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INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

Sixteenth Session
Geneva, May 3 to 7, 2010

GENETIC RESOURCES: REVISED LIST OF OPTIONS

Document prepared by the Secretariat

INTRODUCTION

1. At its fifteenth session, held from December 7 to 11, 2009, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee'):

(a) "invited Member States and observers to make available to the Secretariat papers describing regional, national and community policies, measures and experiences regarding intellectual property and genetic resources before February 12, 2010, and requested the Secretariat to make these available as information documents for the next session of the Committee."

(b) "requested the Secretariat to prepare and distribute, before the end of January 2010, a revised version of working document WIPO/GRTKF/IC/11/8(a), reflecting the proposed amendments and comments made on and questions posed in relation to this document at this session of the Committee. Amendments, comments and questions of observers should be recorded for consideration by Member States. The Secretariat would invite Committee participants to provide written comments on that revised version before the end of February 2010. The Committee invited the Secretariat then to prepare and distribute a further revised

version of the document, reflecting the written comments made, as a working document for the next session of the Committee."[1]

2. Regarding paragraph 1(a) above, the WIPO Secretariat issued a circular to all Committee participants, dated January 15, 2010, recalling that part of the decision concerning genetic resources taken by the fifteenth session of the Committee. Submissions were received from the following Member States: Algeria, Australia, Brazil, China, Colombia, the European Union and its Member States, Kenya, Kyrgyzstan, Mexico, Norway, the Russian Federation, Switzerland, Turkey and Zambia; and from the following accredited observers: the Biotechnology Industry Organization (BIO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Center for Peace Building and Poverty Reduction among Indigenous African Peoples (CEPPER), the International Institute for Environment and Development (IIED), the Food and Agriculture Organization of the United Nations (FAO) and the Nigeria Natural Medicine Development Agency (NNMDA). These written submissions have been made available as information documents for the sixteenth session of the Committee which will take place from May 3 to 7, 2010.

3. Regarding paragraph 1(b) above, a revised version of working document WIPO/GRTKF/IC/11/8(a) was prepared and published, as WIPO/GRTKF/IC/16/6 Prov., on January 22, 2010, and Committee participants were invited to provide written comments on that revised version before February 28, 2010.

4. This present working document is the revised version of working document WIPO/GRTKF/IC/16/6 Prov., reflecting the written comments received thereon during this intersessional written commenting process pursuant to the above invitation. Written comments were received from the following Member States: Germany and Switzerland; and from the following accredited observers: the International Seed Federation (ISF). The written comments, as received, are available online at http://www.wipo.int/tk/en/consultations/draft_provisions/comments-3.html.

Preparation and structure of this document

5. WIPO/GRTKF/IC/11/8 (a) listed options for continuing or further work which were arranged in three clusters, namely (a) defensive protection of genetic resources; (b) disclosure requirements in patent applications for information related to genetic resources used in the claimed invention; and (c) IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources.

6. The cover document of WIPO/GRTKF/IC/11/8 (a) contained ten introductory options for continuing or further work (options i to x). Annex I of the document comprised substantive issues, questions for guidance and nine options for activities arranged in the three clusters. The introductory options for continuing or further work in the cover document overlapped with the options for activities in Annex I.

[1] Decisions of the Fifteenth Session of the Committee (WIPO/GRTKF/IC/Decisions); Draft Report of the Fifteenth Session (WIPO/GRTKF/IC/15/7 Prov.)

7. In the circumstances and in the interest of keeping the present document as clear, concise and current as possible:

(a) the structure and presentation of the working document have been simplified and streamlined, without making any substantive changes to the content of the document itself. These presentational changes are intended to facilitate discussion of the document by the Committee and they respond to the request of Member States to focus on the options within the three clusters of options already identified;

(b) the list of options contained in the cover document to WIPO/GRTKF/IC/11/8 (a) has been aligned and consolidated with the list of options contained in Annex I to WIPO/GRTKF/IC/11/8 (a); and

(c) in line with the decisions of the Committee taken at its fifteenth session, specific comments made by Member States at that session and during the intersessional written commenting process are reflected in Annex I. This Annex also identifies comments and questions of observers which are recorded for consideration by Member States. The comments and questions are, as far as possible, grouped by issue. Several comments made during the intersessional written commenting process related generally to the entire document; these general comments are reflected at the very end of the document.

SUMMARY OF OPTIONS

8. Following is a brief summary of options for continuing or further work identified by the Committee, simplified, streamlined and consolidated as set out above. Further details are provided in the commentary and specific comments set out in Annex I.

9. The options listed below are derived exclusively from proposals put to the Committee by Member States and other Committee participants, including national and regional submissions, proposals by other participants, and the Committee's working documents. Each option would be subject to the overarching requirement in the current mandate of the Committee that its work should not prejudice the work of other fora, both within and beyond WIPO. In some instances, this work corresponds to direct invitations or encouragements of other forums, in particular the Conference of Parties of the Convention on Biological Diversity.

A. Options on defensive protection of genetic resources

A.1 *[Inventory of databases and information resources on GR]*

Extension of already approved defensive protection mechanisms for traditional knowledge to address genetic resources more specifically, including the review and greater recognition of further sources of already disclosed information about genetic resources. The Committee could compile an inventory of existing periodicals, databases and other information resources which document disclosed genetic resources, with a view to discussing a possible recommendation that certain periodicals, databases and information resources may be considered by International Search Authorities for integration into the minimum documentation list under the PCT.

A.2 *[Information systems on GR for defensive protection]*

An Online Portal of Registries and Databases, established by the Committee at its third session, could be extended to include existing databases and information systems for access to information on disclosed genetic resources (additional financial resources would be required to implement this option). A concrete proposal for such a system was presented at the ninth session[2] and proposed that "a new system has to be a one-stop system where genetic resources … can be searched once and comprehensively and not a system in which each database created by each country has to be searched separately. The one-stop database system thus proposed could be an all-in-one consolidated system or be composed of multiple systems easily searchable with one click. Sufficient discussion has to be conducted to determine how to create the most efficient database in the foreseeable future."

A.3 *[Guidelines and recommendations on defensive protection]*

Recommendations or guidelines for search and examination procedures for patent applications to ensure that they better take into account disclosed genetic resources. The Committee could discuss the possible development of recommendations or guidelines so that existing search and examination procedures for patent applications take into account disclosed genetic resources, as well as a recommendation that patent granting authorities also make national applications which involve genetic resources subject to 'international-type' searches as described in the PCT Rules.

B. Options on disclosure requirements

B.1 *[Mandatory disclosure]*

Development of a mandatory disclosure requirement such as has been tabled in the Committee.[3]

B.2 [*Further examination of issues relating to disclosure requirements*]

Further examination of issues relating to disclosure requirements, such as the questions addressed or identified in earlier studies and invitations. Related analysis of patent disclosure issues making use of the information submitted by Committee Members in the context of questionnaire WIPO/GRTKF/7/Q.5 (Questionnaire on recognition of TK and GR in the patent system). The Committee could consider whether there is a need to develop appropriate (model) provisions for national or regional patent or other laws which would facilitate consistency and synergy between access and benefit-sharing measures for genetic

[2] WIPO/GRTKF/IC/9/13.

[3] This option was included in the list of options in the cover document to WIPO/GRTKF/IC/11/8(a) but not in the list of options in Annex I to that document. As part of the alignment and consolidation of the two lists, it is included here.

resources, on the one hand, and national and international intellectual property law and practice, on the other.

B.3 *[Guidelines and recommendations on disclosure]*

The Committee could consider the development of guidelines or recommendations concerning the interaction between patent disclosure and access and benefit-sharing frameworks for genetic resources. The Committee could consider the development of guidelines or recommendations on achieving objectives related to proposals for patent disclosure or alternative mechanisms and access and benefit-sharing arrangements.

B.4 *[Alternative mechanisms]*

Other work on provisions for national or regional patent laws to facilitate consistency and synergy between access and benefit-sharing measures for genetic resources and national and international patent law and practice. The Committee could consider the creation of a dedicated international information system on disclosed genetic resources as prior art in order to prevent the erroneous grant of patents on genetic resources. This was submitted at the ninth session as an alternative proposal for dealing with the relationship between intellectual property and genetic resources (WIPO/GRTKF/IC/9/13).

