to be noted that in the case of genetic and biological resources, monitoring is a very difficult task and may not be technically feasible especially when it leaves the country of origin<sup>12</sup> due to the nature of the product being purloined. One of the major uses of genetic resource and traditional knowledge associated with it takes place through the patent system. The patent system acts as an incentive to the commercial use of genetic resources and associated knowledge by creating a private monopoly over goods which are either public or owned by civil society rather than corporate interests who are able to prevent abuse. The objective of a disclosure of source and country of origin mechanism in the patent system is the prevention of misappropriation of knowledge by preventing the grant of bad monopolies. So a solution within the patent system for monitoring the use of genetic resources and associated knowledge is more appropriate and effective than a fragmented private stakeholder-based contractual system.

## **2. Enforcement of ABS Systems**

15. The United States equates disclosure of origin, as well as evidence of PIC and benefit sharing, with separate regulatory measures in the areas of health, environment and other matters. It is submitted by the United States that like the national regulatory measures enacted in those areas, PIC and benefit sharing could be monitored through separate national regulatory authorities and that the patent system need not be strained for this.<sup>13</sup> As noted above, the prevention of illegal access to genetic resource through regulatory measures is difficult given the ease with which such resources can be purloined. So what is attempted through mandatory disclosure requirement is to ensure that the implementation of the TRIPS Agreement and of the obligations under the CBD should take place in a mutually supportive manner. As explained, this requires internationally binding legal obligations rather than national regulatory measures alone. The US contract-based solution sidelines this issue. The United States also submits that the patent system does not condone or legitimize misappropriation of genetic resources or traditional knowledge in violation of domestic requirements and that as in the

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<sup>11</sup> IP/C/W/449 paragraph 18.

<sup>12</sup> Glowka, "The Next Rosy Periwinkle Won't be Free: Emerging Legislative Framework to Implement Article 15", *Environmental Policy and Law*, 27/6 (1997) p.445.

<sup>13</sup> IP/C/W/449 paragraph 21.

case of other regulatory requirements, inclusion of civil or criminal liability for non-compliance can adequately take care of the question of enforcement. This seems to be an over simplification of the issue. One of the primary justifications for the disclosure proposal as an internationally binding norm is precisely the realization that the effort to get bad patents revoked or PIC/ABS issues addressed in the countries of grant of patents has proven to be costly, burdensome and more complicated than what could be offered by the mutual harmonization of the approaches of TRIPS and CBD through the disclosure requirement.

## B. BENEFIT SHARING

16. The United States observes that "establishing national access and benefit-sharing systems is essential before engaging in discussion of supplemental patent disclosure requirements. Furthermore, it would seem prudent to determine areas of inadequacy, based on experiences, of existing national systems in order to more fully consider these matters."<sup>14</sup> Of course, a national ABS regime is necessary for the proper running of the benefit sharing aspects of the system. But it is not correct to argue that establishment of national access systems is a pre-requisite for discussing an international framework for the disclosure requirement. There are many instances where international norms are set before national systems are put in place. This is all the more true with new and emerging areas, including in the field of intellectual property. An example is the Treaty on Intellectual Property in Respect of Integrated Circuits (the Washington Treaty), which was adopted in 1989 and has never entered into force. No Member states of WIPO at the time had national legislation or experience in implementing that Treaty during the negotiations of the TRIPS Agreement, but its provisions were nevertheless adopted as minimum standards of protection within TRIPS as part of those negotiations. Another example is the protection of copyright in the digital environment. The issue was internationally discussed and the so-called "WIPO Internet Treaties" (WIPO Copyright Treaty and WIPO Performances and Phonograms Treaty) adopted at a Diplomatic Conference in 1996 before many countries, particularly developing and least-developed countries, could even experience and grasp the full extent of the problem, let alone establish an appropriate legal framework to find solutions.<sup>15</sup> The justification for that normative effort had been the need to prevent violation of rights and misappropriation of profits.<sup>16</sup> The international framework, once established, led to the introduction of national systems, including in the United States, where legislation to implement the "Internet Treaties" came into operation only in 2000.<sup>17</sup> Similarly, to prevent violation of rights over genetic resources and associated traditional knowledge, national regimes, howsoever effective they may be, can only require that PIC and benefit sharing should be linked to the grant of access. The effective enforcement of such national regimes will be very weak, unless they are supported by an international legally binding obligation. Moreover, such national ABS regimes cannot prevent the grant of bad patents involving genetic resources and associated traditional knowledge. But if disclosure is made obligatory at the international level, all the concerns will be properly addressed. So the establishment of an international obligation assumes primacy. Furthermore, it is to be noted that many countries have already enacted national laws for ABS and others are in the process of doing so.

