

## **Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore**

### **Third Intersessional Working Group Geneva, February 28 to March 4, 2011**

#### **WIPO/GRTKF/IC/17/6: "GENETIC RESOURCES: REVISED LIST OF OPTIONS AND FACTUAL UPDATE"**

*Document prepared by the Secretariat*

1. At its seventeenth session, held from December 6 to 10, 2010, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') "requested the Secretariat to make available copies of all relevant documents for the third Intersessional Working Group taking place from February 28 to March 4, 2011 (IWG 3), including: [...] WIPO/GRTKF/IC/17/6 [...]."
2. Pursuant to the decision above, the Annex to this document comprises document WIPO/GRTKF/IC/17/6 ("Genetic Resources: Revised List of Options and Factual Update").
3. *The Intersessional Working Group is invited to take note of this document and the Annex to it.*

[Annex follows]





**WIPO/GRTKF/IC/17/6**  
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## **Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore**

### **Seventeenth Session**

**Geneva, December 6 to 10, 2010**

### **GENETIC RESOURCES: REVISED LIST OF OPTIONS AND FACTUAL UPDATE**

*Document prepared by the Secretariat*

#### **INTRODUCTION**

1. At its sixteenth session, held from May 3 to 7, 2010, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (‘the Committee’) decided that the Secretariat should “prepare and make available for the next session of the Committee as a working document, a further draft of document WIPO/GRTKF/IC/16/6. The further draft should include proposed amendments to and comments made by Committee participants during the sixteenth session of the Committee, as well as written comments on that document submitted to the Secretariat before July 31, 2010. The further draft of WIPO/GRTKF/IC/16/6 should also include a factual update on relevant developments in the CBD, FAO and the WTO”.<sup>1</sup>
2. The present working document is the revised version of working document WIPO/GRTKF/IC/16/6 as referred to in the decision quoted above. The document reflects the amendments proposed and the comments made during the sixteenth session of the Committee and the written comments received thereon during the intersessional written commenting process referred to in the decisions of the sixteenth session. Written comments were received from the following Member States and observers: Colombia,

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<sup>1</sup> Draft Report of the Sixteenth Session of the Committee (WIPO/GRTKF/IC/16/8 Prov. 2)

the Association des Étudiants et Chercheurs sur la Gouvernances des États Insulaires (AECG), jointly by the Biotechnology Industry Organization (BIO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Intellectual Property Owners Association (IPO) and the Southeast Indigenous People's Center (SIPC). The written comments, as received, are available online at [http://www.wipo.int/tk/en/consultations/draft\\_provisions/comments-3.html](http://www.wipo.int/tk/en/consultations/draft_provisions/comments-3.html)

3. The document includes in Annex II the factual update on relevant developments in respect of the Convention on Biological Diversity (CBD), Food and Agriculture Organization (FAO) and the World Trade Organization (WTO) requested. Further, it contains a list of resources of the Committee relevant to work on IP and genetic resources in Annex III.

#### *Preparation and structure of this document*

4. In the interest of keeping the present document as clear, concise and current as possible:
  - (a) in line with the decisions of the Committee taken at its sixteenth session, specific comments made by Member States at that session and during the intersessional written commenting process are reflected in Annex I. The comments include comments made and questions posed at the fifteenth and sixteenth sessions and during their respective intersessional written commenting processes, and, where possible, similar views have been grouped together. 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. Comments related generally to the entire document are reflected at the very end of the document;
  - (b) proposed insertions and additions in the revised list of options or in the general commentary are underlined, while words or phrases that a Member State has proposed be deleted or has questioned are put between square brackets. Each drafting proposal is accompanied by a footnote indicating the delegation that made the proposal, and, where applicable, delegations concurring or opposing it, as the case may be. Furthermore, when the delegation provided an explanation for the proposal, it is recorded in the footnote. Footnotes recording the comments and observations made by Member States and observers are indicated as such. The footnote numbering may differ in the various language versions of the present document. Proposed insertions and additions by observers are contained in the comments for consideration of Member States.