C. Options on IP issues in mutually agreed terms for fair and equitable benefit-sharing

C.1 *[Online Database of IP clauses in mutually agreed terms on ABS]*

Considering options for the expanded use, scope and accessibility of the online database of IP clauses in mutually agreed terms for access and equitable benefit sharing. The contents of the Online Database could be published in additional, more easily accessible forms, such as on CD-ROM, for wider accessibility and easier use by all relevant stakeholders.

C.2 *[Draft guidelines for contractual practices]*

Considering options for stakeholder consultations on and further elaboration of the draft guidelines for contractual practices contained in the Annex of document WIPO/GRTKF/IC/7/9, based on the additional information available and included in the online database.

C.3 *[Study on licensing practices on GR]*

Compile information, possibly in the form of case studies, describing licensing practices in the field of genetic resources which extend the concepts of distributive innovation or open source from the copyright field, drawing on experiences such as the Global Public License and other similar experiences in the copyright field.

10. The Intergovernmental Committee is invited to continue to review and comment on the options for future work contained in this document with a view eventually to selecting certain options for further work by the Committee.

[Annexes follow]

ANNEX I

REVISED LIST OF OPTIONS FOR THE PROTECTION OF GENETIC RESOURCES

OPTIONS AND SUBSTANTIVE ISSUES

CONTENTS

Cluster C: *IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources*

C. List of options on IP issues in mutually agreed terms for fair and equitable benefit-sharing

Option C.1: *Online database of IP clauses in mutually agreed terms on ABS*
Option C.2: *Draft guidelines for contractual practices*
Option C.3: *Study on licensing practices on GR*

General Commentary on Cluster C

Specific Comments by Member States and Observers

General Comments

I. INTRODUCTION

1. This Annex provides an overview of the Committee's work on genetic resources issues and suggests certain options for certain technical measures or activities which the Committee may wish to pursue. It covers the three clusters of substantive questions which have been identified in the course of this work, namely technical matters concerning (a) defensive protection of genetic resources; (b) disclosure requirements in patent applications for information related to genetic resources used in the claimed invention; and (c) IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources.

2. It is recalled that the mandate of the Committee indicates that its work is "without prejudice to the work pursued in other fora"[1].

II. LIST OF OPTIONS

Cluster A: Defensive protection of genetic resources

3. To improve the defensive protection of genetic resources, much can be learned from the Committee's extensive work on defensive protection of traditional knowledge (TK). It has been suggested that activities successfully completed for TK could be translated, applied and executed in relation to disclosed genetic resources. The following options may be relevant:

A. <u>Options on defensive protection of genetic resources</u>

A.1 [Inventory of Databases and information resources on GR]
Extension of already approved defensive protection mechanisms for traditional knowledge to address genetic resources more specifically, including the review and greater recognition of further sources of already disclosed information about genetic resources. The Committee could compile an inventory of existing periodicals, databases and other information resources which document disclosed genetic resources, with a view to discussing a possible recommendation that certain periodicals, databases and information resources may be considered by International Search Authorities for integration into the minimum documentation list under the PCT[2].

A.2 [Information systems on GR for defensive protection]
An Online Portal of Registries and Databases, established by the Committee at its third session, could be extended to include existing databases and information systems for access to information on disclosed genetic resources (additional financial resources would be required to implement this option).[3] *A concrete proposal for such a system was presented at the ninth session and proposed that "a new system has to be a one-stop system where genetic resources … can be*

[1] See document WO/GA/38/20, para 217.
[2] This has already been successfully accomplished for periodicals concerning disclosed TK, as foreseen in WIPO/GRTKF/IC/2/6, paras 41 to 45.
[3] See WIPO/GRTKF/IC/3/6, para 15.

searched once and comprehensively and not a system in which each database created by each country has to be searched separately. The one-stop database system thus proposed could be an all-in-one consolidated system or be composed of multiple systems easily searchable with one click. Sufficient discussion has to be conducted to determine how to create the most efficient database in the foreseeable future."[4]

A.3 [Guidelines or recommendations on defensive protection] Recommendations or guidelines for search and examination procedures for patent applications to ensure that they better take into account disclosed genetic resources The Committee could discuss a possible development of recommendations or guidelines so that existing search and examination procedures for patent applications take into account disclosed genetic resources, as well as a recommendation that patent granting authorities also make national applications which involve genetic resources subject to 'international-type' searches as described in the PCT Rules.[5]

[4] See WIPO/GRTKF/IC/9/13, para 40.
[5] This has already been done for patent applications involving disclosed TK. See WIPO/GRTKF/IC/2/6, para 52 on international prior art search.

GENERAL COMMENTARY ON CLUSTER A

4. A range of Committee participants have called for the improved defensive protection of genetic resources against the grant of illicit intellectual property titles (disclosure requirements were highlighted as a particular form of defensive measure, discussed below). Some submissions illustrated specific cases of potential misappropriation of genetic material. In particular, case studies[6] submitted by the Delegation of Peru described "actions against pending patent applications or patents obtained or developed from the use of a biological resource or traditional knowledge without the prior informed consent of the country of origin of the resource or of the indigenous people owning rights in the knowledge, and without providing for any type of compensation to that country or indigenous people" and set out the following purposes:

(a) ascertaining how a mega-diverse country makes a serious attempt to address this phenomenon through its institutions;

(b) understanding to some extent the methodology and standards used in the search for such patents, thereby helping other countries or regions which might wish to initiate similar efforts;

(c) gaining knowledge of the large number of inventions referring to resources of Peruvian origin that might reflect cases of biopiracy (either because such resources have been obtained illegally, or because they involve the unauthorized use, without compensation, of traditional knowledge); and

(d) demonstrating that a systematic and methodical search and analysis of "problem" patents can be undertaken.

5. Submissions by Committee members also put forward options for addressing cases of wrongly granted patents, such as a proposal submitted by the Delegation of Japan. This complements extensive work undertaken in the first six sessions of the Committee to establish an array of defensive mechanisms to promote, and complements the development of patent examination guidelines for TK-related patents. Other UN agencies, such as the FAO, have requested WIPO to cooperate in analyzing and addressing similar concerns in specific sectors.[7] International organizations working in the genetic resources field, such as the International Plant Genetic Resources Institute (IPGRI), have worked closely with WIPO to explore how to reduce the practical likelihood of illegitimate patents by linking their genetic resource information systems to a WIPO Portal which has been created in order to improve defensive protection of disclosed genetic material. The technical measures that have been identified as possible means to address these concerns include improving the availability and searchability of publicly available information about disclosed genetic resources to patent examiners; improved search tools for prior art searches, in particular thesauri for genetic resource nomenclature in order to allow examiners to translate between scientific and vernacular names of genetic resources that might be referred to in patent applications on the one hand and prior art documentation on the other. In furtherance of the work already done for the existing WIPO Portal for defensive protection of genetic resources, specific proposals

[6] See documents submitted by Peru (WIPO/GRTKF/IC/5/13, WIPO/GRTKF/IC/8/12, WIPO/GRTKF/IC/9/10).
[7] See FAO document CGRFA-9/02/REP.

were submitted during the ninth session of the Committee. For example, document WIPO/GRTKF/IC/9/13 suggests that "an effective solution … is to establish a database related to genetic resources and traditional knowledge, which is accessible by examiners in any country, in order to avoid the erroneous granting of patents for genetic resources and related traditional knowledge."[8].

Amendments proposed, comments made and questions posed at the fifteenth session (December 7 to 11, 2009)

Comments made and questions posed

The comments made and questions posed were proposed by Argentina, Canada, Colombia, El Salvador, Japan, Peru, Venezuela (Bolivarian Republic of) and, as observers, by the Coordination of African Human Rights NGOs.

Relation to other Committees at WIPO

A delegation requested analysis and consideration of the issues relating to patents within the Standing Committee on Patents.

Nature of document

A delegation considered that the document on GR and IPRs should be binding.

