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AD HOC INTERGOVERNMENTAL MEETING ON GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS

Geneva, June 3, 2005

COMPILATION OF OBSERVATIONS AND COMMENTS SUBMITTED BY MEMBER STATES AND OBSERVERS ON THE FIRST DRAFT OF AN EXAMINATION OF ISSUES RELATING TO THE INTERRELATION OF ACCESS TO GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS IN INTELLECTUAL PROPERTY RIGHTS APPLICATIONS

Compilation prepared by the Secretariat

1. At its Thirty-first Session the WIPO General Assembly considered an invitation from the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) (see document WO/GA/31/8) and decided that "WIPO should respond positively" and adopted a specific timetable and modalities for this purpose. The third step of the agreed timetable and modalities provides that "all Member States and … accredited observers may submit observations and comments" on a first draft examination of issues relating to the interrelation of access to genetic resources and disclosure requirements, which had been prepared on the basis of proposals and suggestions submitted by WIPO Member States before December 15, 2004. These observations and comments on the first draft of the examination were to be submitted by the end of March 2005.

2. Accordingly, observations and comments were invited from all Member States of WIPO and observers accredited to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, the Standing Committee on the Law of Patents and the Working Group on PCT Reform by the agreed deadline of the end of March 2005 (circular C.7121). A total of six observations and comments were received in response to the circular C.7121.

3. The fourth step in the adopted timetable and modalities provides that "all comments and observations received will be published on the WIPO website as and when received and in a consolidated document following the expiration of the time period for the submission of such comments and observations." Accordingly a webpage was established in which all comments and observations received were published and a consolidated compilation of all the observations and comments received is contained in the Annex to this document.

[Annex follows]

ANNEX

OBSERVATIONS AND COMMENTS SUBMITTED BY MEMBER STATES AND OBSERVERS ON THE FIRST DRAFT OF AN EXAMINATION OF ISSUES RELATING TO THE INTERRELATION OF ACCESS TO GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS IN INTELLECTUAL PROPERTY RIGHTS APPLICATIONS

Brazil
Japan
Switzerland
United States of America

Berne Declaration
Center for International Environmental Law

BRAZIL
Received May 6, 2005

Initial Comments of Brazil on the First Draft of the "Examination of Issues relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications" (Document WIPO/IP/GR/05/01), Prepared in Response to the Invitation of the 7th COP of the CBD

Brazil agrees generally with the approach taken by the International Bureau in preparing document WIPO/IP/GR/05/01. It is important for the response to the CBD to be inclusive of all positions. The following are some initial remarks by Brazil on specific aspects and language contained in the first draft of the response. Brazil reserves the right to make additional comments and proposals on the draft response in the next stages of the exercise.

Comments on specific sections of DOCUMENT WIPO/IP/GR/05/01:

Part I: INTRODUCTION

Paragraph 21: A reference in this paragraph is made to the study commissioned jointly by WIPO and UNEP. Brazil is of the view that the response to the CBD should be based on the submissions and proposals made by WIPO Member States. We question, therefore, the convenience of including references to studies, such as the one mentioned in Paragraph 21, which have been commissioned to individuals from outside of WIPO, without the approval of Member States, and which do not necessarily reflect the views of Member States.

This remark applies to all places in document WIPO/IP/GR/05/01 where the abovementioned study is referred to.

Paragraph 28: In accordance with the CBD, traditional knowledge is linked to biodiversity, instead of genetic resources.

Paragraph 29: In dealing with CBD provisions concerning ABS, the document refers to Article 16 when we believe the intention was to mention Article 15.

Paragraph 37: The paragraph should also clarify that discussions on genetic resources also took place in the 9th session of the SCP, when the Standing Committee considered Article 5 of the draft SPLT.

PART III: TECHNICAL AND LEGAL BACKGROUND

Paragraph 74: This paragraph contains inadequate characterizations of the disclosure proposals, including those put forward by developing countries, and should therefore be either deleted or considerably redrafted. Contrary to what the paragraph suggests, the disclosure proposals do not constitute an attempt to use the patent system to enforce non-patent legal

requirements or for the pursuit of objectives of distinct legal mechanisms. Rather, the objectives of the disclosure proposal, as formulated by Brazil and other developing countries, are quite germane to the patent system, as they essentially seek to ensure that the international patent system operates in a more equitable and balanced manner. A basic concern of most proponents of disclosure requirements is to ensure that the patent system does not reward inequitable behavior, and, in particular, does not reward patent applicants for violating the laws of the countries of origin of genetic resources utilized in developing the invention. The disclosure requirement, as proposed by Brazil and other developing countries, would, in effect, be fully in line with existing principles and objectives of the existing patent system, such as those enshrined in Articles 7, 8, 27.2 and 27.3 of the TRIPS Agreement. It is improper, therefore, for this Paragraph of document WIPO/IP/GR/05/01 to state that "some uncertainty surrounds this kind of mechanism in international policy debate", since the fundamental question and concern of developing countries with respect to this issue are in fact crystal-clear. Simply put, Brazil and other countries proposing disclosure of origin/PIC/benefit sharing requirements believe that the patent system, in order to retain its credibility and robustness, should not reward this kind of inequitable behavior. Other countries, however, have yet to provide a straightforward answer to this basic and simple question.

Paragraph 79: This paragraph states that the patent application plays a secondary role in providing evidence of the legitimacy of the research or commercial behavior that makes use of the GBMR/TK. In our view, this statement is improper as it overlooks the fact that disclosing information about access to GBMR/TK in the patent application helps assessing whether the research activity was carried out in accordance with the applicable rules and, thus, whether it can be considered legitimate.

PART IV: SPECIFIC ISSUES IN THE CBD COP INVITATION

Paragraphs 86 and 87: Brazil does not agree with the characterization of its disclosure proposals as "entirely new", since some of these disclosure mechanisms are already being implemented in some national jurisdictions, as is pointed in document WIPO/IP/GR/05/01 itself. Disclosure of origin, prior informed consent and benefit sharing requirements can only be considered "new" insofar as there is not yet an international mandatory disclosure requirement that can be implemented in all countries. On the other hand, though disclosure of origin/PIC/benefit sharing could be described as a "specific" disclosure mechanism, Brazil believes that such a mechanism would be fully in line with the existing principles and objectives of the patent system and, if adopted and implemented at the international level, would only work to improve the functioning of the existing international patent system.

Paragraph 99: Brazil concurs with the African Group that it would not be appropriate for WIPO to examine "model provisions for disclosure requirements", since model provisions do not constitute an effective measure for combating the misappropriation of genetic resources. Like the African Group, Brazil believes that an effective solution to the global problem of "bio-piracy" would be, among other measures, to adopt and implement a mandatory universal disclosure requirement in all countries alike.

Summary of triggers for disclosure requirements (pages 44 to 45 of document WIPO/IP/GR/05/01): it is inappropriate to characterize different trigger mechanisms as falling into the categories of either adaptations of existing patent law principles or as "further forms of linkage, beyond existing patent law principles". This is not a neutral formulation,

and should be deleted. As explained previously, Brazil believes that the triggers of disclosure requirements that it and other developing countries have proposed, including those listed in the summary as extending "beyond existing patent law principles", are in effect grounded in principles and objectives enshrined in provisions of existing international IP instruments, such as Articles 7 and 8 of the TRIPS Agreement.

Paragraph 119: The CBD is being quoted out of context on the issue of perverse incentives, and this may give rise to considerable confusion. In our opinion, the CBD does not endorse the "perverse incentive" argument that a few countries have tried to use to oppose disclosure of origin proposals. Still with respect to the issue of "perverse incentives", Brazil would like to point out, as it has done in submissions tabled at the WTO TRIPS Council, that the currently existing patent system itself has not been able to prevent cases of misappropriation of genetic resources. The numerous documented cases of bad and questionable patents may suggest that "perverse incentives" may be at play in the existing patent system that one should modify. In this regard, Brazil believes that a universal mandatory disclosure of origin requirement would prove an effective safeguard against misappropriation of genetic resources and associated traditional knowledge, and should, therefore, be seen as a measure destined to rectify a "perverse incentive" inherent to the existing patent system.

Paragraph 128: We believe the document should not reflect personal opinions, as is the case with this paragraph. Therefore, as stated previously, references to the study commissioned by WIPO and UNEP should be avoided, as it does not reflect the views of WIPO Member States.

Summary of incentives, pages 49 and 50:

The list of "perverse" incentives should also include a reference to the fact that the lack of a mandatory universal disclosure of origin obligation provides a "perverse incentive" for misappropriation within the patent system.

JAPAN
Received March 31, 2005

Comments on the WIPO First Draft on Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications (WIPO/IP/GR/05/01)

4. In accordance with the decision adopted at the 31st session of the WIPO General Assembly in October 2004, Japan furnished its commentsen titled "Japan's Comments on Draft Guide on Intellectual Property Aspects of Agreements on Access and Equitable Benefits Sharing Relating to Genetic Resources" on December 17, 2004.

5. In regard to the first draft on *Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications* (WIPO/IP/GR/05/01), this compilation of comments from every member state is very constructive for future discussions of the relevant issues. Taking this opportunity, Japan would like to thank the WIPO secretariat for its efforts to compile the first draft.

6. The following are our comments on the first draft (which utilize and correspond to the numbering of paragraphs in the first draft):

I. Paragraphs 99 to 101: *Concerns about or limits to the development of model provisions*

We assume that a possible explanation of "the need for disclosing the source/country of origin" cannot be found in the disclosure requirements which are required as a prerequisite for granting a patent to an invention under the patent system.