17. Another conclusion asserted by the United States is that "the remedy proposed itself (invalidation due to non-compliant disclosure, etc.) would destroy or have significant negative consequences on the benefit being sought, rather than ensuring that the benefit would be shared with the appropriate party. This would clearly fail to meet the shared objective of ensuring the equitable sharing of benefits arising out of the utilization of genetic resources and/or traditional knowledge."<sup>18</sup>

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<sup>14</sup> IP/C/W/449 paragraph 23.

<sup>15</sup> See [www.wipo.org/treaties/en/ip/wct/](http://www.wipo.org/treaties/en/ip/wct/) - 26k

<sup>16</sup> For a detailed discussion, see Mahaly Ficsor, *The Law of Copyright and the Internet*, Oxford University Press, 2002.

<sup>17</sup> See [www.copyright.gov/legislation/dmca.pdf](http://www.copyright.gov/legislation/dmca.pdf).

<sup>18</sup> IP/C/W/449 paragraph 25.

The goal of the disclosure requirement primarily is to prevent misappropriation of genetic resources and associated traditional knowledge. Disclosure of origin, coupled with disclosure of evidence of benefit sharing and PIC, promotes the equitable sharing of benefits. When there is patent protection involved in the commercialization of genetic resources and associated traditional knowledge, an enforcement mechanism within the patent framework will be more effective in ensuring that fair and equitable benefit sharing takes place. The disclosure requirement will ensure that PIC and fair and equitable benefit sharing agreements are obtained in compliance with the national law of the country of origin of the genetic resources. The consequences of non-disclosure, such as invalidation of patent rights, will flow only in cases of fraudulent claims, not bona fide ones. The intention is to protect the legal rights of the custodians and holders of the knowledge or the resources. The nature of the benefit shared, the mode of its sharing etc., are concerns to be addressed under the national regime. For example, if the person providing the genetic resources is giving only the raw material and he does not have any knowledge of its use value, he can claim benefit sharing for the mere supply of the resources. It is a wrong notion that patent monopoly is essential for the sharing of benefits and that if there is no patent, no benefits can be shared. Furthermore, remedies for non-compliance with disclosure are not limited to invalidation, as they may include other possibilities, such as the full or partial transfer of rights.

18. The United States also argued that "rather than attempting to single out applications involving patents and trying to deal with them with a new patent disclosure requirement that may negatively effect technological development, a more appropriate solution would be strengthening national regimes outside the patent systems in order to take a comprehensive, holistic approach and address all instances of commercialisation of misappropriated resources and/or traditional knowledge that need to be addressed outside the patent system in any event."<sup>19</sup> It is true that misappropriation of traditional knowledge and genetic resources may or may not include patent protection. The new patent disclosure requirement can only deal with situations where there is misappropriation through patents. The instances of other forms of commercialization are dealt with under the national ABS regimes. But it is erroneous to argue that since the patent disclosure requirement does not cover all instances of commercialization, such a requirement is not necessary. The fact that misappropriation may not always involve the granting of patents does not mean that, when patents are actually involved, disclosure of origin may not make a significant contribution to preventing misappropriation. Moreover, when there is a patent, it is only through the disclosure requirement that we can better assess the novelty and inventive step in the claimed invention and thereby prevent the grant of patents to ineligible claims. The ABS regime can do nothing in relation to the grant of bad patents. It is clear, therefore, that we cannot undermine the significance of the new patent disclosure requirement on the ground that it does not cover all instances of commercialization.

19. The United States believes that any international effort should not be focused on new patent disclosure requirements but rather, on efforts to encourage the establishment of appropriate access and benefit-sharing systems that (1) improve compliance by providing users with clear rules for collection of genetic materials; and (2) help ensure that where uses of genetic resources or traditional knowledge are made, benefits are equitably shared with the appropriate parties.<sup>20</sup> Thus the United States also accepts the need to establish an ABS regime with rules for strict compliance ensuring equitable benefit-sharing. The effective way of promoting effective compliance with such national regimes is to create internationally binding obligations in the field, clearly spelling out the requirements of disclosure of source and country of origin, prior informed consent and benefit sharing as proposed. Also, the various situations cited by the United States in footnote 20 of document IP/C/W/449 do not undermine the relevance of establishing an international disclosure requirement. In fact, these examples support the need for a disclosure requirement on PIC and benefit sharing. They show that there is a distinction between commercialization without a patent, where there is no exclusivity and public domain knowledge is exploited by all, including the original owners, and

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<sup>19</sup> IP/C/W/449 paragraph 26.