#### SUMMARY OF OPTIONS

5. Following is a brief summary of the options for continuing or further work identified by the Committee which are more fully set out in Annex I.
  - 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<sup>2</sup> which 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.

#### 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.

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<sup>2</sup> WIPO/GRTKF/IC/9/13

### 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, updated in information document WIPO/GRTKF/IC/7/INF/12<sup>3</sup>, 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.

6. *The 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 or merging certain options*

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<sup>3</sup> In its sixteenth session, the Committee requested the Secretariat to update the draft guidelines for contractual practices contained in document WIPO/GRTKF/IC/7/9 in an information document. The updated version is contained in document WIPO/GRTKF/IC/17/INF/12

[WIPO/GRTKF/IC/17/6, page 5]

*for further work by the Committee. In addition, the Committee is invited to take note of the factual update contained in Annex II.*

[Annexes follow]

## ANNEX I

### REVISED LIST OF OPTIONS

### CONTENTS

### INTRODUCTION

### LIST OF OPTIONS

#### Cluster A: *Defensive protection of genetic resources*

##### A. List of options on defensive protection of genetic resources

Option A.1: *Inventory of databases and information resources on GR*

Option A.2: *Information systems on GR for defensive protection*

Option A.3: *Guidelines or recommendations on defensive protection*

General Commentary on Cluster A

#### Specific Comments by Member States and Observers

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

##### B. List of options on disclosure requirements

Option B.1: *Mandatory disclosure*

Option B.2: *Further examination of issues relating to disclosure requirements*

Option B.3: *Guidelines or recommendations on disclosure*

Option B.4: *Alternative mechanisms*

General Commentary on Cluster B

#### Specific Comments by Member States and Observers

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

B. 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".<sup>1</sup>

## 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 the disclosure of the origin of genetic resources [disclosed genetic resources]<sup>2</sup>. The following options may be relevant:

#### 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]<sup>3</sup>, 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 the disclosure of the origin of genetic resources [disclosed genetic resources]<sup>4</sup>, 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 in cooperation with the national authorities responsible for access to genetic resources<sup>5, 6</sup>.*

- 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 the disclosure of the origin of genetic resources [disclosed*

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<sup>1</sup> See document WO/GA/38/20, para. 217

<sup>2</sup> Delegation of Colombia

<sup>3</sup> Delegation of Colombia

<sup>4</sup> Delegation of Colombia

<sup>5</sup> Delegation of Colombia

<sup>6</sup> This has already been successfully accomplished for periodicals concerning disclosed TK, as foreseen in WIPO/GRTKF/IC/2/6, paras. 41 to 45

*genetic resources*]<sup>7</sup> (additional financial resources would be required to implement this option).<sup>8</sup> A concrete proposal for such a system was presented at the ninth session which 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.”<sup>9</sup>

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 the disclosure of the origin of genetic resources [disclosed genetic resources]<sup>10</sup>. The Committee could discuss a possible development of recommendations or guidelines so that existing search and examination procedures for patent applications take into account the disclosure of the origin of genetic resources [disclosed genetic resources]<sup>11</sup>, 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.<sup>12</sup>*

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<sup>7</sup> Delegation of Colombia. It is necessary to determine exactly what type of information would be included in the databases and how that information would relate to the Clearing-House Mechanism under the CBD and to any Clearing-House Mechanism under the Protocol for ABS. Links or mechanisms would then need to be designed to ensure interoperability between the information systems on genetic resources and those on traditional knowledge and then in turn between those and the CHM of the CBD. Moreover, for the initiatives mentioned here it is important that there is international agreement on minimum standards for the documentation of information