Please add the sentences below as paragraph 102, some of those comments were already submitted from Japan in December 2004.

> 102. Japan has been making a point that "a patent system provides for two categories of disclosure requirements (i.e. substantive and formative requirements) as a prerequisite for granting patent right for an invention. The necessity to disclose the source/country of origin cannot be explained by the requirements of a patent system. Unless the need for such disclosure is clearly explained, any administrative sanctions including invalidation of a patent right should not be incorporated into a patent system." Specifically, in regard to the substantive requirements, Japan expresses the following point.
>
> > Currently, the microorganism deposit system has been able to fully satisfy the application description requirements (including enablement requirements). Therefore, imposing a new obligation to disclose the source/country of origin of genetic resources in patent applications cannot be considered to be such a meaningful approach. For an application for an invention based on a microorganism, which any person skilled in the art can easily access, the applicant is not required to deposit the microorganism. The applicant only has to describe how the invention can be worked, using such a microorganism which is

> accessible to the public, in a manner for any person skilled in the art to be able to work the invention. Information about the source/country of origin of genetic resource cannot be used to satisfy application description requirements (including enablement requirements). Therefore, as for microorganisms made accessible to the public with which the application deals, imposition of a new obligation on applicants to disclose the source/country of origin of genetic resources in their patent applications cannot be considered a meaningful approach in terms of application description requirements (including enablement requirements). Information about the source/country of origin of genetic resources might be unnecessary for judging the level of novelty and inventive step of an invention. Such information cannot be considered to be essential for prior art searches, either. Therefore, there is no reason why such information should be furnished as an additional disclosure requirement from the perspective of the examination process.

In addition, in regard to the formative requirements, Japan raised the following point:

> Such entries as applicant names are to be made formative requirements only when such requirements are regarded as reasonable (see Article 62 of the TRIPS Agreement). As regards the disclosure of the source/country of origin of genetic resources, therefore, we are not convinced that such disclosure requirement is regarded as "reasonable procedures and formalities." Even without such disclosure, there is no problem in carrying out the patent procedure and such lack of disclosure does not make the patent procedure ineffective.

Japan considers that "access to genetic resources and fair/equitable benefit sharing in the context of CBD can be secured without making it an obligation to disclose the source/country of origin of genetic resources in a patent application. Imposition of such an obligation can dampen applicants' will to create an invention using genetic resources and to obtain a patent for that invention. As a result, benefits deriving from genetic resource-related inventions can be reduced, which, thus does not meet the purposes of CBD."

II. Paragraph 126: *Possible undesirable or perverse incentives*

In Paragraph 126, Japan submitted comments in December which were quoted, and we would appreciate, in addition to those comments, that the following comments be added. Specifically, following the last sentence of Paragraph 126, we would like to add the following.

> Japan also added that "where evidences for a prior informed consent or fair/equitable benefits sharing are to be disclosed in a patent application, contracts can be counted as possible evidence. A contract normally contains much information such as trade secrets, which the applicant does not want others to know. If the contents of a contract are to be made open in a patent application, this will not only simply lead to an increased workload but also involve the risk of disclosing important trade secrets. In the end, therefore, the incentive to carry out R&D activities using genetic resources is substantially reduced."

SWITZERLAND
Received March 31, 2005

Comments by Switzerland on

"Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications" (first draft)

"Member State Proposals and Suggestions Regarding the Invitation to WIPO from the Conference of the Parties to the Convention on Biological Diversity on access to Genetic Resources and Disclosure Requirements in Intellectual Property rights Applications" (provisional compilation)

I. GENERAL COMMENTS

7. Switzerland welcomes the first draft examination of issues relating to the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications. Switzerland considers it to be of great importance that WIPO provides a timely and comprehensive response to the CBD's invitation to examine, and where appropriate address, these issues. Switzerland regrets the small number of submissions by WIPO Member States with regard to the CBD's invitation and hopes that additional replies will be submitted in due time.

8. Switzerland has played an active and constructive role in the international discussions on disclosure requirements in patent applications: Switzerland submitted specific and detailed proposals on the disclosure of the source of genetic resources and traditional knowledge in patent applications to the Working Group on Reform of the Patent Cooperation Treaty (PCT) of WIPO in May 2003.[1] Switzerland presented two more submissions containing additional comments and further observations on its proposals in May and October 2004, respectively.[2] Moreover, Switzerland also presented submissions on its proposals to other international fora, namely the TRIPS Council[3] and the CBD[4].

9. In the view of Switzerland, the first draft of this examination provides a thorough analysis of the issues at hand. This first draft, however, does not fully reflect all aspects of the Swiss proposals on the declaration of the source and the various documents submitted by Switzerland to the relevant international fora. Accordingly, Switzerland proposes several amendments to the first draft examination (see below "Comments on draft examination").

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1 See WIPO-document PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11 Rev.
2 See WIPO-documents PCT/R/WG/6/11 and PCT/R/WG/7 Paper No. 7.
3 See WTO-documents IP/C/W/400/Rev.1, IP/C/W/423 and IP/C/W/433.
4 See CBD-document UNEP/CBD/WG-ABS/3/INF/7.

II. COMMENTS ON DRAFT EXAMINATION

– ad "Part II": Switzerland considers Part II "Overview of Existing Proposals and Mechanisms" to be of great value to the examination. Accordingly, Part II should be retained in the document.

– ad para. 35: We propose to add in the list of submissions to the TRIPS Council the submission by Switzerland entitled "*Article 27.3(b), the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge*" of 18 June 2003 (see doc. IP/C/W/400/Rev.1). This submission not only presents the proposals of Switzerland regarding the declaration of the source of genetic resources and traditional knowledge in patent applications, but also contains the position of Switzerland on the proposed requirements to provide evidence of prior informed consent and of benefit sharing in patent applications.

– ad para. 42: We propose to add a footnote containing the references to the three submissions presented by Switzerland on its proposals (that is, WIPO-documents PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11 Rev; PCT/R/WG/6/11; and PCT/R/WG/7 Paper No. 7).

– ad "Proposal by Switzerland to amend the PCT Regulations" (paras. 42-44): We propose to add text summarizing the proposals by Switzerland of May 2003 regarding the establishment of an information system on patent applications containing declarations of the source:

> "*Additionally, Switzerland invited WIPO, in close collaboration with the CBD, to consider the establishment of a list of government agencies competent to receive information on the declaration of the source in patent applications. According to this proposal, the office receiving a patent application containing a declaration of the source of a genetic resource or the associated traditional knowledge would inform the competent government agency of the State declared as the source about the respective declaration. Particularly well suited for this task would seem to be the national focal point for access and benefit sharing as described in para. 13 of the Bonn Guidelines. This list of competent government agencies could be made accessible through WIPO and the Clearing House Mechanism (CHM) of the CBD. States interested in receiving such information could indicate to WIPO the competent government agency, which would then be included in the proposed list*."

– ad para. 54: To better reflect the state of play of the discussions in the TRIPS Council, we propose to amend para. 54 as follows: "It then cites a checklist that was submitted *by a group of WTO Members* in 2004 to the WTO Council for TRIPS ~~as a recent overview~~ *containing* ~~of~~ issues *that these Members propose to be* ~~that are currently under~~ considere*d by the TRIPS Council*~~ation~~ and *that* may ~~therefore~~ be considered relevant to the present examination."

– ad "TRIPS Council Checklist of Issues" (para. 81): Again, to better reflect the state of play of the discussions in the TRIPS Council, we propose to amend the current title of the subsection "TRIPS Council Checklist of Issues" to "Checklist of issues submitted to the TRIPS Council by a group of WTO Members."

– ad para. 87 and footnote 28: Besides the proposals submitted by Brazil mentioned in footnote 28, other delegations have also submitted proposals with regard to these issues as well. Switzerland submitted detailed proposals with regard to the disclosure of the source of genetic resources and traditional knowledge in patent applications (see the documents mentioned in footnotes 1 and 2 above). Switzerland also expressed its position on the proposed requirement to provide evidence of prior informed consent and of benefit sharing in patent applications (see WTO-document IP/C/W/400/Rev.1). Accordingly, we propose to include the just mentioned documents by Switzerland in footnote 28.

– ad "Some possible functions of disclosure requirements" (para. 89): We propose to add the following text:

> "*Switzerland views the declaration of the source of genetic resources and traditional knowledge in patent applications to be a measure that increases transparency in the context of access to genetic resources and traditional knowledge and the sharing of the benefits arising out of their utilization, in particular with regard to the obligations of the users of genetic resources and traditional knowledge, and terms these measures 'transparency measures'.*"

– ad "Other guidance on options for disclosure requirements" (paras. 90-98): We propose to add the following text:

> "*The Swiss proposals use the terms "genetic resources" and "traditional knowledge related to genetic resources" to ensure consistency with the CBD, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization (Bonn Guidelines) and the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty) of the Food and Agriculture Organization (FAO). As a measure under patent law, the focus is on traditional knowledge that can give rise to a technical invention.*
>
> *Switzerland proposes to require patent applicants to declare the "source" of genetic resources and traditional knowledge. The term "source" should be understood in its broadest sense possible. This is because according to the international instrument referred to above, a multitude of entities may be involved in access and benefit sharing. In the foreground to be declared as the source is the entity competent (1) to grant access to genetic resources and/or traditional knowledge or (2) to participate in the sharing of the benefits arising out of their utilization. Depending on the genetic resource or traditional knowledge in question, one can distinguish primary sources, including in particular Contracting Parties providing genetic resources, the Multilateral System of FAO's International Treaty, indigenous and local communities, and secondary sources, including in particular ex situ collections and scientific literature. Accordingly, there is a "cascade" of possible primary and secondary sources: Patent applicants must declare the primary source to fulfil the requirement, if they have information about this primary source at hand. A secondary source may only be declared if patent applicants have no information at hand about the primary source.*

With regard to genetic resources, the proposed new Rule 51bis.1(g)(i) of the PCT Regulations makes clear (1) that the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource, and (2) that the inventor must have had physical access to this resource, that is, its possession or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the invention. With regard to traditional knowledge, the proposed new Rule 51bis.1(g)(ii) of the PCT Regulations makes clear that the inventor must know that the invention is directly based on such knowledge, that is, the inventor must consciously derive the invention from this knowledge."