<sup>20</sup> IP/C/W/449 paragraph 27.

commercialization with a patent, where despite lack of novelty or inventiveness, a monopoly has been created in favour of the patent applicant and against other legitimate exploiters.

### C. PREVENTING ERRONEOUSLY GRANTED PATENTS

20. It is heartening that "the United States generally shares concerns regarding erroneously issued patents."<sup>21</sup> But document IP/C/W/449 refuses to accept that the proposed disclosure requirement would address the issue of bad patents.<sup>22</sup> As explained by India in the TRIPS Council meeting in June 2005, disclosure of origin is crucial in determining novelty and inventive step, giving useful hints in relation to the existing prior art and a way to inquire into the extent of inventiveness. As noted by Brazil in its statement in the same meeting, the patent disclosure requirement is "...critical in ascertaining whether or not the applicant has invented what he claims in the patent, or has just found it in nature or obtained it from traditional cultures. 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 source and country of origin of the resource and traditional knowledge would enable a better assessment by the patent examiner of the novelty and the inventive step involved in the invention". The role of disclosure requirement as information material to patentability in assessing novelty and non-obviousness is clear and the United States accepts this as important in their submission.<sup>23</sup> But in its latest submission the United States misses the point that if the disclosure requirement is made mandatory, the patent examiner can require the applicant during the processing of the application to furnish more information to ensure that patents are not issued for ineligible inventions. This would significantly contribute to addressing the problem of bio piracy and misappropriation. The absence of details such as the ones that would have to be provided by the patent applicant under the proposed disclosure of origin requirement makes the prior art search almost impossible and the patent office is often compelled to issue patents for inventions that do not fulfil the relevant criteria. The revocations of the turmeric and neem patents are cases in point.

21. IP/C/W/449 also argues that determination of inventorship, prior art etc. are rooted in a country's patent law. (Inventorship based on acts of invention; novelty and inventorship based on the country's relevant art). It argues that information regarding the country of origin or the source i.e. country locations or *ex situ* collection sites etc., is not relevant to considerations like inventorship or prior art and would therefore be of little value in that process.<sup>24</sup> One of the primary aims of the proposed disclosure requirement is to check the issue of erroneously granted patent by rooting the patent examination on novelty and inventiveness. In this regard, information on source and country of origin can give useful hints in relation to the holders of the resources and/or the knowledge associated with them. The United States does not accept the fact that this information clearly facilitates the identification of the person skilled in the art and whether there exists a prior use or prior publication of the properties of the claimed invention involving the resources. This is also linked with the practices of a country. Especially when the resource is collected from one country and is indigenous to another country, the information of both source and origin proves to be more helpful in assessing the application on the patentability criteria. So the United States is not correct in arguing that the information that would be provided under a disclosure of origin requirement has nothing to do with considerations like novelty and inventiveness.

22. The United States further argues that "the options of organized searchable databases, information material to patentability, and use of effective post-grant and re-examination procedures"<sup>25</sup> better serve the purpose of preventing the issuance of bad patents. Assuming but not accepting that such systems could be effective, disclosure of source and country of origin is also important for their

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<sup>21</sup> IP/C/W/449 paragraph 29.

<sup>22</sup> IP/C/W/449 paragraph 28 & 29 read with IP/C/W/443 paragraph 17.

<sup>23</sup> IP/C/W/449 paragraph 36.

<sup>24</sup> IP/C/W/449 paragraph 30.

<sup>25</sup> IP/C/W/449 paragraph 31.

effective use. For example, disclosure of origin will surely help the patent examiner to more effectively use the searchable databases in finding out the prior art and undertaking its further analysis. Disclosure of origin also contributes effectively to post-grant and re-examination procedures, since the disclosure would help the opponents collect adequate information on the prior art and obviousness. This is evident from the opposition proceedings in the neem case before the EPO.<sup>26</sup> The disclosure of country of origin helped the opponents to prove the teachings in India during opposition proceedings regarding the healing properties, which led to the revocation of the said patent.