<sup>8</sup> See WIPO/GRTKF/IC/3/6, para. 15

<sup>9</sup> See WIPO/GRTKF/IC/9/13, para. 40

<sup>10</sup> Delegation of Colombia: With regard to option A.3, it is necessary to understand the distinction drawn by the Committee between “recommendations” and “guidelines” and specifically whether or not the requirements are binding, whether they are purely guidelines or recommendations issued by the Committee and whether they entail legislative amendments and the acceptance of commitments under the PCT

<sup>11</sup> Delegation of Colombia

<sup>12</sup> 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<sup>13</sup> 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 Food and Agriculture Organization (FAO), have requested WIPO to cooperate in analyzing and addressing similar concerns in specific sectors.<sup>14</sup> 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 were submitted during the ninth session of the

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<sup>13</sup> See documents submitted by Peru (WIPO/GRTKF/IC/5/13, WIPO/GRTKF/IC/8/12, WIPO/GRTKF/IC/9/10)

<sup>14</sup> See FAO document CGRFA-9/02/REP

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”.<sup>15</sup>

#### *Comments made and questions posed*

##### Complementarity of options

The Delegation of Mexico believed that the options A.1, A.2 and A.3 could be complementary. It highlighted that under option A there was a need for greater information on each of the specific subjects mentioned. The information about policies, measures and experiences in the area of IP and GR would allow this Committee to go into much greater detail in the list of options. It wondered how this information would be incorporated in the information and documents prepared for the Committee.

The representative of BIO and IFPMA supported proposals made in A.1, A.2 and A.3 since they would provide immediate and pragmatic results to achieve the objective of preventing erroneous patenting relating to inventions based on genetic resources. These proposals would be complementary to one another and could be pursued in parallel. The representative of BIO and IFPMA proposed that the Committee should focus initially on the proposals made in A.1 and A.2, in order to establish the new informational mechanisms relevant to consideration of patent claims involving genetic resources. Once these information mechanisms were established, this would better inform the potential formulation of guidelines for search and examination aimed to ensure that patent examiners take better account of “disclosed genetic resources” from such sources. This process should build on the prior work of the Committee which resulted in the compilation of information sources documenting TK and the integration of those sources into the minimum documentation of the Patent Cooperation Treaty (PCT). Similarly, future work could also be integrated with the deliberations of the Meeting of International Authorities under the PCT.

##### Relation to other Committees at WIPO

The Delegation of El Salvador requested analysis and consideration of the issues relating to patents within the Standing Committee on Patents.

##### Nature of document

The Delegation of Colombia considered that the document on GR and IPRs should be binding.

##### Scope and objective of defensive protection

The Delegation of the Bolivarian Republic of Venezuela 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.

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

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<sup>15</sup> WIPO/GRTKF/IC/9/13, para. 34

The Delegation of Argentina 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.

The Delegation of New Zealand supported further work on defensive protection, including options A.1, A.2 and A.3 to avoid misappropriation of TK and GR through erroneously granted patents.

The representative of the AECG drew attention to the experiences of India and the United States of America as guidance. He considered the protection of genetic resources against misappropriation essential. The representative of the AECG opposed any manipulation of human genes.

#### Inventories and PCT Minimum Documentation

The Delegation of the Russian Federation supported in option A.1 conducting additional work to compile a list of existing periodicals, databases and other information resources documenting disclosed GR for a discussion of a possible recommendation whereby certain periodicals, databases and information resources would be examined by International Searching Authorities for their inclusion in the PCT minimum documentation.

The Delegation of Spain, on behalf of the European Union (EU) and its Member States, placed high priority to discussion of options in cluster A, in particular A.1, as an inventory of databases and information resources on GR would strengthen defensive protection of GR and facilitate the task of patent offices in identifying prior art. It welcomed the access agreement concerning the Indian digital library for TK that was signed with the EU, United States of America, the United Kingdom and Germany and supported further cooperation.