– ad B. Triggers for disclosure requirements" (paras. 104-114): Para. 104 distinguishes the "trigger" for disclosure requirements in a substantive and in a procedural sense. Switzerland expressed its views on both of these senses in detail. Accordingly, we propose to add the following text:

"*With regard to the trigger of the disclosure requirement in the substantive sense, the proposals by Switzerland distinguish between genetic resources and traditional knowledge: With regard to genetic resources, the proposed new Rule 51bis.1(g)(i) makes clear (1) that the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource, and (2) that the inventor must have had physical access to this resource, that is, its possession or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the invention. With regard to traditional knowledge, the proposed new Rule 51bis.1(g)(ii) makes clear that the inventor must know that the invention is directly based on such knowledge, that is, the inventor must consciously derive the invention from this knowledge.*

With regard to the trigger of the disclosure requirement in the procedural sense, the proposals by Switzerland proposes to amend the Regulations under the Patent Cooperation Treaty (PCT) to explicitly enable the Contracting Parties of the PCT to require patent applicants, upon or after entry of the international application into the national phase of the PCT procedure, to declare the source of genetic resources and/or traditional knowledge, if an invention is directly based on such resource or knowledge. Furthermore, Switzerland proposes to afford applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase."

– ad "C. Incentive Measures for Applicants" (paras. 115-128): In its submissions on its proposals, Switzerland addressed incentive measures in detail. Accordingly, we propose to add the following text:

"In the view of Switzerland, the sanctions currently allowed for under the PCT and the PLT should apply to failure to disclose or wrongful disclosure of the source of genetic resources and traditional knowledge in patent applications.

Accordingly, if the national law applicable by the designated Office requires the declaration of the source of genetic resources and traditional knowledge, Rule 51bis.3(a) of the PCT Regulations requires the designated Office to invite

the applicant, at the beginning of the national phase, to comply with the disclosure requirement within a time limit which shall not be less than two months from the date of the invitation. If the patent applicant does not comply with this invitation within the set time limit, the designated Office may refuse the application or consider it withdrawn on the grounds of this non-compliance. If, however, the applicant submitted with the international application or later during the international phase the proposed declaration containing standardized wording relating to the declaration of the source (see proposal by Switzerland for new subpara. (vi) of Rule 4.17), the designated Office must accept this declaration and may not require any further document or evidence relating to the source declared, unless it may reasonably doubt the veracity of the declaration concerned.

Furthermore, if it is discovered after the granting of a patent that the applicant failed to disclose the source or submitted false information, such failure to comply with the disclosure requirement may not be a ground for revocation or invalidation of the granted patent, except in the case of fraudulent intention (Article 10 PLT). However, other sanctions provided for in national law, including criminal sanctions such as fines, may be imposed."

– ad para. 164 and 166: As the fifth element of the CBD COP invitation states, the proposed certificate could also cover the "source." Accordingly, we propose to amend para. 164 as follows: "This *proposed* system of certification […] potentially has bearing on specific requirements concerning *the declaration of the source,* evidence of prior informed consent and of equitable benefit sharing." With regard to para. 166, we propose the following amendment: "As noted above, certification may be relevant to any specific requirement concerning *the declaration of the source,* evidence of prior informed consent and of equitable benefit sharing, or more broadly to comply with any requirement to demonstrate that relevant materials have been acquired lawfully."

– ad "comments on certification issues" (paras. 168-171): In this context, Switzerland proposes to establish a list of government agencies competent to receive information on the declarations of the source. Accordingly, we propose the following amendments to the text:

"Several factors weaken the effectiveness of the proposed requirement to declare the source of a genetic resource and/or knowledge, innovations and practices, in patent applications: If the source of a genetic resource or knowledge, innovations and practices, is merely declared in patent applications, States and other stakeholders interested in verifying whether they are named in patent applications would have to scrutinize the large number of patent applications filed annually worldwide. Additionally, some patent offices do not publish patent applications at all or only after the expiration of a certain period of time; furthermore, it may take several years from the filing of a patent application to the granting of a patent and its publication. Thus, if patent applications are not published, the declaration of the source would not become publicly accessible until the patent is granted and published. This could be changed if the office receiving a patent application containing a declaration of the source of a genetic resource or knowledge, innovations and practices, would inform a government agency of the State declared as the source about the respective declaration. Particularly well suited for this task would seem to be the national focal point for access and benefit sharing as

described in para. 13 of the Bonn Guidelines. Switzerland therefore invites WIPO, in close collaboration with the CBD, to consider the establishment of a list of government agencies competent to receive this information. This list could be made accessible through WIPO and the Clearing House Mechanism (CHM) of the CBD. States interested in receiving such information could indicate to WIPO the competent government agency, which would then be included in the proposed list.

The information about the declaration could be provided in a standardized letter which is sent to the competent government agency in the State indicated in the patent application. This letter would inform this government agency that the respective State has been declared as the source of the genetic resource or knowledge, innovations and practices, and contain the name and address of the patent applicant."

III. COMMENTS ON PROVISIONAL COMPILATION OF MEMBER STATE PROPOSALS AND SUGGESTIONS

10. Pages 30 to 40 of the provisional compilation contain the reply by Switzerland to Note C. 7092. The table of contents provided for on pages 30 to 31, however, refers to text not contained in the Swiss reply; this concerns the text referred to on page 8 and pages 44 to 51 in the table of contents. The table of contents should thus be revised accordingly.

UNITED STATES OF AMERICA
Received April 18, 2005

USPTO Comments on WIPO/IP/GR/056/01 Entitled "Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications"

The United States Patent and Trademark Office would like to thank the International Bureau for the opportunity to provide comments on the document entitled "Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications." Below are our comments and suggestions.

On page 19, following paragraph 51, please insert a description of U.S. national measures, as follows:

UNITED STATES

The U.S. National Parks Omnibus Management Act of 1998 expressly authorizes "negotiations with the research community and private industry for equitable, efficient benefit-sharing arrangements" in connection with research conducted in national parks. The Act also mandates increased scientific research in the national parks and the use of science in park management decisions. The law encourages the national parks to be places for scientific study by public as well as private sector researchers, and mandates long-term inventory and monitoring programs that provide baseline information, and document trends relating to the condition of park resources. The law does so by requiring permits to collect samples in the national parks. In order to obtain a permit, parties seeking access must first negotiate a cooperative research and development agreement (CRADA) with the park system.

As an example, a CRADA was entered into between a company named Diversa and Yellowstone National Park in 1999. Under the CRADA, Diversa was allowed to take DNA samples from wolves in Yellowstone. In exchange, Diversa developed the first DNA pedigree for the endangered Yellowstone wolves at no charge to the U.S. government. This pedigree, which the Yellowstone National Park could not have afforded to pay for, helps in understanding the dynamics of the wolf population, assessing the genetic health of the park's wolf population, identifying wolves that are killed illegally, detecting when wolves from other areas immigrate to Greater Yellowstone, and documenting breeding in the wild. This knowledge is used by Yellowstone staff in carrying out their charge to conserve the wildlife in the park for the enjoyment of future generations.

On pages 21-22, paragraph 57, please insert the following bullets, to reflect an additional underlying questions that must be considered with respect to new disclosure requirements:

- Is the patent law the appropriate vehicle for ABS?
- What impact would a new disclosure requirement have on innovation?

– Will the pursuit of ABS through the patent system cause greater harm than benefit?
– How would a new disclosure requirement transfer benefits?
– Have any of the disclosure requirements that have been implemented promoted ABS in an effective manner?
– How have new disclosure requirements affected rates of innovation in those countries?

On page 28, please change the title from "TRIPS Council Checklist of Issues" to "TRIPS Council." Under this heading, please reflect that the TRIPS Council has decided not to structure its work based upon the proposed checklist. Please also note that another proposal was made by the United States to structure work upon widely shared objectives of WTO Members. These objectives consist of (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. This approach is preferred by certain Members in order to ensure that the positions of all Members are fully considered, without prejudice to any particular position, in order to facilitate resolving differences between Members in that forum. Furthermore, this approach has generated significant discussion in that forum as evidenced by a number of papers engaging on that level (see IP/C/W/434 by the United States and IP/C/W/443 by India and Brazil) as well as comments by various Members.

Furthermore, the TRIPS Council, in response to an initial proposal by the delegation of Canada, has embarked upon a more "fact-based" discussion involving national experiences in trying to achieve progress in that area.

On page 31, paragraph 86, please insert a third option for model provisions, as follows:

(iii) maintaining, and not exceeding, traditional disclosure requirements, as these are the most constructive and least harmful model.