23. The United States submitted that post-grant and re-examination procedures play an important role in rectifying erroneously granted patents.<sup>27</sup> It is an established fact that despite the existence of such procedures, many bad patents are still issued in relation to genetic resources and the knowledge associated with them. This shows that post-grant and re-examination procedures alone are not sufficient to effectively deal with the situation. The procedure as proposed by the United States is also complex, lengthy, expensive and burdensome. In addition of being more costly and burdensome, post-grant re-examination and revocation are curative mechanisms for the ailment of the issue of bad patents, rather than preventive steps. What we argue for is an effective procedure to prevent the issue of erroneous patents, which is preferable to relying on the costly post-grant rectification of mistakes committed by patent offices in issuing bad patents. In this context, the proposed disclosure system is an effective preventive mechanism to the increased problem of issue of bad and questionable patent specifically in the area of biotechnology.<sup>28</sup> The above-mentioned post-grant and re-examination procedures could be truly helpful only if coupled with disclosure of origin, which is clearly a more direct, simple and cost effective measure.

24. The United States also argues that information that directly relates to the genetic resources and traditional knowledge provided by organized databases would be more comprehensive than information regarding the source and/or country of origin<sup>29</sup> of the genetic resources, provided under a disclosure of origin requirement. There is no logic in this argument. It is not possible to document the whole knowledge available in a country let alone in the world. Also, the knowledge that is kept confidential by some communities cannot be documented. Since documentation as proposed cannot be exhaustive and comprehensive, it cannot remedy erroneously granted patents. On the other hand, the proposed disclosure requirement gives useful links to the novelty and inventive step in the claimed invention, thereby preventing the grant of bad patents.

25. It is quite interesting to note that the United States concludes that "in other words, it is not the act of patenting or applying for patent, but rather the fact that traditional knowledge or genetic resources were accessed in violation of a national access regime and are being exploited, based on that improper access, without obtaining prior informed consent and without providing for equitable benefit-sharing that is the cause of any potential misappropriation".<sup>30</sup> This conclusion is incorrect, first because erroneous patents are wrongly granted patents, even within the patent system. Second, this conclusion also suppresses the issue of violation of the property rights and misappropriation of genetic resources and associated traditional knowledge by the granting of bad patents.

26. In addition to the issue of benefit sharing, the CBD tries to bring out the global issue of misappropriation of genetic resources and associated traditional knowledge through different means

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<sup>26</sup> For a detailed discussion, see  
<http://www.womenandlife.org/WLOEn/information/globalization/neembriefmar05.html> or  
[http://www.ifoam.org/press/press/pdfs/Briefing\\_Neem.pdf](http://www.ifoam.org/press/press/pdfs/Briefing_Neem.pdf)

<sup>27</sup> IP/C/W/449 paragraph 33.

<sup>28</sup> See US FTC Report on Patent October 2003 "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy".

<sup>29</sup> IP/C/W/449 paragraph 32.

<sup>30</sup> IP/C/W/449 paragraph 35.

including granting of patents good and bad. This is evident from Article 16 of the CBD that mandates the need to use international intellectual property norms supportive of the objectives of CBD. By using the genetic resources or the knowledge associated with them, many actors have been taking out patents, including those that do not even fulfil the criteria of novelty or inventive step. The US submission fails to convince that a contract-based national system could provide solutions to these problems. We submit that only a patent disclosure requirement including the evidence of PIC and benefit-sharing agreement can effectively check the problem of misappropriation of genetic resources and associated traditional knowledge.

#### D. ADDITIONAL ISSUES

27. The United States also addresses other concerns like additional burden created by the new patent disclosure requirement on the patent offices and the applicants.<sup>31</sup> It is to be noted that the applicant is required to submit only information of which he is, or in any case should be, well aware. In most countries having national regimes, the evidence relating to PIC and benefit sharing are conditions precedent for the grant of access. So the new patent disclosure requirement does not impose on him/her any cost or administrative burden while proceeding for a patent. Likewise, the patent office is also not asked to test the veracity of the evidence furnished in relation to PIC or benefit sharing. These serve as prima facie evidence of compliance. Disclosure of source and country of origin of the genetic material or associated traditional knowledge, enhances the capacity of the patent office in examining the patent applications involving biological resources or traditional knowledge and serves as a critical tool in tracking down applications involving them.<sup>32</sup> This gives the patent office useful hints to enquire into the novelty and inventiveness claimed in the invention.

28. Similarly, the United States does not consider the "requirement for source and/or origin to be a requirement to disclose information material to patentability" and adds that thus it cannot remedy the granting of bad patents.<sup>33</sup> As discussed earlier, this requirement alone can deal with the problem of bad patents whereby the patent office can require the applicant to furnish more information during the processing of the application. It checks the grant of bad patents by testing them against novelty and inventive step, being crucial in the determination of the criteria of patentability, it is of course an information material to patentability.

