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WIPO

WIPO/IP/GR/05/INF/5
ORIGINAL: English
DATE: August 15, 2005

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

# AD HOC INTERGOVERNMENTAL MEETING ON GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS

## Geneva, June 3, 2005

COMPILATION OF COMMENTS RECEIVED ON THE SECOND DRAFT OF AN EXAMINATION OF ISSUES RELATING TO THE INTERRELATION OF ACCESS TO GENETIC RESOURCES AND DISCLOSURE REQUIRE MENTS IN INTELLECTUAL PROPERTY RIGHTS APPLICATIONS SUBSEQUENT TO AN AD HOC INTERGOVERNMENTAL MEETING ON GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS

*Document 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 fifth step of the agreed timetable and modalities provides for the convening of a one-day ad hoc intergovernmental meeting to consider and discuss a revised version of the draft Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications. This Ad hoc Intergovernmental Meeting on Genetic Resources and Disclosure Requirements was convened on June 3, 2005, and considered the draft Examination (document WIPO/IP/GR/05/3). At the Ad Hoc Meeting, the WIPO Member States decided to invite further comments in writing on the draft Examination for a certain period of time.

2. Accordingly, 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. A total of six written observations and comments were received on document WIPO/IP/GR/05/3.

3. A compilation of all the written observations and comments received with regard to document WIPO/IP/GR/05/3 is contained in the Annex to this document.

[Annex follows]

ANNEX

# COMMENTS RECEIVED ON THE SECOND DRAFT OF AN EXAMINATION OF ISSUES RELATING TO THE INTERRELATION OF ACCESS TO GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS IN INTELLECTUAL PROPERTY RIGHTS APPLICATIONS SUBSEQUENT TO AN AD HOC INTERGOVERNMENTAL MEETING ON GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS

Comments were received from the following participants in the *Ad Hoc* meeting:

Brazil
Canada
France
United States of America

The United Nations University — Institute of Advanced Studies (UNU-IAS)

International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

BRAZIL

General remarks:

As previously stated in our comments to document WIPO/IP/GR/05/1, Brazil understands that WIPO´s reply to the CBD invitation must contain only the views expressed by its Members, in all relevant fora, either within or outside WIPO. For this reason, it would be inappropriate to reflect opinions set forth by scholars or academic studies which do not constitute formal submissions to the process.

It should also be highlighted that the "disclosure of origin" has already been identified by the CBD as a relevant measure aimed at curbing misappropriation of genetic resources/traditional knowledge in intellectual property rights applications. In this sense, the CBD invitation was proposed with a view to move discussions further in what concerns employing disclosure in intellectual property application, rather than a request to examine the relevance of the measure itself. In order to remain "supportive of the objectives of the CBD", Brazil believes that WIPO's reply should essentially address ways in which disclosure can be employed in the IP system and, consequently, avoid discussing other issues that, albeit related to access and IP applications, do not concern directly "disclosure requirements. "

It is also important to make clear that all references to legislation governing access and benefit-sharing encompass the legislation of the countries of origin of the genetic resources/ traditional knowledge.

Finally, so as not to pass judgement on different options nor seek to advocate specific approaches to the detriment of others, Brazil has concerns with the proposed classification for the triggers for disclosure requirements (triggers related to patentability of the invention as such; triggers related to inventorship and entitlement to apply for a patent; triggers related to equitable principles and compliance with ABS measures), as well as with equivalent language contained in Part III of the document. In our view, the proposed classification is questionable and should be deleted from the text.

Specific remarks:

– Paragraph 22: The paragraph compares the terms "country of origin", used by the CDB, with "center of origin", found in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR). Having in mind that the ITPGR has a different focus from the CBD, such a comparison is, in our view, inappropriate and should be deleted. As this is a reply to the CBD, this exercise should preserve the language set out by the CBD itself.

– Paragraphs 33-34: The language used IN WIPO´s reply should be in line with the one found in the CBD, as recognized by paragraph 35. Therefore, when tackling the concept of traditional knowledge, priority attention should be accorded to the language of article 8(j) of the CBD, instead of the draft articles under discussion at the IGC.