The representative of IPO emphasized that WIPO had demonstrated that defensive protection of TK could be improved by addition of periodicals and databases associated with TK to the minimum documentation list under the PCT. Similarly, periodicals and databases and other information resources exist that are commonly associated with disclosure of genetic resources, including, for example, research publications that focus on natural products research. As part of its ongoing work, the Committee should compile these information resources for inclusion in the PCT minimum documentation list. IPO also supported the proposal in document WIPO/GRTKF/IC/9/13 for a one-stop consolidated portal of databases on genetic resources, which portal would be easily accessible by patent examiners. Several databases that catalogue genetic resources were in existence, they were either not readily accessible to examiners, or the process of searching multiple databases increased the search burden and the possibility of overlooking relevant prior art. While some concerns had been raised about making such databases widely available via such a consolidated portal, these were issues that should be further discussed and resolved in the Committee, as IPO believed all stakeholders share a common interest in ensuring that patent applications are as thoroughly examined as possible.

## TK databases as a means of defensive protection

The Delegation of Japan reiterated its proposal of a database referring to option A.2 of document WIPO/GRTKF/IC/16/6 with the following explanations: At the ninth and eleventh sessions of the Committee, Japan had 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 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 by the initiative of WIPO, which was easily accessible from all IP Offices around the world, was also an aspiration. A step forward towards the realization of this database should be made by deepening such discussion at WIPO. With regard to the concerns on the database expressed by the Tulalip Tribes that the database could disclose information more than necessary, namely provide access to a third party, it pointed out that the proposal took into account such a particular case. It was proposed that an Internet Protocol address authentication system be introduced. Using this system, the database portal site would be made accessible only to IP Offices with specific IP addresses to prevent access by third parties.

The Delegation of Canada 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.

The Delegation of Mexico stated that under option A.1 the following questions should be considered:

- How to broaden the mechanisms of defensive protection that had already been tried in the area of TK to address the issue of GR?
- How and under what criteria to identify the sources of information that is already been disclosed on GR?
- What shall be understood by GR that have already been disclosed?
- In relation to the work of the Committee, a series of publications, databases and other sources of information on disclosed GR could be catalogued. What would be the content of a database on GR and what information would it contain?
- How to link the databases of GR with the databases of TK? Would the databases provide free access or would access be restricted?
- Would the databases only be accessible to IP offices?
- What information on GR would be useful for searches carried out by national patent offices?
- In the case of a centralized database, would WIPO centralize it or would it only administer it?

The Delegation of the Russian Federation supported the proposal in A.2 to extend the previously created online portal of registers and databases, in particular with the creation of a new system which “has to be a one-stop system where GR can be searched once and comprehensively”.

The representative of the Tulalip Tribes of Washington Governmental Affairs Department (the Tulalip Tribes) thanked Japan for its clarification and India for its interesting information on the TKDL which was similar to the model presented by the Tulalip Tribes in its first presentation at a side event at the second session of the IGC in 2002. Protected forms of databases with information on TK and GR could be useful. However, issues such as ownership, custodianship and citing of those databases also needed to be addressed.

The representative of SIPC emphasized that, if someone had signed an agreement not to disclose the origin of the GR and thus its relationship with an indigenous people/nation, they should not be able to register it as theirs.

#### Glossary and databases

The Delegation of Japan underscored that it would be useful drawing up a publicly available database and a 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.

The Delegation of Canada proposed the extension of already approved defensive protection mechanisms for TK to address GR, more specifically, including the review and greater recognition of further sources of already disclosed information about GR including databases and digital libraries. In this regard, it referred to the intervention made by India on the TKDL and its efficiency in recent months in preventing patents from being filed on traditional Indian medicine. A similar scheme for GR could be useful and should be further explored by the IWGs.

The Delegation of Argentina favored dressing a list of publications and databases on all sorts of sources of information on disclosed GR as provided by the inventory of databases and information on GR in option A.1. These databases and information systems on GR should be accompanied by the creation of capacity, training and technical assistance for developing countries having difficulties accessing or processing the information, based on their national requirements.