Scope and objective of defensive protection

A delegation said that besides the commercial aspects, moral and religious aspects of the issue should be taken into account. In addition, GR as well as the products deriving from GR should be taken into account.

A delegation stated that derived products should be considered for the protection of commercial interests and potential future developments which need patenting.

A delegation considered it essential to find a rapid solution to undue appropriation or misappropriation of GR to respect the mandate of the General Assembly for the effective protection of GR, TCEs and also TK.

TK databases as a means of defensive protection

A delegation drew attention to the following: At the ninth and eleventh session of the Committee, Japan made a proposal on establishing a one-click database to improve the prior search environment concerning GR and TK, thereby preventing the so-called erroneous granting of patents. It suggested taking advantage of the existing WIPO website linked to various GR-related national databases of member states, which were open to the public and making the website more user-friendly as a portal. The Government of India had granted the USPTO examiners access to its Traditional Knowledge Digital Library (TKDL). Members could learn a lot from the Indian experiences as to how those libraries can be developed

[8] WIPO/GRTKF/IC/9/13, para 34.

worldwide. The WIPO Secretariat could play an important role in making such a database easily available to examiners around the world. Suggestions made by the Delegation of Singapore at the thirteenth session of the Committee, which indicated several key issues, technical aspects of the international database, contents of the international database and a couple of others were highlighted. The establishment of a powerful search tool, which was easily accessible from all IP Offices around the world, was also an aspiration.

A delegation supported any practical way to address the IP aspects of GR, such as any initiatives that would seek to improve prior art searches conducted by patent examiners. One good example would be to upgrade the access for IP offices to digital libraries.

Glossary and databases

A delegation underscored that it would be useful drawing up a publicly available database and glossary. This could not be considered as the only alternative for patent reviewers, not just the current databases, but a shorter access to publications and to papers. They would have all to review patents requested for GR and related products.

Links to other fora

One observer raised the issue of climate change, biodiversity and TK. The UNFCCC is not referred to in the document even if it was linked; the same for TRIPS.

Cluster B: Disclosure requirements in patent applications for information related to genetic resources used in the claimed invention

6. The implications and possible integration of proposals for additional genetic resource disclosure requirements into specific international IP agreements are being addressed in specialized fora which are competent for amendment or reform of those IP agreements (for example, implications for the TRIPS Agreement are being addressed in the TRIPS Council, and implications for the PCT were discussed in the Working Group for Reform of the PCT). The broader relation between disclosure requirements and access and benefit-sharing frameworks raises a number of conceptual questions which are not being fully analyzed on their own terms in those specialized fora. These broader conceptual linkages exceed the technicalities of integration into specific IP agreements. In part, they emerge in the process of responding to the second CBD invitation on disclosure issues, which WIPO Member States agreed should be prepared in a distinct process separate from the Committee (culminating in the Ad Hoc Intergovernmental Meeting on this matter, held on June 3, 2005 and leading to the examination of issues which WIPO forwarded to the CBD COP). This leaves open the question of whether the Committee would consider options such as the following, which have been identified at previous sessions, while noting the strong concerns expressed that there should be no prejudice to the work of other fora:

B. Options on disclosure requirements

B.1 [Mandatory disclosure]
Development of a mandatory disclosure requirement such as has been tabled in the Committee.

B.2 [Further examination of issues relating to disclosure requirements]
Further examination of issues relating to disclosure requirements, such as the questions addressed or identified in earlier studies and invitations.
Related analysis of patent disclosure issues making use of the information submitted by Committee Members in the context of questionnaire WIPO/GRTKF/7/Q.5 (Questionnaire on recognition of TK and GR in the patent system). The Committee could consider whether there is a need to develop appropriate (model) provisions for national or regional patent or other laws which would facilitate consistency and synergy between access and benefit-sharing measures for genetic resources on the one hand and national and international intellectual property law and practice on the other[9].

B.3 [Guidelines or recommendations on disclosure]
Guidelines or recommendations concerning the interaction between patent disclosure and access and benefit-sharing frameworks for genetic resources. The Committee could consider the development of guidelines or recommendations on achieving objectives related to proposals for patent disclosure or alternative mechanisms and access and benefit-sharing arrangements[10].

[9] The Committee considered such proposals at its first session (WIPO/GRTKF/IC/1/3, Annex 4) and as a request from the CBD-COP at its sixth session (see WIPO/GRTKF/IC/6/11, para. 4, quotation of COP Decision VII/19, para. 8(a) of the CBD).
[10] The Committee considered such proposals at the first and fifth sessions. See WIPO/GRTKF/IC/5/10, para 12(ii).

B.4 [Alternative mechanisms]

Other work on provisions for national or regional patent laws to facilitate consistency and synergy between access and benefit-sharing measures for genetic resources and national and international patent law and practice. The Committee could consider the creation of a dedicated international information system on disclosed genetic resources as prior art in order to prevent the erroneous grant of patents on genetic resources. This was submitted at the ninth session as an alternative proposal for dealing with the relationship between intellectual property and genetic resources (WIPO/GRTKF/IC/9/13).

GENERAL COMMENTARY ON CLUSTER B

7. Discussions have covered questions surrounding specific disclosure requirements in patent applications for information relating to genetic resources which have been utilized in the claimed invention and alternative proposals for dealing with the relationship between intellectual property and genetic resources. This has been highlighted mostly in relation to improved defensive protection of genetic resources and in relation to emerging linkages of IP systems with national and international access and benefit-sharing regimes for genetic resources. As described above, other multilateral fora, such as the CBD, have invited WIPO to examine certain aspects of this cluster of issues, and that examination is currently in progress. Specific WIPO-administered treaties, such as the Patent Cooperation Treaty (PCT), have considered this issue within their own reform processes, and the matter has been raised in the SCP discussions on a draft Substantive Patent Law Treaty. Other multilateral organizations have taken up the issue with regard to specific agreements administered by them, such as the WTO with regard to the TRIPS Agreement; a specific proposal has been tabled to amend the TRIPS Agreement so as to introduce a mandatory disclosure requirement.

8. These discussions have focused on the potential integration of new or expanded disclosure requirements into existing patent systems as well as multiple alternative measures and proposals for dealing with the relationship between intellectual property and genetic resources. The debate also raises conceptual and practical questions about the linkages and synergies of intellectual property mechanisms with access and benefit-sharing regimes. References to disclosure requirements have been included in the terms of reference for negotiations which are currently under way in the CBD on an international regime for access and benefit-sharing. Two formal proposals have already been tabled in the Committee, one for a mandatory disclosure requirement[11], the other one explicitly enabling the Contracting Parties of the PCT to introduce such a requirement[12]. ~~A formal proposal[13] has already been tabled in the Committee for a mandatory disclosure requirement.[14]~~ –Some Committee participants argue for a mandatory requirement but have called for it to proceed in other forums, either within or beyond WIPO, cautioning that the Committee's work should not prejudice outcomes elsewhere. Another view is that it would be wrong to assume that a new disclosure requirement within the patent system will accomplish the objectives of ensuring access and equitable benefit-sharing, and they have cautioned that the Committee should be wary of upsetting the delicately balanced patent system.[15] Another perspective is that disclosure requirements can under certain circumstances relate to larger regulatory questions about access and benefit-sharing frameworks, in addition to the question of their compatibility with, and integration into, specific existing IP agreements. Several further points of view have been expressed by commentators, who have pointed out that these conceptual questions regarding the interrelation and synergies between patent disclosure requirements and access and benefit-sharing regimes are not exhaustively addressed in the discussions on the

[11] Document WIPO/GRTKF/IC/8/11, described further below.
[12] A second submission has been made, by the Delegation of Switzerland, as document WIPO/GRTKF/IC/11/10.
~~[13] Document WIPO/GRTKF/IC/8/11, described further below.~~
~~[14] A second submission has been made, by the Delegation of Switzerland, as document WIPO/GRTKF/IC/11/10.~~
[15] WIPO/GRTKF/IC/8/13 ('Article 27.3(b), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore', submission by the United States of America).

compatibility of disclosure requirements with existing patent systems or their integration into the mechanics of existing systems.