– Paragraph 67: Brazil proposes to delete the entire quote of the UNU-IAS study. As previously stated, WIPO's reply should only contain references to Member States views on the object of the invitation and, therefore, references to studies carried out by academic

institutions, which do not constitute formal submissions to this process, should preferably be left out. It is also relevant to recall that UNU-IAS itself, during the course of the June 3rd Intergovernmental meeting that discussed the 2nd Draft of the WIPO reply, clarified that the quote in document WIPO/IP/GR/05/3 was taken out of context and that UNU-IAS favored a different interpretation of the legality of disclosure of origin requirements. Similarly, a recent legal study requested by PIIPA (Public Interest Intellectual Property Advisors, Inc.)[1] points out that disclosure of origin requirements for patent applicants are compatible with existing international intellectual property agreements.

– Paragraph 72: We believe this paragraph extends beyond the scope of the proposed exercise, which should focus on the interrelation of access to genetic resources and disclosure requirements.

– Paragraph 106: In order to better convey our understanding of the issue, Brazil would like to request that the expression "traditional knowledge" be added after "biological materials. "

– Paragraph 130: We reiterate our concern with respect to quotations of studies, which do not necessarily reflect the views of Member States and, thus, might portray to the CBD a state of discussions that may not correspond to the positions supported by Member States. In this paragraph, the study in question sets a link between the "lawful acquisition" and "the source country. " As previously stressed, we understand that the expression "legislation governing access to genetic resources/traditional knowledge" should refer to the legislation of the country of origin.

– Paragraph 137: In order to better convey our understanding of the issue, Brazil requests that the expression "and information" be included in subitem (e), after "background material". In the third to last sentence of this paragraph, Brazil requests that the expression "or information" be added after "source of the material. "

[1] Memorandum dated June 23, 2004, "Compatibility With Existing International Intellectual Property Agreements of Requirements for Patent Applicants to Disclose Origins of Genetic Resources and Traditional Knowledge and Evidence of Legal Access and Benefit Sharing"

CANADA

On Paragraph 28:

Canada concurs that it is inappropriate and factually incorrect to categorize some country as "providers" and others as "users" of genetic resources (GR). Depending on the instance, the needs and the resources being sought, all Member States are both providers and users of the world's bio-diversity at different times.

On Paragraph 29:

Canada suggests that this paragraph could be strengthened by emphasizing that Member States' views on the nature of WIPO Document WIPO/IP/GR/05/3 is contextualized by their varied interests in the issue of genetic resources (GR) and possible disclosure requirements. Without commenting on the effectiveness or appropriateness of any Member State proposal and without precluding the importance of other reasons, it is recognized that for some the basisfor engaging in enhanced discussions on this issue is to: (i) help ensure that claimed inventions using GR sufficiently and satisfactorily meet the criteria for patentability; and (ii) garner greater information about an applied GR to enable the access and benefit sharing "pillar" of the Convention of Biological Diversity (CBD). In Canada's view, WIPO should clearly continue its work on the technical intellectual property (IP) issues related to GR and possible disclosure requirements that are within its expertise and capacity. At the same time, Canada considers it important that WIPO continue to work in this area in a manner that is mutually supportive of work being done in other international fora such as the CBD.

On Paragraph 33:

Given recent discussions at the Eighth Session of the WIPO-IGC on WIPO Document WIPO/GRTKF/IC/8/5 and lack of consensus from Member States on the Part III of Annex 1 to that Document, which contains the draft definition of traditional knowledge (TK) cited in this paragraph, Canada suggests that the deletion of this definition would be appropriate. Instead, Canada considers it important to clearly state that an international definition for TK has yet to be agreed to by WIPO Member States. We also think it is necessary to include here that there is a diversity of views amongst Member States as to whether a possible disclosure requirement could apply to TK as well as who could be the beneficiaries of any IP protection of TK.

On Paragraph 42:

Canada suggests that the list of relevant submissions to WTO-TRIPS Council on GR and disclosure requirements should be updated to reflect recent inputs the United States, Peru and other Member States.

On Paragraph 43:

To clarify that there is a wide range of proposals currently on the table in the WTO on GR and disclosure requirements, but that they may not express the full range of possibilities here, Canada suggests that the first sentence be revised to read: "*No attempt is made here to summarize the broad range of proposals and views put forward in the context of TRIPS or to provide any commentary on the substance or effectiveness of the existing proposals*."

On Paragraph 51:

Canada suggests that the outcomes of the recent WIPO meeting of the SCP be reflected in this paragraph for the purposes of completeness.