#### Patent examination guidelines

The Delegation of Argentina suggested as regards option A.3 to pay attention to the risk involved in the possibility that national patent applications which have relationship with GR be submitted to an international search. This is a topic which should be analyzed in detail to assess the implications for developing countries.

The Delegation of the Russian Federation approved the proposal on option A.3 for recommendations and guiding principles for search and examination procedures for patent applications to ensure that they better take into account disclosed GR.

The representative of IPO strongly believed that thorough examination of patent applications is a necessary precondition to obtaining valid, enforceable and meaningful patent protection. Therefore, IPO supported all efforts by the Committee to enhance patent examination and to make all existing prior art available to examiners. Each of options A.1, A.2 and A.3 offered different means for accomplishing these goals as an important step in ensuring defensive protection of genetic resources and thorough examination of patent applications.

Links to other fora

The representative of CONGAF raised the issue of climate change, biodiversity and TK. He stated that the UNFCCC was 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<sup>16</sup>.*

*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<sup>17</sup>.*

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<sup>16</sup> 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)

<sup>17</sup> 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 the disclosure of the origin of genetic resources [disclosed genetic resources]<sup>18</sup> 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).*

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<sup>18</sup> Delegation of Colombia: With regard to option A.3, it is necessary to understand the distinction drawn by the Committee between “recommendations” and “guidelines” and specifically whether or not the requirements are binding, whether they are purely guidelines or recommendations issued by the Committee and whether they entail legislative amendments and the acceptance of commitments under the PCT

## 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. Other multilateral fora, such as the CBD, have invited WIPO to examine certain aspects of this cluster of issues. In this respect, two studies on disclosure were submitted to the CBD as described below. 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 WIPO Standing Committee on the Law of Patents (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. Some aspects of the issue have been discussed at the negotiations of an international regime on access and benefit sharing at the CBD<sup>19</sup>.
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<sup>20</sup>, the other one explicitly enabling the Contracting Parties of the PCT to introduce such a requirement.<sup>21</sup> [A formal proposal<sup>22</sup> has already been tabled in the Committee for a mandatory disclosure requirement.<sup>23</sup>] 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.<sup>24</sup> 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

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<sup>19</sup> For further information see Annex II

<sup>20</sup> Document WIPO/GRTKF/IC/8/11, described further below

<sup>21</sup> A second submission has been made, by the Delegation of Switzerland, as document WIPO/GRTKF/IC/11/10

<sup>22</sup> [Document WIPO/GRTKF/IC/8/11, described further below.]

<sup>23</sup> [A second submission has been made, by the Delegation of Switzerland, as document WIPO/GRTKF/IC/11/10.]

<sup>24</sup> 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)

disclosure requirements and access and benefit-sharing regimes are not exhaustively addressed in the discussions on the 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.<sup>25</sup>

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?<sup>26</sup>
- 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?<sup>27</sup>
- are national patent offices the appropriate bodies to enforce licences or

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<sup>25</sup> Annex to document WIPO/GRTKF/IC/5/11, paras. 205 and 206

<sup>26</sup> This and the following six questions were included in the comments of the United States of America on WIPO/IP/GR/05/1

<sup>27</sup> This and the following question were included in comments of an observer, IFPMA, subsequent to the June 3, 2005 Ad Hoc Meeting

contract-based interests of providers of genetic resources or associated TK?<sup>28</sup>

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<sup>29</sup>.

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:
- “(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;

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<sup>28</sup> Annex to document WO/GA/32/8, para. 74

<sup>29</sup> Proposed by Switzerland

- (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.”<sup>30</sup>

#### *Drafting proposals of observers*

The representative of IFPMA and BIO suggested that this option be renamed “Further Examination of Issues Relating to Disclosure Requirements and Alternative Proposals for Dealing with the Relationship of Intellectual Property and Genetic Resources”. He highlighted that this formulation was used in prior documents and in document WIPO/GRTKF/11/8(a) and its reference to “work in the areas of the disclosure requirement and alternative proposals for dealing with the relationship between intellectual property and genetic resources” and provided a more accurate structure for a discussion. Until there was greater convergence among delegations, there must be a full discussion that does not prejudice any particular view or position.