9. The technical study on disclosure issues developed earlier by the Committee and transmitted to the CBD COP identified ‘some key issues’ in the following manner:

A key issue is the relationship between the genetic resource and traditional knowledge, on the one hand, and the claimed invention, on the other. This includes clarification of the range and duration of obligations that may attach to such resources and knowledge, within the source country and in foreign jurisdictions, and how far these obligations ‘reach through’ subsequent inventive activities and ensuing patent applications. Clarity in this area is required so that patent or judicial authorities and the patent applicant or owner know when the obligation takes effect, and when on the other hand the relationship between background genetic resources or traditional knowledge is sufficiently remote or non-essential not to trigger the obligation. This is particularly so if the obligation is mandatory, bears a burden of proof or due diligence responsibility, or may lead to invalidation of patent rights. In the discussion of possible disclosure requirements, a diverse range of ways of expressing a linkage between genetic resources and traditional knowledge is canvassed. General patent law principles provide certain more specific ways of expressing this relationship, even if the objective of the requirement is not conceived in traditional patent terms. Patent law may also be drawn on to clarify or implement more generally stated disclosure requirements: for example, a general requirement to disclose genetic resources used in the invention may be difficult to define in practice, and may be implemented through a more precise test that requires disclosure only when access to the resources would be necessary to reproduce the invention. The degree of clarity and predictability of impact of any disclosure requirement, and thus its practical impact, is likely to depend on whether the requirement can be analyzed or expressed in terms of patent law.

Another key issue is the legal basis of the disclosure requirement in question, and its relationship with the processing of patent applications, the grant of patents and the exercise of patent rights. This raises also the legal and practical interaction of the disclosure requirement with other areas of law beyond the patent system, including the law of other jurisdictions. Some of the legal and policy questions that arise are:

– the potential role of the patent system in one country in monitoring and giving effect to contracts, licenses, and regulations in other areas of law and in other jurisdictions, and the resolution of private international law or ‘choice of law’ issues that arise in interpreting and applying across jurisdictions contract obligations and laws determining legitimacy of access and downstream use of GR/TK;

– the nature of the disclosure obligation, in particular whether it is essentially a transparency mechanism to assist with the monitoring of compliance with non-patent laws and regulations, or whether it incorporates compliance;

– the ways in which patent law and procedure can take account of the circumstances and context of inventive activity that are unrelated to the assessment of the invention itself and the eligibility of the applicant to be granted a patent;

– the situations in which national authorities can impose additional administrative, procedural or substantive legal requirements on patent applicants, within existing international

legal standards applying to patent procedures, and the role of non-IP international law and legal principles in this regard;

– the legal and operational distinction (to the extent one can be drawn) between patent formalities or procedural requirements, and substantive criteria for patentability, and ways of characterizing the legal implications of such distinctions;

– clarification of the implications of issues such as the concept of 'country of origin' in relation to genetic resources covered by multilateral access and benefit-sharing systems, differing approaches to setting and enforcing conditions for access and benefit sharing in the context of patent disclosure requirements, and coherence between mechanisms for recording or certifying conditions of access and the patent system.[16]

10. The 'examination of issues' developed in response to the second invitation by the CBD COP (prepared not within the Committee, but by a separate ad hoc intergovernmental process within WIPO culminating in the Ad Hoc Intergovernmental Meeting (WIPO/IP/GR/05/1) held in June 2005) noted that:

Analyzing disclosure requirements may also require some consideration of such underlying questions as:

– who is the true inventor of a claimed invention, when the invention uses TK directly or substantially?

– what external circumstances affect the entitlement of the applicant to apply for and to be granted a patent, especially the circumstances that surround the obtaining and use of inputs to the invention, and any broader obligations that arise?

– is the claimed invention truly new and inventive (non-obvious), having regard to already known TK and GBMR?

– has the applicant disclosed all known background knowledge (including TK) that is relevant to the claim that the invention is patentable?

– apart from the applicant, are there other interests that should be recognized: ownership interests (e.g. arising from benefit-sharing obligations), licensing or security interests, or interests arising from a TK holder's role in an invention?

– how can the patent system be used to monitor and sanction compliance with laws governing access to GBMR and compliance with the terms of laws or regulations governing ABS, mutually agreed terms, permits, licenses or other contractual obligations, especially when these obligations arise under foreign jurisdictions?

– is the patent law the appropriate vehicle for ABS?[17]

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[16] Annex to document WIPO/GRTKF/IC/5/11, paras 205 and 206.
[17] This and the following six questions were included in the comments of the United States of America on WIPO/IP/GR/05/1.

– 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?

– are additional disclosure requirements necessary in view of already existing patentability requirements?[18]

– are national patent offices the appropriate bodies to enforce licences or contract-based interests of providers of genetic resources or associated TK?[19]

10bis. In 2003, Switzerland submitted proposals for an amendment of the PCT Regulations, which would explicitly enable the national legislator to require patent applicants to disclose the source of genetic resources and/or traditional knowledge. The concept of "source" should be understood in its broadest sense possible. This is because according to the relevant international instruments, in particular the CBD, a multitude of entities may be involved in access and benefit sharing. In order for the disclosure requirement to apply, the invention is to be directly based on the genetic resource or traditional knowledge. If patent applicants have no information at hand about the source, they would have to declare that the source is unknown to them or the inventor. In case an international patent application does not contain the required declaration, national law may foresee that in the national phase the application is not processed any further until the required declaration is furnished. If it is discovered after the granting of a patent that the applicant failed to declare the source or submitted false information, this may not be ground for revocation or invalidation of the granted patent; however, other sanctions provided for in national law, including criminal sanctions such as fines, may be imposed. Moreover, Switzerland invited WIPO, in close collaboration with the CBD, to establish an online-list of government agencies competent to receive information about the declaration of source. The office receiving a patent application containing such a declaration would inform the listed government agency about the respective declaration.

11. At the eighth session of the Committee, in June 2005, the European Community and its Member States submitted a proposal entitled 'Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications.' This proposal included the following summary:

[18] This and the following question were included in comments of an observer, IFPMA, subsequent to the June 3, 2005 Ad Hoc Meeting.
[19] Annex to document WO/GA/32/8, paragraph 74.

"(a) a mandatory requirement should be introduced to disclose the country of origin or source of genetic resources in patent applications;

(b) the requirement should apply to all international, regional and national patent applications at the earliest stage possible;

(c) the applicant should declare the country of origin or, if unknown, the source of the specific genetic resource to which the inventor has had physical access and which is still known to him;

(d) the invention must be directly based on the specific genetic resources;

(e) there could also be a requirement on the applicant to declare the specific source of traditional knowledge associated with genetic resources, if he is aware that the invention is directly based on such traditional knowledge; in this context, a further in-depth discussion of the concept of 'traditional knowledge' is necessary;

(f) if the patent applicant fails or refuses to declare the required information, and despite being given the opportunity to remedy that omission continues to do so, then the application should not be further processed;

(g) if the information provided is incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law;

(h) a simple notification procedure should be introduced to be followed by the patent offices every time they receive a declaration; it would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the available information.

These proposals attempt to formulate a way forward that should ensure, at global level, an effective, balanced and realistic system for disclosure in patent applications."[20]

Amendments proposed, comments made and questions posed at the fifteenth session (December 7 to 11, 2009) and during the intersessional written commenting process

The specific drafting amendments reflected in the list of options were proposed by Switzerland.

Comments made and questions posed

The comments made and questions posed were proposed by Australia, Bolivia, Brazil, Canada, China, Colombia, Mexico, Norway, Peru, the Russian Federation, South Africa, Sweden, on behalf of the European Union, Switzerland, the United States of America and, as observers, by the Eurasian Patent Organization (EAPO), the Food and Agriculture Organization (FAO), the Indigenous Peoples Council on Biocolonialism (IPCB), the International Chamber of Commerce (ICC), the International Seed Federation (ISF), and the Tulalip Tribes.

[20] Document WIPO/GRTKF/IC/8/11.

Proposals on disclosure

A delegation did not believe that the disclosure requirement would be useful and meet its needs.