On Paragraph 67:

At the June 3, 2005 Ad Hoc Intergovernmental Meeting, it is recalled that Brazil suggested that the reference to the UNU-IAS study (UNEP/CBD/COP/7/6) should be deleted in this paragraph. Canada does not support such a deletion as it is necessary in this document, and in general in any technical response of this issue from WIPO to the CBD, to ensure that the plurality of views on GR and possible disclosure requirements is adequately and appropriately reflected.

On Summary of Options for Model Provisions:

Given that this technical discussion is still ongoing in WIPO and Member States have yet to converge upon a consensus of the issue of model provisions for GR and disclosure requirements, Canada suggest that this list be amended to make it clear that is a non-exclusive list of *some possible* options for model provisions.

On Summary of Triggers for Disclosure Requirements :

Again, since the international discussion is still ongoing on this issue and useful information about national experiences in this area is still emerging, Canada suggests that this list be amended to make it clear that it is a non-exclusive list of *some possible* triggers for disclosure requirements.

On Paragraph 213:

Canada recognizes and agrees with the caveats outlined in this paragraph, but would add that it should be made clear here that this document should not be seen as a limitation upon a substantive work that WIPO itself could undertake in this area in line with the directions, requirements and input of Member States.

On Paragraphs 214 and 215:

Canada supports the inclusion of these two paragraphs. As stated earlier in these comments, Canada considers it important that WIPO continue its work on the issue of GR and possible disclosure requirements consistent with its expertise and capacity and in a manner that is mutually supportive of work ongoing in other international fora like the CBD. In that spirit, Canada suggests that WIPO could refer the following additional questions to the CBD for their input: (i) ask the CBD to please keep WIPO apprised of the progress on the ongoing ABS International Regime negotiations which are relevant to WIPO's work; (ii) ask the CBD's Secretariat to continue to work with WIPO's Secretariat on issues of mutual relevance (for example: certificates of origin/source/legal provenance and options for incentive measures for patent applicants); (iii) ask the CBD to provide views on the benefits and/or the feasibility of establishing national or international (centralized under the CBD clearing-house mechanism) GR databases and ensuring their interoperability with patent office search mechanisms and techniques, as a means of facilitating patent examination and preventing

misappropriation of GR; (iv) ask the CBD to look for low cost, efficient, and internationally consistent solutions for achieving access and benefit-sharing and disclosure objectives, including contractual approaches with mutually agreed terms, national databases and bilateral agreements or memorandums of understanding between research institutions, users, etc.

FRANCE

By way of introduction, it should be recalled that the European Community and its Member States have already submitted document WIPO/GRTKF/IC/8/11 relating to the disclosure of the origin or source of genetic resources and associated traditional knowledge in patent applications, to the eighth session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, and that the observations below merely serve to emphasize certain elements which could not be discussed at the session.

Document WIPO/IP/GR/05/3, Genetic or Biological Material or Resources (GBMR):

The question of the disclosure of origin was raised in the context of the implementation of the provisions of the Convention on Biological Diversity (CBD), in relation to access to genetic resources and the sharing of benefits resulting from their use, as it is presented moreover in paragraph 35 of the document. The access and benefit sharing mechanism covers only genetic resources (Article 15 of the CBD) and traditional knowledge within the limits of Article 8(j) of the CBD. It could not be extended to biological resources such as extracts, essences and other biological raw materials, which are the subject of international trade, and trade in which takes the form of a sale with transfer of ownership. The broadening of this issue of access and benefit sharing to biological resources or materials, which document WIPO/IP/GR/05/3 undertakes using the abbreviation "GBMR", is therefore in contradiction with the CBD and is likely to give rise to confusion with international trade in raw materials of biological origin. In order to remain faithful to the negotiating mandate given to the parties as regards access and benefit sharing, the question of disclosure of origin should therefore be limited to genetic resources and traditional knowledge, and the wording of document WIPO/IP/GR/05/3 amended accordingly.

Document WIPO/IP/GR/05/3, paragraph 214:

A negotiating mandate has been entrusted to the CBD Working Group on Access and Benefit Sharing in order to produce a relevant "international regime." At this stage of the negotiations, numerous points appear in the mandate only "for consideration", since their possible inclusion in a future regime, or their exclusion therefrom, has not been decided. The first four subparagraphs of the list appearing in paragraph 214 are therefore at this stage still premature as they stand. They may only be taken into account by WIPO in relation to the international regime (fifth subparagraph of paragraph 214) until such time as they have been selected by the CBD Working Group on Access and Benefit Sharing for inclusion in the international regime.