29. Another argument extended by the United States is that "...the disclosure requirement would be new and would provide an additional avenue to litigation and other uncertainties that would undermine the role of the patent system. Particularly where the sanction would be, as has been proposed, revocation of the patent right, this would cause undue uncertainties in these patent rights, even where a good faith attempt has been made to comply with such requirements."<sup>34</sup> It also adds the statement of the Biotechnology Industry Organization to the WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore that patent exclusivity is justified on the risks and investment involved in discovering and developing inventions and that the proposed requirement and sanctions, that may block the patent of an otherwise eligible invention, would create unacceptable risks.<sup>35</sup> It also argues that it would have detrimental effects on the developmental incentives of the patent system and benefit sharing. However, it is an accepted fact that an invention is eligible for patent protection only if it satisfies the universally recognized criteria of novelty, inventive step and industrial applicability. An invention that lacks these basic elements cannot be protected under patent law only on the ground that there is a huge investment behind it. Thus the new requirement is not

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<sup>31</sup> IP/C/W/449 paragraph 36.

<sup>32</sup> Statement by Brazil in the TRIPS Council in June 2005.

<sup>33</sup> IP/C/W/449 paragraph 37.

<sup>34</sup> IP/C/W/449 paragraph 38.

<sup>35</sup> IP/C/W/449 footnote 31.

creating any unacceptable risk, but adds to the legitimacy and certainty of the patent system that only the eligible inventions are protected. The sanctions are only affecting fraudulent claims, without any uncertainty as alleged and a bona fide researcher need not worry about the same. On benefit sharing also, no ambiguity is created. It is not true that the proposed requirements will have negative effects on the possible benefit sharing. If a patent is granted, the benefits arising out of such monopoly should be shared with the resource providers. It is true that if there is no patent, benefits from a patent cannot be claimed. But, it does not undermine the possibility of getting benefits from commercialization or the grant of access itself.

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## ANNEX

### FOOTNOTE 5 - A SAMPLE LIST OF BAD PATENTS

1. The Quinoa Case - US patent 5,304,718  
Source: Graham Dutfield, Intellectual Property, Biogenetic Resources and Traditional Knowledge, Earth Scan, UK and USA, 2004, Chapter 5, p. 53
  2. The Enola Bean Case - US patent 5,894,079  
Source: Graham Dutfield, Intellectual Property, Biogenetic Resources and Traditional Knowledge, Earth Scan, UK and USA, 2004, Chapter 5, p. 54 –55.
  3. Dupont's Biopiracy Challenged - EP 744888, issued to Dupont Aug. 2001  
Source: "Dupont claims patent monopoly over natural maize traits", Greenpeace press release, May 29th 2001 <http://www.greenpeace.org>
  4. Ayahuasca patent - U.S. Plant Patent 5,751 on June 17, 1986  
Source: Glenn M. Wiser, PTO Rejection of the "Ayahuasca" Patent Claim: Background and Analysis, Center for International Environmental Law, November 1999, <http://www.ciel.org/Biodiversity/ptorejection.html>
  5. "Ampalaya" – Philippines - US 5484889, JP 6501089 and EP 553357  
Source: <http://lists.essential.org/pipermail/upd-discuss/2001q1/000127.html>
  6. Turmeric Patent - US patent 5,40,504 on 28 March 1995  
Source: Mashelkar, R. A., Intellectual Property Rights and the Third World, Journal of Intellectual Property Rights, Vol.7, July 2002, p.317.
  7. The Hoodia Case - WO 9846243  
Source: Graham Dutfield, Intellectual Property, Biogenetic Resources and Traditional Knowledge, Earth Scan, UK and USA, 2004, Chapter 5, p.52
  8. Toxin of the Amazon frog *Epipedobates tricolor*  
Source: [http://www.metu.edu.tr/~mengu/biopiracy\\_mengu\\_odev.pdf](http://www.metu.edu.tr/~mengu/biopiracy_mengu_odev.pdf)
  9. Maca  
Source: <http://fletcher.tufts.edu/research/2003/MaliniGoel.pdf>
  10. Patent for composition of bringal, Karela, Jamun and Gurmar - US patent 5,900,240
  11. Patent for Arhar or Pigeon pea or *Cajanus* – US patents 6,410,596 and 6,541,522
  12. Patents for Pepper – US patents 5,536,506, 5,744,161 and 5,972,382
  13. Patent for Amla - US patent 5,529,778
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