Another delegation requested that further analysis of the disclosure requirement should be a priority, including analyzing information received in response to surveys and particularly referring to disclosure requirements. As regards mandatory requirements for disclosure of GR when filing a patent, the delegation believed an ultimate decision can be made only after going through all of the studies and all of the work.

It was stated by a delegation that work on disclosure requirements should be continued under the new mandate. A Member State recalled the proposals which it had submitted on disclosure (WIPO/GRTKF/IC/11/10) in which the PCT was proposed to be amended.

Several delegations proposed disclosure of a region or source of GR and associated TK in patent applications. A binding and mandatory disclosure requirement should be applied to all patent applications. The amendment of the Patent Law Treaty (PLT), the Patent Cooperation Treaty (PCT) and, as the case may be, regional agreements such as the European Patent Convention (EPC) would consequently be necessary (WIPO/GRTKF/IC/8/11). According to the proposal, a mandatory requirement should be introduced to disclose the country of origin or source of GR in patent applications. The requirement should apply to all international regional and national patent applications at the earliest stage possible. The applicant should declare the country of origin. If unknown, the source of the specific GR to which the inventor had physical access and which was still known to him should be declared. If the patent applicant failed or refused to declare the required information and continue to do so after being given the opportunity to remedy that omission, the application should not be processed further.

Several delegations considered that disclosure of the source of GR and related TK in a patent application would be very useful for the patent application. It was extremely rational and logical, and was absolutely irreplaceable.

It was stated by a delegation that disclosure of origin was necessary as part of a detailed description of the patent application. Disclosure requirements should be included as formal requirements for patent applications regarding GR.

An observer believed that a disclosure should only be necessary for those materials where the applicable form of IP would prevent further research and breeding with that material. If origin had the meaning of “country of origin” in the sense of the CBD, the disclosure of origin was extremely difficult as in most cases it was impossible to trace the origin of a biological resource. Moreover, it was also very difficult to determine when and where biological materials, in the form received, had developed these distinctive properties. All nations grew, imported, and exported many food and agricultural crop species whose centers of diversity lied outside their national boundaries, and were thus inherently dependent on multiple and foreign GR for food and agriculture. The historic widespread use of plant GR for food and agriculture was evident in the ancestry of individual crop varieties. Disclosure of source of GR, i.e. where the material was obtained, would be possible when the source was known. Normally the applicant knew and was allowed to indicate this with possible exceptions: (1) In the breeding community, one reason why the source could not be known is that the biological material came from the breeder’s nursery and there was no record of the original

source; and (2) Sometimes the biological resource had been received in the frame of a confidential contract and the disclosure of the origin would be a breach of that contract. If the applicant did not know the "source" of the material, or was not allowed to disclose it by contractual agreement, he/she might reasonably be asked to explain why not. The disclosure of the "source", in the meaning as summarized in the following paragraph, should be an administrative requirement only and thus, the failure to disclose, except in the case of proved fraudulent intention, could not invalidate the title of protection. Therefore the disclosure of origin should never be a criterion for patentability as it was in conflict with paragraph 1 of Art. 27 of the TRIPs agreement, and other international patent treaties. In summary, the observer could accept the disclosure of the "source" of the biological material, in the sense of where the material had been obtained from, where it was known, and if it was not a breach of a contract.

National experiences on disclosure

In China, the patent law had just been amended and has just entered into force. A new clause requiring the disclosure of the origin of the GR was added.

Switzerland has introduced such a mandatory disclosure requirement concerning GR and TK at the national level.[21]

In Mexican legislation there was no specific requirement to disclose the source of an invention that had been obtained from GR. Mexico was interested in assessing the pros and cons of drawing up new legislation.

Disclosure was implemented in Norwegian legislation for GR in 2004 and for TK in July of 2009 by amendments to the patent law. The Delegation highlighted that all TK should be included, not just TK connected to GR. A failure to meet such a disclosure requirement should not affect the validity of a granted patent. After the patent was granted, a failure to fulfill the disclosure requirement should be sanctioned outside the patent system. Before a patent was granted, a failure to fulfill the disclosure requirement should have the effect of not being processed further before the requirement was met. If the disclosure requirement was not met, when the patent application had been sent, it was not being processed further until the requirement was met.

South Africa has made disclosure of origin a requirement of its patent law in 2005. South Africa had put in place a bioprospecting regulatory system that included not only the defensive protection of GR and TK but also the positive protection of TK and associated GR. The South African government had initiated an amendment of all IP laws, not only patent laws.

Sanctions on insufficient disclosure

A delegation stated that disclosure should also be extended to products derived or stemming from GR. It was important to establish sanctions when disclosure of the use of GR is not made. Within Colombia's national legislation there was a direct correlation between the sanction and violation of patents and similar approach should be followed with GR.

[21] See WIPO/GRTKF/IC/16/INF/14.

Commercial and non-commercial/moral aspects of GR

A delegation stated that the multilateral agreement on GR linked to TK of indigenous peoples should not just be considered under its commercial aspects as has been suggested or as is the case in various places in the document. It was important at this stage to make a reference to the moral rights and beliefs of indigenous peoples in the pluri-national states and in many other countries as well. The Constitution of Bolivia expressly prohibits the ability to misappropriate or to appropriate life in any form including microorganisms. For this reason, a clear definition avoiding ambiguity in multilateral legislation was needed.

Alternative and complementary mechanisms

A delegation stated that work on alternative and complementary mechanisms should be continued, such as the use of TK databases. The papers on the Swiss and the EU proposals could serve as examples to consider such issues relating to the impact and implementation of patent disclosure requirements. There was a need for substantive legal and technical discussion of patent disclosure, in particular the 'examination of issues' undertaken by an ad hoc process in June 2005 developing a list of underlying questions that would benefit from further technical consideration.

Disclosure and relation to CBD

It was highlighted by a delegation that the issue of disclosure of origin should be dealt with at WIPO, in this Committee, as soon as possible, because the CBD could make a decision on that in March. It also suggested that the Intersessional Working Group should take place as early as possible because it could inform what was going on at the CBD and make sure that actually making a decision on the issue of disclosure requirement would be taken at WIPO, not at the CBD.

Another delegation added that the negotiations at the CBD needed to be supported and commented on by IP experts. Support should be mutual and neither of the two processes should be slowed down. Timing in life was everything. It was time to negotiate at WIPO, taking the interests of all Member States into account, and it was time to be more constructive.

An observer strongly felt that the discussions and decisions on disclosure should be made within a WIPO and TRIPS context and not within any other organization, such as the CBD.

Disclosure requirements and ITPGRFA

An observer said that it would be useful to recognize the Multilateral System of the Treaty in disclosure requirements in patent applications for GR in a claimed invention, if the Committee was to further work on such a requirement. In practical and concrete terms, it meant that if the disclosure requirement required a patent applicant to disclose the source of the genetic material in the claimed invention and if that material had been received by the patent applicant from the Multilateral System of the Treaty, the applicant would indicate as the source of the GR in the application the Multilateral System or the International Treaty. In addition, transfers of material within the Multilateral System occurred under a standardized private contract which was adopted by all the contracting parties of the Treaty, namely the Standard Material Transfer Agreement (SMTA).

The observer also highlighted the non-commercial benefit sharing mechanisms of the Treaty which equally entailed intellectual property related aspects and were of equal importance to the Treaty and the work of this Committee.

Practical relevance of disclosure

An observer said that the current patent legislation had very strict rules which contained a complex system for determining patentability and the applicant had to go through all the various stages one by one in order to obtain a patent. There was disclosure of the inventions in whatever area they were. In fact, all biotechnological inventions in one way or another were connected with GR. After defining the source or the origin, the disclosure requirement could be discussed. In any case, this requirement can be included in patent legislation. The observer was concerned that it might make the work of the Patent Office even more difficult if this requirement did come into force.

Disclosure and public domain

It was added by an observer that some of the approaches assumed TK and associated GR existed in the public domain and there were still the issue of lack of PIC for historical access to TK and the issue related to customary law related to TK and associated GR. With regard to the disclosure requirement, once something gets disclosed in a patent application under existing patent rules, even if an indigenous community did get a contract, that knowledge would enter the public domain without special protection within 20 years. With regard to the so called embodied TK which led to GR: What were the rights that indigenous peoples had on those genetic products which they had modified so that their knowledge was embodied in the structure?