Disclosure of origin in the context of plant selection for food and agriculture (paragraphs 53 to 56 of document GRTKF/IC/7/9):

Several elements make the question of the disclosure of the origin of genetic resources used irrelevant in the context of plant selection for food and agriculture. Firstly, taking into account domestication processes, origin is defined in broad "geographical centres" rather than in countries, and it is "diversity centres", broadly spread throughout the planet, rather than origin, which are of interest in terms of selection. Furthermore, a new plant variety is the crossing of several dozen different genetic resources, the individual contribution of which to

the final product is generally impossible to determine. Finally, in order to overcome this near impossibility to negotiate bilaterally benefit sharing based on the origin of the resources for selection purposes, the International Treaty on Plant Genetic Resources for Food and Agriculture has established a multilateral system for access and benefit sharing "without the need to track individual…" genetic resources (Article 12.3(b)), and taking full account of the specific features of breeder's rights. In this context, the questions raised in paragraphs 53 to 56 of document GRTKF/IC/7/9 have already received a response within the multilateral system of the International Treaty on Plant Genetic Resources for Food and Agriculture, and referring where necessary to this multilateral system as the "source" of the genetic resources used represents the most relevant response to the question of disclosure of origin.

UNITED STATES OF AMERICA

In light of the one-day mandate that the General Assembly has provided to this committee to perform its work, we offer the following, specific suggestions:

On page 13, in paragraph 33, we are concerned that a definition of TK is provided, and other information is provided on TK, that has not yet been discussed in WIPO. For this reason, please replace everything after the first sentence of the paragraph with the following:

– There is no agreed definition of TK among WIPO Member States.

On page 19, following paragraph 45, we would like to insert a paragraph to reflect the position of the U.S. proposal. Please insert the following:

– The United States of America proposal to the TRIPS Council, IP/C/W/434, provides an explanation of why proposed disclosure requirements would fail to achieve their stated objectives and would create harmful uncertainties in the patent system. It also provides concrete proposals to advance the widely shared objectives of: (1) authorizing access; (2) ensuring benefit sharing and (3) preventing erroneously issued patents.

On page 35, following paragraph 90, please insert the following U.S. views:

– On the other hand, the United States of America explains, the patent system was intended to promote innovation and to publish new, useful and nonobvious inventions, among other things. New disclosure requirements create uncertainties in the patent system that discourage research and development, the use of the patent system and the corresponding publication of inventions that may otherwise remain in confidence. Recent evidence suggests that new disclosure requirements would have a significant, negative economic impact.

On page 39, in paragraph 101, please insert the following U.S. views before the last sentence:

– Or, according to the United States of America, model provisions may serve no useful purpose at all. This is because new disclosure requirements would not effectively facilitate access to genetic resources and equitable benefit sharing, and they would discourage innovation. Furthermore, such provisions might distract from effective mechanisms to address the concerns of Member States, such as the implementation of effective national access and benefit sharing regimes. The United States of America considers existing provisions to be more appropriate.

On page 42, following paragraph 108, please insert the following new paragraph:

– The submission of the United States of America points out that traditional disclosure requirements serve to promote innovation and disseminate information. Any new disclosure requirement may have unintended, negative consequences on benefit sharing, in particular.

On page 49, in the first line of paragraph (f), please insert the following after “not relevant”:

– as it appears that new disclosure requirements would not be effective in achieving their intended objectives of facilitating access to genetic resources and equitable benefit sharing or ensuring transparency.

On page 61, following the third indented paragraph on that page, please insert the following paragraph:

– No legal effect, as the status quo is preferential to a new disclosure requirement.

On page 61, following the fifth indented paragraph on that page, please insert the same language.

On page 64, following paragraph 163, please insert the following new paragraph:

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

On page 65, following the last bullet under “perverse or undesirable incentives,” please insert the following:

– A new disclosure requirement would provide a perverse incentive by discouraging innovation, the use of the patent system, and the publication of new, useful and non-obvious inventions. In addition, new disclosure requirements would serve as a perverse incentive to benefit sharing.

On page 77, following the last line in the box at the top of the page, please insert the following:

– New disclosure requirements may conflict with WIPO-administered treaties and TRIPS.

On page 80, following the last sentence in the box, please insert the following:

– Certification should be separate from the patent system in order to maximize effectiveness and to avoid a negative impact on innovation.

On page 83, please insert the following bullet at the end of paragraph 213:

– There is no agreement among members as to the usefulness and to the extent of the harm that would be caused by a new disclosure requirement.