On page 33, after paragraph 89, please insert the following:

The submission of the United States pointed out that that new disclosure requirements may be inconsistent with, or may conflict with, WIPO-administered treaties such as the PCT and PLT, as well as the WTO-administered TRIPS Agreement.

On page 37, in the Summary of Options for Model Provisions, please insert a new subparagraph, as follows:

(f) The form or status of model provisions for new disclosure requirements is not relevant, as the best option is to not adopt a new disclosure requirement in the patent laws because a new disclosure requirement would not effectively facilitate ABS, and it would discourage innovation.

BERNE DECLARATION
Received March 29, 2005

Comment on the draft of the "examination of issues relating to the interrelation of access to genetic resources and disclosure requirements in Intellectual property right applications"

The Berne Declaration welcomes the opportunity to submit comments on the draft prepared by the WIPO secretariat. We would like to emphasise following points:

1. The wording of the invitation of the Conference of Parties of the CBD, stating that the work of WIPO regarding the interrelation of access and to genetic resources and disclosure requirements should be supportive of and does not run counter to the objectives of the CBD, should be the guiding principle of WIPO's work.

2. Disclosure requirements are one important tool to make sure that no patents are granted for inventions which are based on genetic resources or traditional knowledge which have been accessed in contradiction to the CBD rules and the relevant national laws.

3. Disclosure requirements will not only support the objectives of the CBD but also preserve confidence in the IP-System. Giving monopoly rights to inventors which have bio-pirated genetic resources or traditional knowledge undermines this confidence.

4. In relation to the Swiss proposal for incorporating the disclosure requirement into national patent law, the Berne Declaration has made some precise recommendations for a practical option for such requirements that should be noted (http://www.wipo.int/tk/en/igc/ngo/meienberg2.pdf).

5. Taking in to account the objectives of the Convention on Biological Diversity, especially the fair and equitable sharing of the benefits and the appropriate access to genetic resources, which shall be on mutually agreed terms and subject to prior informed consent (pic), the Berne Declaration is of the view that disclosure requirements should incorporate the evidence of compliance with pic and with fair and equitable benefit sharing under the relevant national regime. For patent applicants who have chosen the legal path to access genetic resources this disclosure represents no additional effort since they already needed these documents in order to gain access to resources and/or traditional knowledge. It is possible that this information is part of a Material Transfer Agreement (MTA).

6. A regulation only makes sense if disclosure is made an integral part of the application process and false statements are subject to severe penalties. Consequently, any patent based on false statements should be revoked.

7. The right of a country of origin or an indigenous community to claim their share of the benefits deriving from the illegal (i.e. not CBD compatible) use of their resources under a patented invention must be anchored in the law. More thoughts on this often neglected issue could be found at http://www.wipo.int/tk/en/igc/ngo/meienberg1.pdf .

CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW
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Observations from the Center for International Environmental Law (CIEL)
on the First Draft of the WIPO Examination of the Issues

I. Introduction

11. In October 2004, the Assemblies of the World Intellectual Property Organization (WIPO) decided to respond positively to the invitation of the Convention on Biological Diversity (CBD) for WIPO "to examine, and where appropriate address, taking into account the need to ensure this work is supportive of and does not run counter to the objectives of the CBD, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications" and established a procedure for preparing the response.[5] The modalities and timetable adopted included the possibility for all Member States and observers accredited to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), Standing Committee on the Law of Patents (SCP) and Working Group on the Reform of the Patent Cooperation Treaty (PCT) to submit observations and comments on the First Draft of the WIPO Examination of the Issues (First Draft) by the end of March 2005.

12. The Center for International Environmental Law (CIEL), an accredited permanent observer to WIPO, has the honor to request that the present comments on the First Draft be appropriately considered in the process of developing a response to the CBD request. In this regard, after the introduction, Section II will present several principles that should be considered in order to establish an adequate framework and approach to the WIPO response. Principles that will be addressed include, among others, the need to support of the CBD objectives and to respond to the guidance of WIPO Member States and accredited observers, which would assure that the WIPO response constructively contributes to the CBD process while maintaining a focus on integrating the CBD principles into the international intellectual property system. Then, Section III will analyze the specific elements of the CBD request in the First Draft, indicating in particular the lack of emphasis on avoiding the misuse of the intellectual property system and on developing the mandatory international rules needed to effectuate the CBD objectives as well as those of the intellectual property system itself. Lastly, these comments will finalize with some concluding thoughts.

[5] See Decision taken by the 2004 meeting of the WIPO General Assembly on Item 10 of the Consolidated Agenda: "Matters concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore," Report of the Thirty-First (15th Extraordinary) Session of the WIPO General Assembly, held in Geneva on September 27 to October 5, 2004, WIPO document WO/GA/31/15, at paragraph 119. The invitation was made by the Seventh Meeting of the Conference of Parties of the CBD, held in Kuala Lumpur on 9-20 and 27 February 2004, in Decision VII/19.

II. Establishing an Adequate Framework and Approach to the WIPO Response

13. The CBD invitation to WIPO elicited a number of concerns, both in the CBD and the WIPO contexts. In discussions at the Seventh Conference of the Parties of the CBD (COP VII) and later at the IGC and the Assemblies in WIPO, developing countries and observers emphasized the need for any WIPO response to adequately reflect the context of the invitation – the CBD objectives and process – as well as the state of discussions in its own bodies.[6] The importance of adequately approaching the development of a WIPO response, from the process itself to the substance of an eventual document thus became evident. The decision by the WIPO Assemblies to address the CBD request in a cross-cutting manner with the participation of all WIPO Members and accredited observers was, in this regard, a very positive development.[7]

14. Ensuring the WIPO response approaches the issue of interrelation of access to genetic resources and disclosure requirements in patent applications within an appropriate framework should continue to be a fundamental consideration throughout the process established by the WIPO Assemblies. In this regard, the First Draft would significantly benefit from a more systematic and thorough recognition of the objectives and principles of the CBD and the Bonn Guidelines and of the need and value of disclosure requirements for the conservation and

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[6] See, e.g., discussions on the bracketed references to cooperation with WIPO reported by the Environmental Negotiations Bulletin (ENB Vol. 09 No. 284 CBD COP-7 - Summary and analysis). See also discussions in the Sixth Session of the IGC, held in Geneva in March 2004, under Agenda Item 6: Genetic Resources in regards to Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, Report, WIPO document WIPO/GRTKF/IC/6/14, starting at paragraph 140, as well as discussions leading to the WIPO General Assembly decision in *supra* note 1.

[7] The following modalities and timetable were adopted:

(i) the Director General will invite all Member States of WIPO to submit proposals and suggestions before December 15,2004;

(ii) a first draft of the examination (the draft) will be prepared by the International Bureau and published on the WIPO website and circulated by the end of January 2005 to all Member States of WIPO and observers accredited to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), Standing Committee on the Law of Patents (SCP) and Working Group on PCT Reform (PCT Reform WG) for observations and comments;

(iii) all Member States and these accredited observers may submit observations and comments on the draft by the end of March 2005;

(iv) all comments and observations received will be published on the WIPO website as and when received and in a consolidated document following the expiration of the time period for the submission of such comments and observations;

(v) a one-day ad hoc intergovernmental meeting will be held in May 2005 to consider and discuss a revised version of the draft. The revised version of the draft will be made available at least 15 days before the Meeting. All Member States of WIPO and the accredited observers will be invited to attend the Meeting, which shall elect its chair and will be held under the General Rules of Procedure of WIPO. With respect to the scheduling of this meeting, the meeting shall be scheduled to occur on a date that will permit the participation of the maximum number of observer organizations of indigenous and aboriginal peoples;

(vi) the International Bureau, shall prepare a further revised draft following the Meeting which shall be presented to the WIPO General Assembly at its ordinary session in September 2005 for consideration and decision.

sustainable use of biodiversity already identified in that context.[8] The WIPO response should also fully reflect the views and proposals put forth by Member States and accredited observers in the WIPO context, as well as relevant WIPO decisions and processes.[9] Principles that should be acknowledged in the WIPO response, in this regard, include the need to recognize the leading role of the CBD in biodiversity-related issues; to support and not run counter to the objectives of the CBD; to respond to the guidance of WIPO Member States and accredited observers; and to fully integrate the development dimension. Incorporating these principles would ensure the WIPO response constructively contributes to the CBD process while maintaining a focus on integrating the CBD principles into the international intellectual property system.

II.1 The WIPO response should recognize and reflect the leading role of the CBD in international biological diversity issues

15. The WIPO response should consider not only the immediate context of the CBD request but also the continuing leadership of the CBD in access and benefit-sharing issues. Indeed, COP VII, while emphasizing the need for international collaboration and inviting several international organizations to examine issues related to disclosure requirements, clearly recalled the leading role of the CBD in international biological diversity issues. The prominence of the CBD on biodiversity issues is recognized due to its comprehensive and balanced approach to the conservation and sustainable use of biodiversity, as well as its broad membership and stakeholder participation.[10] On access and benefit-sharing issues in particular, the CBD is a fundamental reference. The CBD Working Group on Access and Benefit-sharing, for example, is currently negotiating an international regime on access to genetic resources and benefit-sharing.