Disclosure and rights of indigenous peoples

An observer emphasized that instruments such as disclosure of origin in patent applications or any other IP mechanisms must prevent the usurping of their sovereignty and wrongful taking of their biological resources as well as TK to be consistent with international human rights laws, in particular, Article 31 of the UN Declaration referred to the right to maintain, control and protect GR as part of cultural heritage.

An observer supported the proposal made for an exchange of national experiences.

Cluster C: IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources.

12. Mutually agreed terms for benefit-sharing have been widely discussed as an element of of access frameworks for genetic resources pursuant to the CBD. In this context, they are crucial for regulating access and ensuring benefit-sharing. Choices made by access providers concerning IP may play a role in contributing to equitable benefit-sharing arising from such access, including both commercial and non-commercial benefits. More recently, however, contractual practices for new IP management models in the field of genetic resources have also been discussed in relation to an extension of the concepts of distributive innovation to the utilization of genetic resources. Again, it should be noted that strong concerns exist that any work by the Committee should not prejudice work in other fora. Some options for further development of this work, which have been identified in the past, include:

C. Options on IP issues in mutually agreed terms for fair and equitable benefit-sharing

C.1 [Online Database of IP clauses in mutually agreed terms]
Considering options for the expanded use, scope and accessibility of the Online Database of IP clauses in mutually agreed terms for access and equitable benefit sharing. The contents of the Online Database could be published in additional, more easily accessible forms, such as on CD-ROM, for wider accessibility and easier use by all relevant stakeholders[22].

C.2 [Draft guidelines for contractual practices]
Considering options for stakeholder consultations on and further elaboration of the draft guidelines for contractual practices contained in the Annex of document WIPO/GRTKF/IC/7/9[23]*, based on the additional information available and included in the online database.*

C.3 [Study on licensing practices on GR]
Compile information, possibly in the form of case studies, describing licensing practices in the field of genetic resources which extend the concepts of distributive innovation or open source from the copyright field, drawing on experiences such as the Global Public License and other similar experiences in the copyright field.

13. It is to be emphasized that all the possible options identified above would be categorically without prejudice to the work undertaken in other fora. While the Committee may consider initiating some of these activities, it should at all times take into account the work of these other fora and should conduct this in a manner of mutual supportiveness.

[22] See WIPO/GRTKF/IC/2/12; WIPO/GRTKF/IC/2/16.
[23] See WIPO/GRTKF/IC/5/9; WIPO/GRTKF/IC/6/5; WIPO/GRTKF/IC/7/9.

GENERAL COMMENTARY ON CLUSTER C

14. A primary means of giving effect to the equitable sharing of benefits arising from the use of genetic resources is through mutually agreed terms, which are to be developed between provider and user of the resource for the granting of access to the resource, according to the CBD. The CBD thus foresees that "[a]ccess, where granted, shall be on mutually agreed terms,"[24] which are mostly agreed through contracts or permit systems. IP potentially plays a role in mutually agreed terms for the sharing of monetary benefits, according to the CBD Bonn Guidelines (Appendix II),[25] as well as in the sharing of non-monetary benefits.[26] The CBD-COP, in its Decision VI/24, "*encourages* the World Intellectual Property Organization to make rapid progress in the development of model intellectual property clauses which may be considered for inclusion in contractual agreements when mutually agreed terms are under negotiation."[27] The initial task which the Committee adopted on IP and genetic resources concerned IP clauses in access and benefit-sharing agreements. As described above, a database of existing access and benefit-sharing agreements was created under the Committee's oversight as a capacity building tool, a questionnaire on such agreements was prepared and circulated, and initial drafts of guide practices for access and benefit-sharing agreements were prepared. The database[28] has been updated with several new agreements, and has been increasingly used as a practical capacity building (non-normative) tool.

15. The latest draft on guide practices – 'Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing'[29] – was circulated for consideration at the Committee's seventh session. This document noted that the terms of access to genetic resources may include a requirement not to take out IP at all on derivative research, or an obligation to consult with the resource provider in the event of potential IP activity, and may structure ownership and management of any agreed resultant IP in a range of different ways, including co-ownership between access provider and resource user and different mechanisms for ensuring access to technology and other equitable benefits. These draft guidelines were developed according to the principles set out and discussed by the Committee since its second session:

> Principle 1: *The IP-related rights and obligations set out in [the Guide Contractual Practices] should recognize, promote and protect all forms of formal and informal human creativity and innovation, based on, or related to, the transferred genetic resources.*
>
> Principle 2: *The IP-related rights and obligations set out in [the Guide Contractual Practices] should take into account sectorial characteristics of genetic resources and genetic resource policy objectives and frameworks.*
>
> Principle 3: *The IP-related rights and obligations set out in [the Guide Contractual Practices] should ensure the full and effective participation of all relevant stakeholders and address process issues related to contract negotiation and the development of IP*

[24] Art. 15.4 CBD.
[25] See Items 1(j) in the catalogue of Monetary Benefits listed in Appendix II of the Bonn Guidelines.
[26] See item 2(q) of Appendix II, Bonn Guidelines.
[27] See Decision VI/24 C, Convention on Biological Diversity, para. 9.
[28] The database is available at http://www.wipo.int/tk/en/databases/contracts/index.html.
[29] See WIPO/GRTKF/IC/7/9.

clauses for access and benefit-sharing agreements, including in particular traditional knowledge holders where traditional knowledge is covered by the agreement.

Principle 4: *The IP-related rights and obligations set out in [the Guide Contractual Practices] should distinguish between different kinds of use of genetic resources, including commercial, non-commercial and customary uses.*

16. Additional principles put forward by Committee members included:

- the Guide Contractual Practices should be non-binding,[30] flexible[31] and simple;[32]
- the Committee's work on the Guide Contractual Practices should be without any prejudice to, and closely coordinated with, the work of the CBD and FAO;[33]
- the IP rights and obligations set out in the Guide Contractual Practices should reflect the requirements of Prior Informed Consent which may apply to genetic resources;[34]
- the Guide Contractual Practices should recognize the sovereign rights of Member States over their genetic resources;
- the Guide Contractual Practices should provide for terms on access to and transfer of technology as established in the CBD;[35] and
- the Guide Contractual Practices should foresee the possibility of a special tribunal established to adjudicate issues surrounding contracts for access to genetic resource and benefit-sharing.[36]

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[30] See Canada (WIPO/GRTKF/IC/2/16, para. 77), China (WIPO/GRTKF/IC/2/16, para. 82), Colombia (WIPO/GRTKF/IC/2/16, para. 58), European Community and its Member States (WIPO/GRTKF/IC/2/16, para. 75), Indonesia (WIPO/GRTKF/IC/2/16, para. 63), Japan (WIPO/GRTKF/IC/2/16, para. 76), New Zealand (WIPO/GRTKF/IC/2/16, para. 73), Peru (WIPO/GRTKF/IC/2/16, para. 69), Switzerland (WIPO/GRTKF/IC/2/16, para. 83), United States of America (WIPO/GRTKF/IC/2/16, para. 74), BIO (WIPO/GRTKF/IC/2/16, para. 92), ICC (WIPO/GRTKF/IC/2/16, para. 95), Chair (WIPO/GRTKF/IC/2/16, para. 54 and 96).

[31] See Canada (WIPO/GRTKF/IC/2/16, para.77), USA (WIPO/GRTKF/IC/2/16, para.74).

[32] See European Community and its Member States (WIPO/GRTKF/IC/2/16, para. 75), United States of America (WIPO/GRTKF/IC/2/16, para. 74).

[33] See Ecuador (WIPO/GRTKF/IC/2/16, para.55), European Community and its Member States (WIPO/GRTKF/IC/2/16, para.75), Morocco (WIPO/GRTKF/IC/2/16, para.79), Peru (WIPO/GRTKF/IC/2/16, para.69), Singapore (WIPO/GRTKF/IC/2/16, para.66), Switzerland (WIPO/GRTKF/IC/2/16, para.83), Turkey (WIPO/GRTKF/IC/2/16, para.67).