On page 83, please insert the following bullet at the end of paragraph 214:

– The extent of the harm that would be caused to innovation that would be caused by a new disclosure requirement.

– Whether a new disclosure requirement would be effective in promoting ABS or ensuring transparency.

THE UNITED NATIONS UNIVERSITY –
INSTITUTE OF ADVANCED STUDIES
(UNU-IAS)

The United Nations University, Institute of Advanced Studies, (UNU-IAS) welcomes WIPO document WIPO/IP/GR/05/3 which is an important addition to existing materials on the issue of Disclosure of origin. The information provided will serve not only the purpose of responding to the CBD's request for information on these issues, it will also serve to more fully inform participants ongoing negotiations in other fora, including the SPC, PCT, WTO and IGC.

UNU-IAS has been active in promoting research and outreach activities in this area through its Biodiplomacy Initiative. This work has been organized with a view to integrating research on a number of key interrelated issues including disclosure of origin, certificates of origin and documentation of TK in registers and databases. This has led to the publication of a number of policy reports on 1) User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-sharing Provisions of the Convention on Biological Diversity and 2) TK registers and databases: The Role of Registers and Databases in the Protection of Traditional Knowledge, as well as an information document for the third meeting of the Ad-hoc working Group on ABS, which met in Bangkok earlier this year on the feasibility practicality and cost of certificates of origin (*UNEP/CBD/WG-ABS/3/INF/5)*. Copies of the user measures paper and the executive summary of this latter study are available at the UN publications desk outside.

To inform this research work and in order to build greater dialogue on these issues UNU-IAS has during the past 12 months organized a series of roundtables on the issue of Certificates of origin, at IAS in Yokohama in June 2004, at the Smithsonian Institution in Washington in September 2004, and an International Roundtable in Paris in collaboration with IDDRI and the University of Louvain, in November of last year. More recently UNU-IAS organized a Seminar in Yokohama in collaboration with the Japan Bioindustry Association, to promote debate on disclosure of origin, certificates of origin and the draft Japanese guidelines on ABS. Copies of a summary report of this event are also available outside the hall.

UNU-IAS believes that it is necessary to consider the issue of disclosure of origin not on a stand alone basis but rather as part of a package of measures which together serve to provide for a paradigm shift in the manner in which IP regimes interface with issues of equity, rights and justice. In this vein UNU-IAS considers it necessary to approach the issue of disclosure of origin not merely as a quick fix for ABS and TK but rather as the basis for a new approach to the protection of intellectual property which seeks to recapture its roots in fair reward and equitable sharing of benefits.

In relation to the specific focus of this present discussion we would like to make 4 quick observations.

1. The current document although it refers to utility patents, petty patents and plant breeders rights, does not explore these in any depth, and although the basic principles of disclosure can no doubt apply to these forms of IP as well, the specificities of disclosure obligations, term of protection etc. under these regimes merits some more detailed consideration. It is to be hoped that a future report may include information on these areas as well.

2. With regard to the compatibility of existing requirements for disclosure with international IP law the IAS User Measures report recognizes uncertainty amongst the international community on this point, a conclusion cited in the WIPO report. However the report tends towards an interpretation which finds existing disclosure of origin measures compatible with international IP law, an interpretation which we consider merits inclusion in WIPO's report. Copies of the IAS report are available online at the IAS website (www.ias.unu.edu) and a limited number of hard copies are available at the UN publications desk outside the hall.

3. There is a clear overlap between the work of WIPO on disclosure of origin and that of the IGC with regard to protection of TK. Two documents prepared for the upcoming meeting of the IGC, (8/4 and 8/5) utilize the concept of misappropriation, as an organizing principle for development of regimes for protection of TK and folklore. Original work proposing the utilization of misappropriation as an organizing concept for TK protection included notably, mechanisms for documenting TK and disclosure of origin. Considering the nexus between the preparation of this study on disclosure of origin and the IGC's work on misappropriation, UNU-IAS considers it valuable for greater consideration in both areas of the relationship between these two concepts, and reflection in their working documents..

Certificates of Origin

The first proposal for the development of a comprehensive disclosure of origin regime included a suggestion that any regime be complemented by and facilitated through the establishment of a certificate of origin system. The WIPO paper touches on this issue only very briefly. It is proposed that WIPO revise this section of the paper to draw upon a range of materials which have become available more recently, including Information Document number *UNEP/CBD/WG-ABS/3/INF/5* of the Working Group on ABS, on Certificates of Origin: practicality, feasibility and cost. To help in the wider dissemination of information relevant to the dialogue on Certificates of Origin UNU-IAS has opened a special section of its website dedicated to this issue.