#### *Comments made and questions posed*

##### Proposals on disclosure

The Delegation of the United States of America did not believe that the disclosure requirement would be useful and meet its needs.

The Delegation of the Russian Federation 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 the Delegation of Switzerland that work on disclosure requirements should be continued under the new mandate. It recalled the proposals which it had submitted on disclosure (WIPO/GRTKF/IC/11/10) in which the PCT was proposed to be amended. It felt encouraged by the considerable number of documents that had been submitted for this meeting of the Committee, in particular pointing out the Swiss submission in WIPO/GRTKF/IC/16/INF/14. It provided explanations with regard to the mandatory disclosure requirement introduced in Switzerland for patent applications in relation to GR and TK. In addition, Switzerland had submitted proposals to WIPO on the disclosure of the source of GR and TK in patent applications. The proposed amendment of the Regulations of the PCT would explicitly enable the national legislator to introduce such a disclosure requirement. To further strengthen the effectiveness of the proposed requirement, it proposed the establishment of an online-list of government agencies competent to receive information about patent applications containing a declaration of the source. Patent offices receiving such patent applications would inform the

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<sup>30</sup> Document WIPO/GRTKF/IC/8/11

competent government agency in a standardized letter about the respective declaration of the source. Moreover, Switzerland had proposed the establishment of an international gateway for TK. This gateway, to be administered by WIPO, would electronically link existing databases and thus facilitate access to their contents by patent authorities. It had submitted the mentioned proposals to WIPO in order to contribute in a constructive manner to the international discussions. It remained committed to discuss its proposals in the Committee, provided there was the political will to resolve the IP related issues arising in the context of access and benefit-sharing. Taking into account the introduction of disclosure requirements in various national patent laws, and bearing in mind the growing importance attached to GR and TK in recent years, time might now be ripe to address these issues at the international level. It noted that it would be crucial to keep in mind that the disclosure of source requirement would by itself not be sufficient to resolve all issues arising in the context of access and benefit sharing. It was only one element to be integrated in a more global approach that would fully address the issues related to access and benefit sharing. In the view of Switzerland, additional measures had to be taken outside of the patent system in other fields of law. Such measures needed to be in harmony with and mutually supportive of the relevant international instruments and fora, including the decisions adopted by the CBD. Switzerland wished to hear further reflections of parties on GRs and disclosure requirements.

The Delegations of Sweden and Spain, both on behalf of the European Union and its Member States,<sup>31</sup> as well as Switzerland, Peru, China and Colombia, respectively, proposed disclosure of origin or source of GR and associated TK in patent applications as a very useful tool in patent applications. The Delegation of China said that it was extremely rational and logical, and was absolutely irreplaceable. It believed that the source/origin disclosure requirements of GRs in patent applications worked in favor of not only the IP system but also in favor of a prior-informed-consent and benefit-sharing approach. The Delegation of Peru stated 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.

The Delegations of Sweden and Spain, both on behalf of the European Union and its Member States,<sup>32</sup> stated that 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. It reaffirmed its full support of this proposal as a potential part of a balanced final solution.

The representative of the International Seeds Federation (ISF) 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

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<sup>31</sup> These delegations spoke at the 15<sup>th</sup> and 16<sup>th</sup> sessions of the IGC, respectively

<sup>32</sup> These delegations spoke at the 15<sup>th</sup> and 16<sup>th</sup> sessions of the IGC, respectively

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.

The Delegation of the Russian Federation stated that there were a number of issues which should be clarified when examining the proposal made, some outlined by the Delegation of the Russian Federation at the Committee's tenth session. It was necessary to discuss the issues listed in paragraphs 7 to 11 of document WIPO/GRTKF/IC/16/6 (page 8 of the Annex to the document), in particular relating to the range and term of obligations linked to GR and TK in the country of origin and foreign jurisdictions, and also to what extent those obligations affected subsequent inventive activity and corresponding patent applications. Clarity was essential for patent or judicial authorities and also for patent applicants or patent owners so that they know when the obligation for disclosure entered into force, as well as when the mutual relation between original GR or TK was so remote and secondary that it could not bring such an obligation into effect.