[34] See Brazil (WIPO/GRTKF/IC/1/13, para. 106), Ecuador (WIPO/GRTKF/IC/2/16, para. 55), Bolivia, Cuba, Dominican Republic, Ecuador, Panama, Nicaragua, Peru, and Venezuela (WIPO/GRTKF/IC/2/16, para. 56).

[35] See Algeria (WIPO/GRTKF/IC/2/16, para. 78), Bolivia, Cuba, Dominican Republic, Ecuador, Panama, Nicaragua, Peru, and Venezuela (WIPO/GRTKF/IC/2/16, para. 56), Venezuela (WIPO/GRTKF/IC/2/16, para. 57).

[36] See INADEV (WIPO/GRTKF/IC/2/16, para. 88).

Amendments proposed, comments made and questions posed at the fifteenth session (December 7 to 11, 2009)

Comments made and questions posed

The comments made and questions posed were proposed by Australia, Brazil, Indonesia, Nigeria, Peru, South Africa, Sweden, on behalf of the European Union, the United States of America, Venezuela (Bolivarian Republic of), and, as observers, by the Tulalip Tribes and the Tupaj Amaru.

General

Several delegations favored giving the third cluster increased attention.

Need for principles and objectives

A delegation said that numerous written submissions, oral statements and other positions had been offered with respect to the various proposals, but the objectives and principles for the protection of GR have not been yet created. If the Secretariat could help to create such a document, it would be very useful to have them all written down in a single document. Objectives and principles were very important because they define what to do and why. Once agreed, further work would be much easier.

Practical questions on protection of GR and ABS

It was asked by several delegations:

How was access to GR both *in situ* and *ex situ* treated?
What was a relationship between GR and TK and the invention?
What kind of evidence was required?
What was the compliance burden, penalties for non-compliance and effect on rights?
What level of benefit sharing had occurred as a consequence of these regimes if known?
What procedure for ABS to consider for this system? Requirements, benefits and use of benefits should be defined. It was difficult to understand how this is going to be protected and what are the requirements for this protection.
Why prioritize the third cluster before the others?
Would an patent application again be considered to determine whether the proof of PIC/mutually agreed terms are required?
Would the access contract no longer be necessary when the application was amended to eliminate claims related to a GR?

IP issues of ABS

A delegation raised the issue of collective ownership of GR and its associated TK. A contractual obligation could take care of the benefit sharing in the process.

PIC and ABS

Several delegations highlighted the need for further study of issues on development, a range of options for IP related aspects of PIC and access and benefit sharing, development of alternative proposals and developing guidelines and procedures and to link the work of the

Committee with the ongoing negotiations in the CBD even though that was not the mandate and task of the Committee. WIPO should provide its input through the WIPO Secretariat to the CBD.

Experiences in ABS

A delegation suggested, within the next three months or so, that the Secretariat should collect updated information related to the sharing of national experiences, experiences with contracts and what additional capacity building was required, and the other items identified in WIPO/GRTKF/IC/11/8(A), and provide the updated information to the next meeting of the Committee.

A delegation shared its experiences on the fair and equitable sharing of benefits. If there was a patent application involving GR, the national law required that a letter should be written in front of the application indicating where the origin of GR was and what the number was under the Genetic Resource Council. There was a Council under the Ministry of Environment, specifically dealing with genetic patrimony of Brazil. Provided TK associated with GR in the patent application was received from a tribe, the person who applied this patent should show this Council the contract agreed between him and the tribe first. This Council would take note of it without analyzing or subscribing it and give a number to the applicant. If the contract was found unfair or against the interests of a third party who had the same GR or TK, the general public attorney of Brazil who defends the interest of the people of Brazil or the third party could go legally against that contract until the contract was considered fair and equitable which was decided by the Council or a judge. There were definitely some other pros and cons. The granting of the patent could be reviewed at any time if it was proved that the number of the Council was fraud, there was no number or there was no contract or authorization of the benefit sharing, or if the third party proved that there was some problem in that contract.

A delegation had had its ABS regimes reviewed by WIPO. Australia had a national approach to ABS for GR which was operated at a State and a commonwealth level. Because Australia had a federal system, ABS regimes were operated at both levels and there were consistent guidelines and principles. PIC arrangements and the facilitation of mechanisms were incorporated to negotiate benefit-sharing directly with the indigenous communities.

In Peru's legislation there was a parallel decision on access and patent application. The State was the owner of GR and there was a contract between the applicant and the State to be concluded.

Proposal for guide to contractual practices and model IP clauses

A delegation proposed the preparation of draft principles for the development of guide contractual practices or model IP clauses (WIPO/GRTKF/IC/7/9). It advocated for instruments of a non-binding character such as guide practices and model intellectual property clauses and that the Committee should ensure coherence and mutual support with the work of CBD, FAO and WTO. There was an actual demand for developing model intellectual property clauses that could be fed into the CBD process.

A definition of GR was contained in the CBD and other international instruments had to be kept in mind. CBD recognized the close link between indigenous peoples and communities and their traditional systems based on GR and the need to share equitably the benefits derived

from the use of traditional knowledge, innovations and the relevant practices for the biological conservation and diversity of these resources. The purpose of these guidelines for contractual practice was to help parties to draft legislation or administrative measures or access clauses and involvement of the beneficiaries in the drafting of contracts. Indigenous peoples are firmly opposed to the inclusion of human GR in databases.

Link to other organizations

A delegation highlighted the importance of maintaining perspective of the work being carried out in CBD, WTO and other UN and regional organizations.

One observer drew attention to a study of the CBD, "Study on Compliance in Relation to the Customary Law of Indigenous and Local Communities, National Law, across Jurisdictions, and International Law", UNEP/CBD/WG/ABS/7INF 5. He quoted as follow: "Rights recognition is a precondition to contractual negotiations. All users will explicitly recognize and affirm that indigenous peoples have prior rights, including a right to self-determination within their territory. Indigenous decision-making processes will be incorporated into the negotiation of ABS arrangements, the contractual terms themselves and the dispute resolution processes arising from the contract. Indigenous peoples' representatives will be pre-certified as the appropriate representative body. Indigenous customary law will be given equal weight in dispute resolution processes. Free, prior and informed consent (FPIC) will form a substantive part of all ABS arrangements and incorporate Indigenous customary law. All ABS arrangements will serve as positive evidence that FPIC of indigenous peoples has been obtained. All ABS arrangements will provide for a process to withdraw FPIC." The document might be brought into the process as an INF document. When developing contractual approaches, there needed to be a way that indigenous peoples defined to deal with such situations where TK and GR were shared among multiple communities and for institutions to be developed to deal with those situations.

GENERAL COMMENTS

Comments made at the fifteenth session (December 7 to 11, 2009) and during the intersessional written commenting process

The comments made and questions posed were proposed by Australia, Canada, Sweden, on behalf of the European Union, Germany, Mexico, Senegal, on behalf of the African Group, Switzerland and the United States of America.

Several delegations stated that all three clusters should continue to be addressed. These three clusters would constitute a good basis for continuing this work.

A delegation said that a number of elements in the list of options could usefully be discussed in more detail in the first instance, which were (1) defensive protection of GR, (2) disclosure requirements in patent applications for information related to GR used in the claimed inventions, and (3) IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of GR.

A delegation proposed: (1) To elaborate a series of options on various aspects of intellectual property in this area, particularly focusing on PIC and the conditions to access benefits. A well structured and targeted list is needed in order to make appropriate decisions easier. (2) To elaborate further proposals to deal with the relationship between IP and GR. (3) Develop and elaborate guidelines and procedures to allow the Committee to deal effectively with aspects of IP, conditions of access and benefit-sharing.

Several delegations stated that the list of options should not be exhaustive. The existing options should be not mutually exclusive and could be complementary.