UNU-IAS has developed a collaborative program of work with WIPO and also collaborates with a range of indigenous, academic, NGO and governmental authorities to promote more informed research and debate on a range of IP issues including disclosure of origin and related matters. We look for continuing close collaboration in this area and stand ready to provide support in helping to facilitate this important process.

Additional Remarks

The citation in document WIPO/IP/GR/05/3, specifically:

"even though there is a growing body of law and policy which establishes either mandatory or voluntary requirements to disclose the origin of genetic resources and traditional knowledge in patent applications, there still remains significant and wide spread uncertainty as to even the legality of such measures, to say nothing about their effectiveness."

is taken from a report on User measures prepared by UNU-IAS in March 2003. At the end of the same section in the UNU-IAS paper we note that the "initial findings of the (WIPO draft) Report are of interest because they seem to imply that disclosure of origin requirements may

in some cases be compliant with existing IPR practices and failure to comply with such requirements may entitle imposition of significant sanctions.

This was noted to draw attention to the fact that although there was little agreement on the state of the law WIPO's findings were shedding light on the apparent legality of some measures.

A revised version of the report was published in December 2003 in which the words cited in the WIPO paper on Disclosure were deleted. The UNU-IAS study was revised to draw closer attention to the WIPO Draft Study – saying that it "concludes that there is a range of methods for requiring disclosure that are consistent with the essential elements of patent law and key aspects of WIPO Treaties." (p31 - see attached file) Further on the UNU-IAS report notes: that the WIPO Draft Study and the Various proposals to the TRIPS council and other for a suggest a range of potential options for disclosure which are worthy of more in-depth investigation with regard to their practicality, functionality and cost, as well as that of other measures which may facilitate their operation. (page 33)

Overall the tone of our report seeks to demonstrate that there disclosure of origin options require further study, however it is clear that it is possible to establish disclosure requirements that do not conflict with IPR laws.

We would like to suggest therefore that WIPO delete the citation relating to UNU-IAS in the report. In the event that there is a desire to reference the UNU-IAS report we would ask you to reference the 2nd edition (attached) and refer to it along the following lines.

UNU-IAS has prepared a report discussing the potential of disclosure of origin requirements to act as a user measure to secure protection of rights over genetic resources and traditional knowledge. The report recognizes that no consensus exists regarding the legality of measures taken to date in establishing requirements for disclosure but notes the WIPO Draft study and various proposals to the TRIPS council suggest a range of potential options for disclosure which are worthy of further consideration.

INTERNATIONAL FEDERATION
OF PHARMACEUTICAL MANUFACTURERS ASSOCIATIONS (IFPMA)

GENERAL COMMENTS

1. In accordance with the decision taken during the Ad Hoc Intergovernmental Meeting on Genetic Resources and Disclosure Requirements on 3 June 3005, to allow additional comments on the second draft examination, WIPO/IP/GR/05/3, IFPMA submits its written comments herein.

2. IFPMA welcomes the second draft examination, but notes that, regrettably, few stakeholders commented on the first draft examination (WIPO/IP/GR/05/1). For this reason, we are grateful for the additional opportunity to comment on the second draft, with a view to presenting the concerns of traditional intellectual property rights holders. IFPMA wishes to thank the secretariat for its efforts to incorporate these comments and suggestions into the final document.

3. The paragraph numbers referred to below correspond with paragraph numbering in the second draft examination (WIPO/IP/GR/05/3).

PART I: INTRODUCTION

Paragraph 18: As an organization whose members regularly use and rely on intellectual property rights, IFPMA notes that existing intellectual property rules need to be properly applied and enforced, rather than modified, to protect against misappropriation of genetic resources or traditional knowledge. It is important to note that many of the publicized cases of alleged misappropriation were ultimately resolved by proper application of the patent laws.

Paragraph 29: We note that it is not only important to ensure that this document supports the objectives and principles of the CBD, it is also important that this document provide guidance on how the objectives of the CBD can be achieved without impeding on existing intellectual property protections. Thus, we propose to add to paragraph 29 the following:

> (i) The response should provide guidance on methods to achieve the objectives of the CBD without negatively impacting existing intellectual property protections.