The representative of IPO reiterated that the patent system was not the appropriate vehicle for monitoring access to GR or ensuring compliance with benefit-sharing. Proposed requirements for disclosure of information relating to GR in patent applications would not meet either of the desired goals of enabling patent examiners to fully examine patent applications or of ensuring access and benefit-sharing. As many members and stakeholders had noted in interventions and written comments, the justifications for requiring such patent disclosure were not supported by facts. For example, while some had asserted that disclosure could prevent so called "erroneously-granted" patents, little evidence had been provided to support this. In fact, some of the more notable examples of "erroneously-granted" patents had indeed included detailed information on source and/or origin; however, such information did nothing to enhance the ability of patent examiners to thoroughly examine patents. In contrast, as noted above, the proposals in Cluster A directly addressed this issue in a more practical and effective manner. It had also been argued that disclosure will assist in ensuring that benefits from commercialization of GR are shared with the provider country. However, as had been noted repeatedly, this proposal would do nothing to assist access and benefit-sharing for those GR that were commercialized but not patented. Furthermore, current proposals for mandatory patent disclosure include sanctions for non-compliance, such as not processing a patent application or revoking a patent that included incorrect or incomplete information. For these reasons, IPO believed that the justifications for mandatory patent disclosure found little or no practical support. Many stakeholders, including

IPO, had previously expressed concerns about the lack of clarity in current proposals relating to patent disclosure. It was not clear, despite proponents' attempts to clarify the proposals, what must be the relationship between the GR and the invention, or the extent of information sought about source or origin. Given these uncertainties, a more complete discussion of appropriate sanctions for incorrect or incomplete information was also required. For these reasons, IPO strongly urged Member States to thoroughly examine these questions before implementing any such new disclosure requirements. For the reasons set out above, IPO did not support proposals for patent disclosure of GR beyond those disclosures necessary to support patentability – including novelty, inventive step, and a sufficiently enabling description to allow practice of the invention.

The representative of the AECG stated that mandatory disclosure was necessary for practical reasons. Any invention that drew on TK as a source should indicate the origin. This would without a doubt breach the confidentiality agreement existing between the applicant and the real holders of the knowledge. In certain situations, there might be numerous origins of the genetic resources. From that point of view, it was a very constraining legal obligation. Where there would be no disclosure or elements missing in the file (such as origin), appropriate sanctions should be applied. Therefore, WIPO should work closely with the various instruments such as the CBD.

#### National experiences on disclosure

The Delegation of China informed the Committee that in China, the patent law had just been amended and entered into force. A new clause requiring the disclosure of the origin of the GR had been added. Thereafter two additions were made to the legislation clearly establishing a disclosure requirement. All of the details of that legislation could be found in document WIPO/GRTKF/IC/INF/27. In the future, China would continue to explore the experience gained in this area in order to find the best possible solutions to enable it to protect GRs through the IP system. The Delegation said it would like to have further exchanges and cooperation with other countries. It would specifically support the work of the Committee on the issue relating to the disclosure requirement, including exchanging information among countries and within regions, drafting principles and guidelines and further exploring the possibility of internationally binding rules in this area. It noted that although many international fora like CBD, FAO and TRIPS were presently looking at issues relating to the protection of GRs, they had a different approach and priorities. For that reason, Member States should make use of the advantages the Committee offered to do what they could in playing their unique role in promoting the protection of GRs.