16. The First Draft does, for instance, suggest a disclaimer that explicitly frames the document as "technical input to facilitate policy discussion and analysis in the Convention on Biological Diversity."[11] Nevertheless, it would be important for the WIPO response to include a clearer recognition that, while WIPO as an institution has a significant role in terms of addressing these challenges within its own intellectual property rules, it is only able to provide peripheral input into the CBD process. In particular, recognizing the leading role of

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8 The Bonn guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization were adopted in the Sixth Meeting of the Conference of the Parties to the CBD (see Decision VI/24). The Guidelines are recognized a first step of an evolutionary process in the implementation of relevant provisions of the Convention related to access to genetic resources and benefit-sharing. They aim to assist Parties, governments and other stakeholders in developing an overall access and benefit-sharing strategy and in establishing legislative, administrative or policy measures on access and benefit-sharing.

9 Including the decision taken by the 2004 meeting of the WIPO General Assembly on Item 12 of the Consolidated Agenda: "Proposal for Establishing a Development Agenda for WIPO," see *supra* note 1, at paragraph 218, and the ongoing process on the WIPO Development Agenda.

10 The CBD focuses on biological diversity in the context of promoting sustainable development, recognizing the intrinsic value of biological diversity as well as its value in the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic contexts. It has 188 Parties to date.

11 See First Draft of "Examination of Issues relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications," prepared by the WIPO Secretariat, WIPO document WIPO/IP/GR/05/01, at paragraphs 8 and 9.

the CBD on access and benefit-sharing issues would entail making the following modifications:

17. First, it is important for WIPO to strictly limit its response to the scope defined by the CBD request. The First Draft notes that the CBD request has some distinct elements. These elements aim primarily to delimitate the scope of the invitation and qualify the nature and content of the response. They were introduced as a result of the growing concern that an excessive participation and influence of WIPO in the CBD process could prove detrimental to effectively achieving CBD objectives and to promoting mutual supportiveness.[12] In this regard, the Memorandum of Understanding between the CBD and WIPO also emphasizes that undertaking studies and providing other technical inputs is solely upon request and subject to the relevant approvals.[13] Consequently, any analysis of the issues should be strictly guided by the character of the CBD invitation and broader CBD process, and thus focus primarily on addressing current gaps and shortcomings in international intellectual property rules, rather than dealing with other aspects of access and benefit-sharing. Expounding on technical and legal issues related to terminology and other topics, for instance, does not seem appropriate for the WIPO response.[14] Although some clarification on the use of terms in the context of the WIPO response may be necessary, elaborating on the points of difference between diverse expressions in the CBD and on their relevance in access and benefit-sharing, for instance, may be seen as prejudging the work on use of terms currently undertaken by the Working Group on Access and Benefit-sharing.

18. Second, it is fundamental for the WIPO response to explicitly recognize and make reference to the other organizations that have also been asked to contribute to the CBD process. The CBD decision that extended the request to WIPO also invited other relevant organizations to examine the issues of the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications and to report their findings, including the United Nations Conference on Trade and Development (UNCTAD). The First Draft should thus be complemented with an acknowledgement that the WIPO response is only one particular contribution to the discussion and analysis of disclosure requirements and should be considered alongside the work of other relevant international organizations.[15] The work of UNCTAD, for instance, which has a mandate on issues such as ensuring that the framework of intellectual property contributes to technological development and achieving protection in intellectual property rules of traditional knowledge and folklore, without prejudice to the work undertaken in other fora, is particularly significant.[16] Moreover, the last meeting of the Working Group on Access and Benefit-sharing identified a number of fora as pertinent to issues related to disclosure requirements in applications for intellectual property rights, including – in addition to UNCTAD and WIPO – the Food and Agriculture

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12 See, e.g., discussions in COP VII mentioned in *supra* note 2. In addition, discussions at the Third Meeting of the CBD Working Group on Access and Benefit Sharing, which took place in Bangkok in February 2005 and in which CIEL participated as an observer, also reflected concerns regarding achieving an adequate relationship between WIPO and the CBD.

13 See *supra* note 7, at paragraph 15.

14 See, e.g., discussion in *supra* note 7, at paragraphs 25 to 29.

15 The disclaimer and the recognition that the WIPO response cannot provide any definitive examination of disclosure requirements, advocate any particular approach, or develop any guidelines or recommendations with respect to the implementation of the CBD in the First Draft are also important to adequately qualifying the role and scope of the document.

16 "Sao Paulo Consensus", UNCTAD document TD/410 (June 25, 2004), at paragraph 68, available at www.unctad.org/en/docs/td410_en.pdf.

Organization of the United Nations (FAO), the United Nations Environment Programme (UNEP), and the World Trade Organization (WTO).[17]

19. Finally, it is crucial that, as WIPO considers the interrelation of disclosure requirements and intellectual property applications, it recognize that its main focus should be to address these issues within its own bodies, treaties, and negotiations. The draft response does suggest the need for an analysis of how relevant parts of WIPO's work program need to address disclosure requirements, notably work taking place in the SCP, the Working Group on the Reform of the PCT, and the IGC.[18] This point has been repeatedly made by developing countries, who have stated that the priority should be dealing with the gaps in international intellectual property rules that allow the misappropriation of genetic resources and traditional knowledge in all relevant WIPO instruments and activities.[19] Thus, whereas collaborating with the CBD process is valuable, the WIPO response should make clear that such collaboration does not replace nor detract from discussions aimed at ensuring international intellectual property rules in WIPO and other fora do not promote or permit the misappropriation of genetic resources and traditional knowledge. International intellectual property rules need to be modified to guarantee they do not allow illegal and unethical practices, and thus do not undermine sustainable development objectives and rules. The priority of the work on genetic resources and traditional knowledge in WIPO and other intellectual property fora should thus focus on adequately modifying those rules.

II.2 The WIPO response should support and not run counter to the objectives of the CBD

20. Intellectual property is only relevant in the context of the CBD as an instrument to support the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources and, as a result, the First Draft adequately indicates that its analysis is inherently restricted.[20] Indeed, access to and sharing of the benefits arising out of the commercial and other utilization of genetic material is part of the biodiversity debate because products developed from genetic resources found in developing countries often, instead of fueling their economic and social development, are protected by patents or other intellectual property rights that do not recognize or equitably reward the provider countries.[21] The CBD has thus developed a

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17 See Recommendation 3/4 on "Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the contracting party providing genetic resources and mutually agreed terms on which access was granted, in Contracting Parties with users of such resources under their jurisdiction," adopted by the *Ad Hoc* Open-ended Working Group on Access and Benefit-sharing at its Third Meeting (February 2005), at paragraph 5.

18 See *supra* note 7, at paragraph 13.

19 See, e.g., statements of Kenya, India, Brazil, Peru, and others at the Seventh Session of the IGC on the need to deal with the problems posed by intellectual property rules to the effective protection of genetic resources and traditional knowledge and statements of the Asian and African Groups at the 2004 Assemblies on the need to mainstream issues related to genetic resources and traditional knowledge in intellectual property discussions. See also the proposals and statements of developing countries in the Council for TRIPS in the WTO.

20 See *supra* note 7, at paragraph 11.

21 CBD Secretariat, "Sustaining Life on Earth: How the Convention on Biological Diversity promotes nature and human well being," available at www.biodiv.org/doc/publications/guide.asp.

number of principles on the relationship between its provisions and intellectual property. Article 16, for instance, requires Contracting Parties to ensure intellectual property rights are supportive of and do not run counter to CBD objectives. The CBD also recognizes intellectual property rules can play an important role in supporting prior informed consent and fair and equitable benefit sharing, the core requirements in the CBD access and benefit-sharing objectives.[22] Article 15, for example, calls upon each Contracting Party to take legislative, administrative or policy measures aiming to ensure benefits arising from the use of genetic resources are shared in a fair and equitable way with the Contracting Party providing the genetic resources.

21. While WIPO cannot purport to analyze or interpret the objectives and principles of the CBD, as the First Draft recognizes, its work must fully take them into account to adequately reply to the CBD request.[23] In this regard, the examination of the different issues raised by disclosure requirements should begin with the acknowledgement that the need and value of disclosure requirements for the conservation and sustainable use of biodiversity have already been identified by the CBD. The First Meeting of the Panel of Experts on Access to Genetic Resources and Benefit-sharing, convened by the COP in 1999, stated, for instance, that a system in which intellectual property applications required evidence of PIC would create an incentive for users to ensure the traceability of genetic resources and to support compliance with PIC and fair and equitable benefit sharing.[24] The Ad Hoc Open-ended Working Group on Access and Benefit-sharing recognized that disclosure of the use of genetic resources and traditional knowledge in applications for intellectual property rights may assist patent examiners in the identification of prior art and noted that disclosure of origin and evidence of PIC requirements already exist in a number of countries as a precondition for the granting of patents.[25] Moreover, the Sixth Meeting of the COP in 2002 invited Parties and Governments to encourage the disclosure of the country of origin of the genetic resources and traditional knowledge in applications for intellectual property rights, where the subject matter of the applications concerns or makes use of genetic resources or such knowledge in its development, as a possible contribution to tracking compliance with PIC and the mutually agreed terms on which access to those resources and knowledge was granted.[26] As a result, the introduction in the First Draft of commentary questioning the legality and effectiveness of these requirements, for instance, seems highly inappropriate.[27]

22. Supporting the CBD principles and objectives also clarifies the role of WIPO and other intellectual property fora. Since the need for disclosure requirements in intellectual property applications has been clearly identified in the CBD context, the aim of intellectual property discussions generally and of the WIPO response in particular should be to advance the adequate integration of such requirements into the international intellectual property system.