Paragraphs 31 and 32: While the terms used to define the scope of protection have varied widely – ranging from "genetic resources" to "biological materials" – it is important to note that the CBD itself refers specifically to ensuring "the fair and equitable sharing of the benefits arising out of the utilization of *genetic resources*…" (Article 1, CBD). Article 15 of the CBD itself is entitled "Access to *Genetic Resources*" and uses the term "*genetic resources*" throughout. Article 16, which requires Contracting Parties to take measures to ensure appropriate transfer of technology, also refers specifically to countries that provide access to *genetic resources*, and the transfer of technology arising from the use of such *genetic resources*. Thus, the scope and objectives of the CBD are limited to access to *genetic resources* and the sharing of benefits arising out of the use of such *genetic resources*. The use of any other terms, such as "genetic material," "biological resources" or "biological materials," therefore extends beyond the scope of the CBD.

PART II: OVERVIEW OF EXISTING PROPOSALS AND MECHANISMS

Paragraphs 38 to 41: The Bonn Guidelines suggest disclosure of origin of genetic resources and traditional knowledge as only one of several possible means to ensure prior informed consent (See Section II.C.d (ii)). Other measures are also discussed, and countries of origin of genetic resources are encouraged to implement such measures, including creation of a national focal point, implementation of measures to inform potential users of their obligations, and negotiation of mutually agreed terms.

PART III: TECHNICAL AND LEGAL BACKGROUND

Paragraph 68: In response to the final sentence of this paragraph, IFPMA wishes to point out that the traceability, compliance with prior informed consent, and assurance of benefit sharing goals would remain unfulfilled if no patent application is filed by the user of genetic resources.

Paragraph 72: Several of the questions raised under paragraph 72 presuppose that patenting of an invention, regardless how remotely it may be related to genetic resources or traditional knowledge associated with such genetic resources, requires different standards. In fact, the criteria for patentability require that an invention be novel and inventive (non-obvious) over prior existing knowledge or resources, and this is not dependent on whether that knowledge is traditional knowledge or the resource is a genetic resource. All inventions build on prior public knowledge. Patentability is judged by the novelty and non-obviousness (inventive step) of the invention in light of that public knowledge. It is thus inherent in the patent laws that no invention should be granted which uses traditional knowledge "directly or substantially." Furthermore, the use of patent offices to enforce legal agreements would impose a significant administrative burden on already over-burdened patent offices. Therefore, we propose to add the following two underlying questions to paragraph 72:

– are additional disclosure requirements necessary in view of already existing patentability requirements?

– are national patent offices the appropriate bodies to enforce licenses or contract-based interests of providers of genetic resources or traditional knowledge associated with genetic resources?

Paragraph 76: IFPMA notes that it is not the objective of existing intellectual property laws to monitor compliance with contractual provisions and that accordingly, use of the patent application process for this purpose would significantly impact already overburdened patent offices. Furthermore, for reasons of privacy to the provider or business reasons of the user, both parties to an agreement relating to access and benefit sharing may desire or require that the existence of such agreement be kept confidential.

Paragraph 90: In response to the comments and question posed by Brazil, IFPMA proposes addition of the following statement in a separate paragraph to follow paragraph 90:

> On the other hand, those who would engage in inequitable behavior could easily avoid disclosure requirements by simply using GR or TK associated with GR without filing an application for intellectual property rights. As a result, disclosure requirements may introduce unnecessary burdens into the intellectual property system, but would not remedy the concerns of inequitable behavior.

PART IV: SPECIFIC ISSUES IN THE CBD COP INVITATION

Paragraphs 106-109: Regarding the subsection relating to "Some possible functions of disclosure requirements," IFPMA proposes the addition of the comments below after paragraph 109:

> IFPMA notes that disclosure of origin may not be the most appropriate mechanism for ensuring access and benefit sharing or prior informed consent, and in fact, may serve some negative functions.

(i) Disclosure requirements may serve as a disincentive that ultimately will decrease expenditures on research and development, and thereby stifle innovations that could otherwise benefit all societies. The legal uncertainty introduced by disclosure requirements that are unclear in terminology, scope and applicability, especially if linked to patent validity, would dramatically decrease the value of innovations, which take significant time and resources to develop. Indeed, in the pharmaceutical industry, new medicines are estimated to take 10-12 years to develop, at a cost of approximately USD $1.5 billion.