A delegation noted that future discussion might well be based on document WIPO/GRTKF/IC/11/8(a), however it should not be the only basis for future work. As stated by the European Union at the fourteenth session of the Committee, the discussions should be based on the entire work carried out by the Committee, not excluding any particular document or documents. Document WIPO/GRTKF/IC/14/7 contained a comprehensive list of other documents with possible relevance for future discussions. Just to pick one, document WIPO/GRTKF/IC/8/9 (updated by document WIPO/GRTKF/IC/13/8(B)) should also be taken into consideration since it provided general information on the Committee's activities relating to GR and IP. It considered that the Committee should continue primarily to explore substantive IP issues concerning the relationship between IP and GR as summarized in the three substantial clusters mentioned in document WIPO/GRTKF/IC/13/8 with the following priority: (1) IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of GR, of which results could certainly enrich the discussions in the other international fora; (2) the interface between the patent system and GR, particularly defensive protection; and (3) IP issues concerning disclosure requirements and alternative proposals for dealing with the relationship between IP and GR.

A delegation stated that all three substantive issues (GR, TK and TCEs) should be treated on an equal footing. Accordingly, all three issues should be dealt with at each session of the Committee and be allotted comparable attention and time.

[Annex II follows]

ANNEX II

IGC RESOURCES RELEVANT TO WORK ON IP AND GENETIC RESOURCES

Overview of issues

WIPO/GRTKF/IC/1/3	Initial outline of potential issues and activities, including those concerning genetic resources
WIPO/GRTKF/IC/8/9	Overview of the committee's work on genetic resources
WIPO/GRTKF/IC/11/8 (A)	Genetic Resources: List of Options
WIPO/GRTKF/IC/13/8 (B)	Genetic Resources: Factual Update of International Developments

Intellectual property clauses in mutually agreed terms for access and equitable benefit-sharing

WIPO/GRTKF/IC/2/3	Operational principles for IP clauses of mutually agreed terms concerning access to genetic resources and benefit-sharing discussed and supported in WIPO/GRTKF/IC/2/16 (paragraphs 52 to 110)
WIPO/GRTKF/IC/2/13	Information document on contractual agreements concerning access to genetic resources and benefit-sharing (submitted by the Delegation of the United States of America)
WIPO/GRTKF/IC/3/4 WIPO/GRTKF/IC/5/9 WIPO/GRTKF/IC/6/5 WIPO/GRTKF/IC/7/9	Progressive development of draft guidelines on IP aspects of mutually agreed terms for access and equitable benefit-sharing

Database of clauses relating intellectual property, access to genetic resources and benefit-sharing

WIPO/GRTKF/IC/2/12	Proposal for establishment of the database (submitted by the Delegation of Australia)
WIPO/GRTKF/IC/3/3	Call for comments on the draft structure of the database
WIPO/GRTKF/IC/3/4	Proposed structure of the database
WIPO/GRTKF/IC/3/Q.2	Questionnaire and stakeholder responses on current practices and clauses
WIPO/GRTKF/IC/5/9	Analysis of stakeholder responses to the questionnaire on current practices and clauses

WIPO/GRTKF/IC/6/5	Draft IP guidelines, based on responses to the questionnaire and subsequent analysis, concerning IP aspects of mutually agreed terms for access and benefit-sharing
WIPO/GRTKF/IC/7/9	Draft IP guidelines, based on responses to the questionnaire and subsequent analysis - reissued version of document WIPO/GRTKF/IC/6/5, as requested by the Committee
WIPO/GRTKF/IC/4/10	Report on establishment of the database
URL of database:	http://www.wipo.int/tk/en/databases/contracts/index.html

Disclosure requirements relating to genetic resources and TK

WIPO/GRTKF/IC/1/6	Information provided by Member States in response to a questionnaire on protection of biotechnological inventions, including questions on disclosure requirements
WIPO/GRTKF/IC/1/8	Directive 98/44/EC on the Legal Protection of Biotechnological Inventions and an Explanatory Note on Recital 27 of the Directive, which concerns the indication of the geographical origin of biotechnological inventions. Also contains a paper on the relationship between IP rights and biodiversity (submitted by the European Community and its Member States)
WIPO/GRTKF/IC/2/11	Report of the CBD Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing (submitted by the CBD Secretariat)
WIPO/GRTKF/IC/2/15	Survey of patents using biological material and mentioning of the country of origin of the material (submitted by the Delegation of Spain)
WIPO/GRTKF/IC/3/Q.3	Questionnaire and stakeholder responses on disclosure requirements
WIPO/GRTKF/IC/4/11	First report on technical study
WIPO/GRTKF/IC/5/10	Draft technical study
UNEP/CBD/COP/7/INF/17	Technical study on disclosure requirements related to Genetic resources and traditional knowledge. Submission by WIPO
WIPO/GRTKF/IC/6/9	Report on the transmission of the Technical Study to the CBD
WIPO Publication 786	Final text of the technical study
WIPO/GRTKF/IC/6/13	Decisions of the CBD-COP concerning access to genetic resources and benefit-sharing, including an invitation to WIPO to examine certain issues related to disclosure requirements (Submitted by the CBD Secretariat)

WIPO/GRTKF/IC/7/INF/5	Further Observations by Switzerland on its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications (Submitted by the Government of Switzerland)
WIPO/GRTKF/IC/7/10	Update on recent developments regarding disclosure requirements
WIPO/GRTKF/IC/8/11	Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications (submitted by the European Community and its Member States)
WIPO/GRTKF/IC/11/10	Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Proposals by Switzerland

Technical standards on databases and registries

WIPO/GRTKF/IC/4/14	Proposal of the Asian Group (adopted by the Committee)

Studies and texts on IP and equitable benefit-sharing

Publication 769	WIPO-UNEP Study on the Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge
WIPO/GRTKF/IC/1/9	Draft Guidelines on Access and Benefit Sharing Regarding the Utilization of Genetic Resources (submitted by the Government of Switzerland)
WIPO/GRTKF/IC/1/11	Decision 391 - Common Regime on Access to Genetic Resources, and Decision 486 - Common Intellectual Property Regime (submitted by the Member States of the Andean Community)
WIPO/GRTKF/IC/2/INF/2	International Treaty on Plant Genetic Resources for Food and Agriculture (submitted by the FAO)

Other defensive protection measures

WIPO/GRTKF/IC/5/6	Practical Mechanisms for the Defensive Protection of Traditional Knowledge and Genetic Resources within the Patent System (includes discussion of the Enola case referred by the FAO)
WIPO/GRTKF/IC/6/8	Further update on defensive protection measures relating to intellectual property, genetic resources and traditional knowledge
WIPO/GRTKF/IC/7/Q.5	Questionnaire on Recognition of TK and GR in the patent system

WIPO/GRTKF/IC/8/12	Patent System and the Fight against Biopiracy - The Peruvian Experience
WIPO/GRTKF/IC/9/10	Analysis of Potential Cases of Biopiracy (submitted by the Delegation of Peru)
WIPO/GRTKF/IC/9/13	The Patent System and Genetic Resources (submitted by the Delegation of Japan)
WIPO/GRTKF/IC/9/INF/6	First Collation of Responses to the Questionnaire on Recognition of Traditional Knowledge and Genetic Resources in the Patent System
WIPO/GRTKF/IC/10/INF/7	Response to the Questionnaire on Recognition of Traditional Knowledge and Genetic Resources in the Patent System
WIPO/GRTKF/IC/11/11	Additional Explanation from Japan Regarding the Document WIPO/GRTKF/IC/9/13 on the Patent System and Genetic Resources
WIPO/GRTKF/IC/11/13	Combating Biopiracy - The Peruvian Experience (submitted by the Delegation of Peru)

Further IGC resources

WIPO/GRTKF/IC/2/14	Declaration of Shamans on Intellectual Property and Protection of Traditional Knowledge and Genetic Resources (submitted by the Delegation of Brazil)
WIPO/GRTKF/IC/4/13	Access to Genetic Resources Regime of the United States National Parks (Submitted by the Delegation of the United States of America
WIPO/GRTKF/IC/5/13	Patents Referring to Lepidium Meyenii (maca): Responses of Peru
WIPO/GRTKF/IC/13/8(C)	Genetic Resources: Comments Received

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