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22 See, e.g., decision II/12 of the Second Meeting of the Conference of the Parties to the CBD, CBD document UNEP/CBD/COP/2/19, Annex II, and report of the First Meeting of the CBD Working Group on Access and Benefit Sharing, CBD document UNEP/CBD/ABS/EW-CB/1/3 (including in a draft action plan on capacity building several references to intellectual property).

23 See *supra* note 7, at paragraphs 18 and 20.

24 See Report of the First Meeting of the Panel of Experts on Access and Benefit-sharing, CBD document UNEP/CBD/COP/5/8, at paragraph 127.

25 See Recommendations adopted by the First Meeting Ad Hoc Open-ended Working Group on Access and Benefit-sharing, CBD document UNEP/CBD/COP/6/6, at Annex.

26 See Report of the Sixth Meeting of the Conference of the Parties to the CBD, CBD document UNEP/CBD/COP/6/20, at 274.

27 See *supra* note 7, at paragraph 53.

Indeed, as has been acknowledged by WIPO Member States, the purpose of discussions on the relationship between intellectual property and biodiversity should be to prevent the misappropriation of genetic resources and traditional knowledge, ensure prior informed consent and equitable sharing of the benefits arising from the use of genetic resources and traditional knowledge, and promote the conservation and sustainable use of biodiversity.[28]

II.3 The WIPO response should respond to guidance of Members States and accredited observers

23. Since WIPO does not have a leadership role in biodiversity issues nor is in a position to advocate any particular approach to disclosure requirements in the context of the CBD, the value of its response necessarily rests in transmitting the proposals put forth and subsequent discussions in different WIPO bodies with the aim of ensuring access and benefit sharing needs and concerns are adequately integrated into the international intellectual property system. Indeed, WIPO Member States, in their initial comments, expressed the need for WIPO to respect these parameters, and the First Draft states it is based on the submissions and proposals made by WIPO Member States within WIPO, with the added value of providing a possible framework of presenting the information in an accessible, concise and neutral manner.[29] Moreover, the First Draft adequately includes developments in intellectual property discussions in other fora, such as the WTO, which are inherently linked to discussions in WIPO. Nevertheless, although the draft response reflects certain aspects of the state of discussions in WIPO and other international fora – from its definition of the "examination" conducted to, for instance, limiting the discussion to patent applications and only briefly addressing the issue of certificates of origin – its format and content do not sufficiently emphasize the proposals and positions of Member States, nor do they consider those of accredited observers that have actively participated in these discussions.[30]

24. Though a section in the First Draft provides an overview of existing proposals and mechanisms in regards to genetic resources, traditional knowledge, and disclosure requirements in patent applications, it does not take full account or reflect all the proposals and views expressed by WIPO Member States both within WIPO and beyond, as requested by a number of countries.[31] In addition, these proposals are unreasonably separated from the consideration of the specific questions raised by the CBD request, though in fact they address many of these questions. Proposals and discussions in WIPO bodies that need to be identified or further analyzed include: the debate around the Swiss proposal to amend the PCT regulations – the proposal is one of the few to be described in detail, but there is no description of other countries' views or concerns;[32] the African Group proposal to introduce disclosure requirements in patent rules as one of the elements of an international instrument on genetic resources and traditional knowledge;[33] and the proposals for the SPLT that have

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28 See, e.g., the submission of the African Group to the IGC on the "Objectives, principles and elements of an international instrument, or instruments, on intellectual property in relation to genetic resources and on the protection of traditional knowledge and folklore," WIPO document WIPO/GRTKF/IC/6/12**,** March 15, 2004.

29 See *supra* note 7, at paragraphs 5 and 6.

30 See *supra* note 7, at paragraph 11 f.

31 The African Group and Brazil, for instance, are mentioned in the First Draft in paragraph 24 b.

32 See *supra* note 7, at paragraph 42 and subsequent.

33 See *supra* note 22.

addressed, for example, the potential scope of disclosure requirements.[34] In addition, the references to national laws are limited, with no mention of patent rules in Switzerland, Brazil, Norway, and other countries that currently require or are in the process of developing requirements on disclosure in relation to genetic resources.[35] Similarly, the description of discussions in the WTO is limited and does not focus on developments over the last couple of years, during which significant progress has been made.[36] The checklist and several subsequent submissions presented by a group of developing countries, for instance, have addressed many of the issues raised in the CBD request, including the function of disclosure requirements, its potential elements, triggers, and consequences of non-compliance and other incentives.[37] All the ideas put forth in these proposals need to be fully considered and addressed as the main elements of the WIPO request examination.

25. Finally, it is critical to note that the description of the state of play in discussions in WIPO and other international fora cannot be complete or accurate without reference to the positions of the numerous non-governmental organizations (NGOs) and indigenous and other local groups that are fundamental stakeholders in these discussions. Over 100 NGOs are accredited to the IGC, for instance, where they continue to play and active and important role.[38] Public interest NGOs are also increasingly participating in other WIPO bodies,

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34 In the Ninth Session of the SCP, for instance, the delegation of Argentina noted that, while paragraph (2)(a) prevented a Contracting Party from imposing further requirements, paragraph (1) did not appear to prevent a Contracting Party from requiring parts of an application additional to those listed, including information on the geographical origin of biological material. This view was supported by the delegation of India, which suggested that ambiguity be avoided by deleting paragraph (2) and clarifying the chapeau of paragraph (1) to make it clear that extra parts could be required. See the report of the Ninth Session, document SCP/9/8, at paragraph 78.

35 The Patent Act of Norway in English is hosted by the Norwegian Patent Office at www.patentstyret.no/. A description of the language and discussions on the introduction of disclosure requirements in Switzerland by the Bern Declaration, a Swiss NGO, is available at www.wipo.int/tk/en/igc/ngo/meienberg2.pdf. In Brazil, Correa points out in a 2003 paper that the grant of industrial property rights by the competent bodies for a process or product obtained using samples of components of the genetic heritage is contingent on the observance of a Provisional Measure obliging the applicant to specify the origin of the generic material and the associated traditional knowledge, as the case may be (the paper is available at www.geneva.quno.info/pdf/Disclosure%20OP%2012.pdf).

36 For an analysis of developments in the Council for TRIPS in 2004, see South Centre and CIEL IP Quarterly Update: Fourth Quarter 2004, available www.ciel.org/Publications/pubipqu.html.

37 Bolivia, Brazil, Cuba, Ecuador, India, Peru, Thailand, and Venezuela presented, in the first meeting of the Council for TRIPS in 2004, a Checklist of Issues to facilitate a more focused and result-oriented discussion by concentrating on the need for coherence between the TRIPS Agreement and the CBD. The proposal put forth a series of elements that need to be addressed to prevent misappropriation, developed on the basis of points made by delegations in previous discussions. These elements relate to disclosure of source and country of origin of biological resources and traditional knowledge and of evidence of prior informed consent and benefit sharing under relevant national regimes. The checklist is contained in WTO document IP/C/W/420 and Add. 1. The group of developing countries has since built on the each of these elements through three further proposals, WTO documents IP/C/W/429, IP/C/W/438, and IP/C/W/442. Other proposals put forth include those by Switzerland (WTO documents IP/C/W/423 and 433) and the United States (WTO document IP/C/W/434).

38 See, e.g., the WIPO webpage on NGO participation in the IGC, available at www.wipo.int/tk/en/ngoparticipation/.

including the SCP and the Working Group Reform of the PCT.[39] The statements, proposals, and positions of these civil society groups – both presented in the context of the process to develop a response to the CBD request and in the context of other ongoing discussions and negotiations – should be reflected in the WIPO response in order to provide more transparency, balance, and legitimacy to the process.

II.4 The WIPO response should fully integrate the development dimension

26. The First Draft recognizes the need for its work to be guided by and to support the objectives and the legal provisions of a broad range of legal and policy instruments, including agreements dealing with access to and use of genetic resources and those dealing with intellectual property rules. In elaborating a response to the CBD invitation, however, as in all its activities, WIPO needs to look at an even broader body of provisions to adequately address the development dimension of its work. Indeed, at the 2004 Assemblies in which the request by the CBD request was addressed, WIPO welcomed the initiative to incorporate a development dimension into all of its activities.[40] WIPO thus accepted the challenge of determining how intellectual property, as a tool for public policy, should address and support sustainable development needs. In this regard, WIPO acknowledged internationally agreed development goals, including those in the United Nations Millennium Declaration and the Johannesburg Declaration on Sustainable Development.[41]

27. The conservation and sustainable use of biodiversity, which plays a critical role in overall sustainable development and poverty eradication, has been recognized as essential in achieving these development goals. The Johannesburg Declaration acknowledged the importance of biodiversity to human well-being and the livelihood and cultural integrity of people, and stated the loss of biodiversity can only be reversed if local people benefit from the conservation and sustainable use of biological diversity, in particular in countries of origin of genetic resources, in accordance with article 15 of the CBD.[42] Moreover, it called for actions at all levels to integrate the objectives of the CBD into global, regional, and national programs and policies, in particular in those of the economic sectors of countries.[43] The Seventh Meeting of the CBD COP also noted that achievement of the Millennium Development Goals are dependent on the effective conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. It thus urged Parties, Governments, and relevant intergovernmental organizations, as a contribution towards the Millennium Development Goals, to implement their activities in ways that are consistent with, and do not compromise, the achievement of the objectives of the CBD.[44] The WIPO response to the CBD request should bear in mind these instruments and adequately address the issue in light of development concerns. In this

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39 In 2004, for instance, CIEL, the Civil Society Coalition (CSC), and Genetic Resources Action International (GRAIN), among others, participated as observers in the Tenth Session of the SCP and in the Sixth Session of the Working Group. An even larger number of NGOs is following discussions in the Standing Committee on Copyright and the WIPO Development Agenda.