(ii) A system of disclosure in patent applications will do little to satisfy the objectives of the CBD. If disclosure mechanisms are used to track benefit sharing and prior informed consent, such use could not be monitored where no intellectual property protection is sought by the user of GR or TK. Furthermore, use of genetic resources and/or traditional knowledge associated with genetic resources does not always lead to a patentable invention. On the other hand, if an invention does result, it can often occur years after the initial use of the GR or TK, and any benefit sharing that would arise as a result of disclosure could be many years after the actual use. This would be lost revenue that could otherwise have flowed to the provider of GR or TK if an agreement were first established between the user and provider.

(iii) Sanctions for failure to comply, however technical, could lead to loss of patent rights to the patent owner, with no rights to any other party, thereby making the invention free to the public. The goal of benefit sharing would not be furthered as there would be no benefits to flow to the provider of GR or TK.

Paragraph 115: It is important to note that current intellectual property laws already disallow the patenting of an invention that is anticipated, whether the anticipatory prior art is traditional knowledge or otherwise. Traditional knowledge is not, by definition, anticipatory prior art. Inventions that are novel and involve an inventive step (non-obviousness) should continue to be patentable. This does not address the issue of whether a benefit-sharing obligation exists that may lie outside the patent system. Benefit-sharing obligations associated with securing TK may exist, but they should not impact patentability where the TK is enhanced by an inventive step.

Paragraph 122: IFPMA notes that many genetic resources may have been removed from their country of origin and utilized by societies for centuries.
(See UNEP/CBD/WG-ABS/3/INF/2, Discussion Paper Prepared by the ICC Commission on Biosociety and Commission on Intellectual Property.) Such transfer and use may have preceded the creation of national regimes and mechanisms for prior informed consent. Therefore, it is inaccurate to suggest that providing documents to support evidence of access or prior informed consent would be no burden on legal users of genetic resources. The non-existence of such documents should not create a presumption that there was no legal right to use such genetic resources.

Paragraphs 131-146: Regarding the section entitled "Triggers for Disclosure Requirements," IFPMA proposes the addition of the following comments:

> With regard to triggers for disclosure requirements, IFPMA believes it is important to note that there are already existing triggers for disclosure, to the extent that disclosure is material to the determination of novelty, inventive step (non-obviousness), enablement, and best mode (where applicable). Disclosure of the use of GR or TK, if such disclosure is not material to patentability would only introduce an undue administrative burden on patent offices and would create a barrier to patentability that may have little relationship to the invention.

Paragraph 155: It is overly simplistic to draw the conclusion that patent applications found to be non-compliant with disclosure requirements must necessarily be a result of negligent or fraudulent disclosure. The fact that such presumptions exist only highlights the legal uncertainty that would accompany the filing of patent applications under such a system. Thus, IFPMA notes that proposed disclosure requirements remain unclear in terminology, scope and applicability. Where overly broad disclosure requirements are mandated, information may not be relevant to inventorship or patentability, nonetheless, that information could be used to invalidate a patent or to apply severe sanctions against an unwitting applicant.

Paragraphs 160 to 164: In the section relating to "Possible undesirable or perverse incentives," IFPMA proposes the inclusion of the following information, which highlights the possible perverse incentives of a disclosure requirement:

(i) The pharmaceutical industry invests heavily in research and development in an effort to bring new medicines to the market. In order for those costs to be recouped, the industry requires the legal certainty that its patents are valid and enforceable. Overly broad disclosure requirements would have a chilling effect on investment in the development of new products, the research required for that development, and, as a consequence, continued innovation. This would be equally true for those products that might otherwise be developed through the use of legally-acquired genetic resources or traditional knowledge.

(ii) The proposed disclosure requirements also do little to meet the access and benefit sharing objectives of the CBD. As noted earlier, use of genetic resources and/or traditional knowledge associated with genetic resources does not always lead to a patentable invention. Alternatively, true misappropriation of GR or TK could continue by those who choose not to use the very public process of filing a patent application.

(iii) Disclosure requirements may have the perverse incentive of keeping use of GR or TK confidential, thereby depriving the public of innovation. Alternatively, invalidation of a patent on the basis of lack of disclosure would dedicate the invention to the public, where any third parties could use the invention without the need to provide benefit sharing. It is also possible that the GR or TK could be used without first obtaining intellectual property protection, and this would also do nothing to provide for benefit sharing.

(iv) In the “Summary of Incentives,” under the subsection “‘Perverse’ or undesirable incentives,” please add the following:

– Discouraging the investment required for research and development into new products, thereby stifling innovation.

[End of Annex and of document]