40 See *supra* note 4.

41 Id.

42 See Plan of Implementation of the World Summit on Sustainable Development, Chapter IV "Protecting and managing the natural resource base of economic and social development," at paragraph 44.

43 Id.

44 See Decision VII/32 in the Report of the Seventh Meeting of the COP of the CBD, CBD document UNEP/CBD/COP/7/21.

regard, discussions taking place at the Inter-sessional Intergovernmental Meeting on a Development Agenda for WIPO in April and the Joint International Seminar on Intellectual Property and Development should provide important input into the process.[45]

III. SPECIFIC ISSUES IN THE CBD COP INVITATION

28. As noted above, the contribution of the WIPO response to the CBD process is inherently limited. Nevertheless, by submitting the proposals put forth and discussions taking place in WIPO bodies and other international intellectual property fora to ensure conservation and sustainable use concerns are integrated into the international intellectual property system, the WIPO response may provide an accessible account to the CBD of these parallel efforts towards fair and equitable access and benefit-sharing. In addition, information presented bearing in mind the CBD objectives and the guidance of Member States and accredited observers, could move forward discussions on disclosure requirements in the intellectual property context, which could in fact be the most valuable outcome of the process. In this regard, however, the examination of the specific issues related to disclosure requirements raised by the CBD request in the First Draft falls short in several aspects, as will be detailed below.[46]

29. Moreover, the First Draft fails to concentrate on two fundamental and horizontal issues. First, it largely does not focus on the necessary international rules for imposing mandatory legal recognition and enforcement of national disclosure obligations by all States, which will be critical if the intellectual property law system is to support and not run counter to the objectives of the CBD. On the contrary, the First Draft often does not distinguish between unilateral disclosure requirements, which existing intellectual property law treaties clearly allow, as reflected in the existing practices of a number of WIPO Member States that have adopted such requirements, and the need to modify international intellectual property rules to ensure disclosure requirements are mandatory and effective.[47] Second, the First Draft does not adequately discuss the integral relationship between equitable principles and intellectual property laws, which would require an effective system of mandatory international

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45 See *supra* note 4.

46 The five issues identified in the CBD request include: (a) model or draft domestic and international guidance or legal provisions regarding disclosure obligations, including identification of the range of materials and information for which disclosure obligations may arise; (b) procedural and substantive triggers for disclosure obligations, including the relationship between such materials and information and the subject matter of the intellectual property application or right; (c) incentives for applicants and rights holders and the relation of the incentives to the disclosure obligations; (d) treaty implications; and (e) implications of international certifications of origin.

47 A detailed analysis of the legality of such unilateral disclosure of origin requirements under existing patent law treaties, prepared by the Glushko-Samuelson Intellectual Property Law Clinic at the Washington College of Law, American University for the Public Interest Intellectual Property Advisors, is available at http://www.piipa.org/library.asp. The memorandum concludes that such disclosure obligations are legitimate substantive conditions of eligibility to apply for patents that are designed to prevent misappropriation. The memorandum also concludes that typical arguments that such disclosure obligations are inconsistent with specific provisions of the TRIPS Agreement, the Patent Cooperation Treaty, and the Patent Law Treaty "do not survive close inspection." *Id.* at 3.

recognition and enforcement of national disclosure requirements to prevent misuse of the intellectual property system. These equitable issues have been indirectly raised by a number of developing countries and accredited observers and need to be explicitly recognized and incorporated into policy discussions and implementation options in order for the intellectual property system to further sustainable development goals, as well as to protect its function as a tool of public policy and its legitimacy.

III.1 MODEL PROVISIONS

30. The First Draft notes the examination of options for model provisions may serve as a supplementary mechanism for advancing understanding and international consensus on disclosure requirements.[48] The need for effective international recognition and enforcement of disclosure obligations, however, clearly identified by the CBD and thus fundamental to consolidating international consensus and reflecting it in the international intellectual property context, is not adequately addressed or explained. The First Draft thus fails to focus on the main issues contained in the discussion of model provisions of disclosure requirements.

31. An international system of recognition and enforcement of national access and benefit sharing requirements is indispensable. The commercial benefits that may result from any violations of CBD access and benefit sharing requirements or from unauthorized uses of traditional knowledge are not limited to the jurisdictions in which those violations or unauthorized uses occur. The policy debate recited in the First Draft, while focusing on whether model provisions linking the intellectual property system to CBD obligations are necessary to such recognition and enforcement, does not consider the issue from the perspective of the need to ensure effective international requirements.[49] For example, the general option of adapting existing patent disclosures discussed by the First Draft identifies existing patent law requirements, but it does not fully discuss where and how it has been noted existing patent law requirements would need to be revised to be effective in disclosing violations or unauthorized uses. An enhanced consideration of effective mechanisms for protecting the intellectual property system from misuse (discussed below in regard to triggers) and of how existing international treaties impose legal obligations in regard to conduct occurring within a jurisdiction based on the legality of prior actions taken in other jurisdictions or based on consideration of the values and norms of other jurisdictions (discussed below in regard to treaty implications), for example, would be extremely useful. Such analysis, nevertheless, should still note that the formulation of any type of model provisions "should not prejudice national positions on the development of legally binding international law.[50]"

III.2 TRIGGERS

32. The First Draft describes a wide range of substantive and procedural triggers for disclosure requirements and properly identifies a number of equitable issues that relate to these triggers. For example, in the Illustrative Table at pages 40 and 41, the First Draft identifies "[p]rinciples governing equitable behavior" and "ABS or related law in country of

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48 See *supra* note 7, at paragraphs 83 and 84-103.

49 See, e.g., *supra* note 7, at paragraph 89-101.

50 Id. at paragraph 85

origin" as a legal basis, as distinct from patent law, for "specific disclosure" and "access/use" disclosure obligations. Similarly, in the Table at page 44, it distinguishes (in regard to the relationship to the invention or application) between existing patent law principles and "further forms of linkage." In addition, in the earlier analysis on options for model provisions, the First Draft includes a discussion of "'rightful' acquisition," which would require explicit consideration of ethical issues.[51] These equitable issues are critically important, as they portray how basic principles of the intellectual property law system not only allow but also require prevention of the misuse of intellectual property rules. As a result, beyond identifying these equitable issues, it would be fundamental for the First Draft to elaborate on the integral relationship of equitable principles to intellectual property and to analyze how these principles should be taken into account through binding international legal requirements.

33. In intellectual property law, equitable principles provide authority to refuse to grant or to enforce intellectual property rights when they would be or have been procured by fraud or deception, because to not do so would allow the intellectual property system to assist and reward the inequitable conduct. Existing intellectual property law systems thus recognize equitable limitations on the acquisition and enforcement of intellectual property rights. For example, statutory or regulatory requirements (derived from the equitable doctrine of "unclean hands") prohibit the vesting of intellectual property rights when the applicant has improperly acquired the knowledge on which intellectual property rights would be based, or mandate disclosures of information so as to assure that rights are not improperly acquired.[52] Similarly, patent misuse doctrines limit the ability of patentees to enforce their rights when they have used those rights contrary to public policy.[53] To assure equity, significant burdens may be imposed on intellectual property applicants.[54] Further, where the grant of intellectual property rights has resulted in an unjust enrichment to the rights holders, the unjust rewards may be forcibly disgorged under other laws.[55] These equitable doctrines reflect a more

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51 Id. at paragraph 103 (citing the UNEP-WIPO study at 57-58).

52 See, e.g., 17 U.S.C. § 103(a) (prohibiting copyright protection from extending to "any part of the work in which [pre-existing copyrighted] material has been used unlawfully"); 37 C.F.R. § 1.56 (requiring of information relating to statutory criteria of patentability, including investigation of the knowledge of numerous persons involved in developing the invention or application).

53 These misuse doctrines also derive from the equitable doctrine of unclean hands. The unclean hands doctrine has been traditionally applied by courts to "withhold their aid where the plaintiff is using the right asserted contrary to the public interest." *Morton Salt Co. v. G.S. Suppiger Co.,* 314 U.S. 488, 492 (1942).

54 Courts, as part of the patent system, "are a vehicle for affirmatively enforcing the requirements of conscience and good faith. This presupposes a refusal on [the court's] part to be the 'abetter of iniquity.'" *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.,* 324 U.S. 806, 814 (1945) (citation omitted). Applicants thus shoulder "an uncompromising duty to report to [the Patent Office] all facts concerning possible fraud or inequitableness underlying the applications in issue." *Id.* at 818.

55 See, e.g., *Univ. of Colo. Found. v. American Cyanamid Co.*, 342 F.3d 1298, 1309-12 (Fed. Cir. 2003) (requiring under state law restitution of profits from a patent that resulted in an unjust enrichment at the expense of the actual inventors, without regard to any claim under the patent statute) (*citing Restatement of Restitution* § 1 (1937)).

general principle, that governmental power should not be used to further undesirable conduct.[56] Equitable doctrines also exist in civil law jurisdictions.[57]

34. Significantly, each of the areas identified by WIPO in regard to substantive and procedural triggers requires analysis in regard to prevention of misuse of the intellectual property system.[58] Equitable principles traditionally linked to the intellectual property system demand the consideration of the need to prevent misuse of the system in a manner that would advance and provide benefit to inequitable conduct. Such principles may extend the need for linkages in fact much further than suggested by some of the Member State submissions that the First Draft refers to. For example, preventing the misuse that would result from the grant and enforcement of intellectual property rights for unjust commercial benefit may require ensuring that disclosure requirements apply to a very broad range of source materials and information that are not "directly related to" the invention and to inequitable conduct that does not violate substantive criteria of patentability or of entitlement to apply for patents. In addition, preventing such misuse will also require international recognition of disclosure obligations by all states, because the materials and information will originate in or the relevant inequitable conduct will occur in jurisdictions other than (or in addition to) those where intellectual property rights will be obtained.

35. Traditionally, equitable principles and the law of remedies have been flexibly applied on a case-by case basis to assure that such inequitable conduct is not rewarded and that unjust enrichment does not occur.[59] Nevertheless, given the recognized need for generally applicable rules in the access and benefit-sharing context, analysis of existing practices in regard to the application of equitable principles could be very useful. It would thus advance work to assure that these principles are adequately integrated into the intellectual property system in regards to genetic resources and traditional knowledge. Moreover, it might contribute to the CBD process by identifying specific legal measures to prevent intellectual property misuse that exist in various jurisdictions and that could be included in an international regime.

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56 See, e.g., *Shelley v. Kraemer*, 334 U.S. 1, 20-22 (1948) (prohibiting judicial enforcement of restrictive racial covenants in real property, because the exercise of judicial power would violate constitutional rights).

57 See, e.g., M. Rodriguez Ramos, *"Equity" in the Civil Law: A Comparative Essay*, 44 Tul. L. Rev. 720 (1970); Hessel E. Yntema, *Equity in the Civil Law and the Common Law*, 15 Am. J. Comp. L. 60 (1966-67).

58 The First Draft describes several substantive and procedural triggers for disclosure requirements, including: (1) the source materials or information; (2) the relationship to the invention or application; (3) the investigatory and other disclosure obligations imposed on the applicant for or owner of the right; (4) additional legal or contractual obligations relating to disclosures; (5) the timing of disclosures in regard to filing or processing of applications and enforcing rights; and (6) the consequences of failing to provide required disclosures or of providing incorrect or fraudulent disclosures.

59 For example, in determining restitution, courts "'resort to general considerations of fairness, taking into account the nature of the defendant's wrong, the relative extent of his or her contribution, and the feasibility of separating this from the contribution traceable to the plaintiff's interest.'" *Univ. of Colo. Foundation*, 342 F.3d at 1311 (*citing* 1 George E. Palmer, *The Law of Restitution* § 2.12 at 161 (1978)).

III.3 INCENTIVES

36. Developing additional legal, economic, social and moral incentives in the context of the CBD to comply with disclosure requirements, as well as determining how those incentives relate to the broader framework established by Article 11 of the CBD, are issues that undoubtedly the CBD is best poised to address. The First Draft, in this regard, adequately distinguishes the incentives that may be developed in the CBD context from the consequences or outcomes of non-compliance with disclosure requirements that should be incorporated in international patent rules.[60] The First Draft rightly considers the discussion of incentives should involve consideration of how the intellectual property system should contribute to the objectives of conservation, sustainable use and equitable benefit-sharing.[61] The First Draft fails to emphasize, however, the need to advance the introduction of disclosure requirements in international intellectual property rules with significant sanctions for non-compliance and thus ensure the intellectual property system is not misused to further inequitable conduct. Indeed, it is the various consequences of failure to provide required disclosures, including loss or revocation, transfer, and narrowing of patent rights, that should be highlighted, while the potential use of intellectual property rights in themselves as an incentive for the conservation of genetic resources and traditional knowledge, mentioned in paragraph 128 of the First Draft, is an issue clearly outside the scope of the CBD request and thus of the WIPO response to that request.

III.4 TREATY IMPLICATIONS

37. In the discussion of the implications of disclosure requirements on WIPO-administered treaties, the First Draft would particularly benefit from distinguishing between the relationship of international intellectual property rules with disclosure requirements developed at the national level and the need for these intellectual property rules to adequately incorporate disclosure requirements. In this regard, it should be noted that existing WIPO treaties and the TRIPS Agreement do not meaningfully prohibit unilateral imposition of disclosure obligations to focus the analysis of the WIPO response, as well as ongoing discussions in intellectual property fora, on ensuring international recognition of such obligations by all countries. For example, while the earlier WIPO Technical Study recognized that disclosure obligations would be permitted under the PCT and PLT as substantive conditions of eligibility for patent rights, the First Draft fails to acknowledge that disclosure obligations are validly considered substantive conditions and thus are permissible.[62] Similarly, although it is careful to not make pronouncements on the consistency of national disclosure requirements with provisions of the TRIPS Agreement, the First Draft may wrongly convey that the comments of Member States recited in the First Draft suggesting inconsistency with TRIPS Agreement requirements are valid, by omitting arguments to the contrary.[63]

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60 See *supra* note 7, at paragraph 117.

61 Id. at paragraph 128.

62 Id. at paragraphs 132-35.

63 Compare, e.g., *supra* note 7, at paragraph 160 (discussing a comment that Article 27.1 of TRIPS prohibits disclosures applicable only to genetic based resources as an impermissible discrimination by "field of technology") *with* Canada – Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS114/R, paragraphs 7.99-7.105 (Mar. 17, 2000), available

[Footnote continued on next page]

38. The WIPO response to the CBD request would thus be most valuable by focusing on the modifications needed in international intellectual property rules to ensure international recognition of requirements imposed by various national jurisdictions. Such international recognition would benefit, as suggested above, from further analysis of the modifications needed for imposing mandatory obligations on states to ensure compliance with legal obligations and equitable principles in other jurisdictions to prevent misuse of the intellectual property system. In this way, WIPO could introduce these elements into relevant discussions in WIPO bodies, as well as identify elements of an effective system for international recognition and enforcement of the norms that could be considered in the CBD process.

III.5 INTERNATIONAL CERTIFICATION

39. As noted above, the issue of international certificates of origin, source, or legal provenance has not been addressed in discussions in the WIPO context. It may thus not be appropriate for the WIPO response to address this particular element of the CBD request. However, if the final WIPO response should examine the issue of international certification, it would be important for it, rather than dealing with aspects that would be better developed and discussed in the CBD framework, to focus on the existing examples of linkages between certification regimes and the intellectual property system. For example, the First Draft notes two purportedly comparable existing patent requirements – the filing of priority documents to claim a right of priority and the certification of biological deposits – but fails to analyze how those requirements might provide useful models for international recognition of documents certifying compliance with access and benefit sharing requirements.[64]

40. Further, there are potentially more comparable private and public "certifications" in the patent system, including the oath or declaration of applicants of their entitlement to apply for a patent and the license required before a foreign application may be filed.[65] Such oaths and licensing requirements help to assure that the applicant is entitled to seek the intellectual property rights, and restrict the ability to seek to acquire such rights when contrary to public policy. By comparison, an international certification regime could prohibit the right to file a patent application without an affirmative certification of entitlement, based on compliance with legal requirements and equitable principles of the country of origin of relevant materials and information. Again, if WIPO addresses the issue, it might assist the CBD process by providing examples of how certification requirements could be recognized and supported by the intellectual property system and also introducing such examples into discussion in its own bodies.

IV. Conclusion

41. WIPO has taken a fundamental step in addressing the request of the CBD in a cross-cutting manner and promoting the participation of WIPO Member States and accredited observers. Establishing an adequate approach to the WIPO response is critical to providing appropriate input into the CBD process and to ensuring the analysis is constructive for related

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[Footnote continued from previous page]

at http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm (holding that the discrimination prohibition does not prohibit justified distinctions).

64 See *supra* note 7, at paragraph 167.

65 See, e.g., 35 U.S.C. §§ 115, 184.

discussions in international intellectual property fora. In this regard, recognizing the leading role of the CBD in biodiversity issues, supporting its principles and objectives, following the guidance of WIPO Member States and accredited observers, and fully introducing sustainable development concerns are important ways to assure that the WIPO response constructively contributes to the CBD process while maintaining the necessary focus on integrating the CBD principles into the international intellectual property system.

42. Ensuring such an approach is reflected throughout the WIPO response, particularly in the analysis of the specific elements of the CBD request, is also fundamental. In this regard, the First Draft's lack of emphasis on avoiding the misuse of the intellectual property system and on developing the mandatory international rules needed to effectuate the CBD objectives, as well as those of the intellectual property system itself, is problematic. It is essential for the WIPO response to focus on advancing the necessary international rules for imposing mandatory legal recognition and enforcement of national disclosure obligations by all States, which will be critical if the intellectual property law system is to support and not run counter to the objectives of the CBD. The WIPO response should also adequately discuss the integral relationship between equitable principles and intellectual property laws, which require an effective system of mandatory international recognition and enforcement of national disclosure requirements to prevent misuse of the intellectual property system.

43. Through these comments and observations, CIEL aims to contribute to developing a balanced and appropriate framework for the response of WIPO to the CBD request. We look forward to our comments and the comments of other accredited observers being introduced in the revised draft of the WIPO response, as well as to participating in the Ad Hoc Intergovernmental Meeting to be held in May 2005 to consider and discuss that revised draft.

[End of Annex and of document]