Switzerland had introduced a mandatory disclosure requirement concerning GR and TK at the national level.<sup>33</sup>

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. 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 of Norway highlighted that all TK is included, not just TK connected to GR. A failure to meet such a

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<sup>33</sup> See WIPO/GRTKF/IC/16/INF/14

disclosure requirement does not affect the processing or the validity of a granted patent. After the patent is granted, a failure to fulfill the disclosure requirement is sanctioned outside the patent system\*.

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.

The Delegation of Spain, on behalf of the European Union and its Member States, informed that voluntary disclosure of origin of GR in patent applications had been put in place in some European Union Member States for the last 12 years and had become mandatory in some countries since then.

The Delegation of Norway stated that, according to the Norwegian Patents Act section 8(b) (3), if access to biological material had been provided pursuant to Article 12.2 and Article 12.3 of the International Treaty, it was sufficient for the applicant to submit with its patent application a copy of the standard material transfer agreement (MTA), as stipulated in Article 12.4 of the Treaty.

#### Sanctions on insufficient disclosure

The Delegation of Colombia 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.

#### Commercial and non-commercial/moral aspects of GR

The Delegation of Bolivia 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

The Delegation of Argentina suggested an international information system specific to GR as part of the state of art.

The Delegation of Australia 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.

The representative of BIO and IFPMA endorsed Option B.4 including the proposal of a "one-stop-shop" database from Japan, as noted in document under Option B.4. For reasons

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\* This correction to document WIPO/GRTKF/IC/17/6 was provided by the Delegation of Norway at the seventeenth session of the Committee

expressed at length by various delegations in previous sessions of the Committee, patent disclosure requirements would not accomplish the objectives of ensuring appropriate access and benefit-sharing nor the objective of preventing the erroneous grant of patents. Further, such requirements would undermine the incentives of the patent system and the generation of benefits that might be equitably shared, thereby running counter to the objectives of the CBD. Rather than continue the contentious debate over patent disclosure and risk not reaching agreement on a legal instrument for the protection of GR, more pragmatic solutions should be considered to resolve concerns over improper patenting and misuse of GR while preserving the role of the patent system in encouraging innovation. Nonetheless, it recognized the continued concerns expressed by a number of delegations regarding objectives sought by proponents of new patent disclosure requirements. To the extent that there was still a lack of consensus to move forward with “alternative mechanisms”, there might be a need to continue discussions as proposed under B.2. For the reasons expressed above, it did not view options B.1 or B.3 as a viable way forward. Proposals for new disclosure requirements in patent or other intellectual property applications would not achieve the objectives sought by proponents, but would likely have significant negative consequences on both the incentives of intellectual property for innovation and the generation of benefits from the utilization of GR that could be shared.

#### Disclosure and relation to CBD

It was highlighted by the Delegation of Canada 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. 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.

The Delegation of Brazil 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.

The representative of the International Chamber of Commerce (ICC) 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.

The representative of IPO emphasized that, because WIPO is the forum with relevant patent expertise, any issues relating to patentability, including the interface between the patent system and access and benefit-sharing, must be addressed in WIPO, rather than the CBD. Therefore, IPO supported continued discussion of these issues in the Committee, which discussions must include concrete examples and national experiences.

### Disclosure requirements and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

The Delegation of Canada proposed an examination of disclosure requirements and the FAO International Treaty.

The representative of the Food and Agriculture Organization (FAO) 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

The Delegation of Canada proposed an examination of the practical relevance of disclosure.

The representative of the Eurasian Patent Organization (EAPO) 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

The Delegation of Canada proposed an examination of disclosure and the public domain.

By the representative of the Tulalip Tribes it was added that some of the approaches assumed TK and associated GR existed in the public domain and there were still the issue of lack of prior informed consent 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

The Delegation of Canada proposed an examination of disclosure and rights of indigenous peoples.

The representative of Indigenous Peoples Council on Biocolonialism (IPCB) 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.

The representative of ICC supported the proposal made for an exchange of national experiences.

#### Further examination of issues relating to disclosure requirements

The Delegation of New Zealand saw option B.2 as the ideal way to address disclosure requirements. Further consideration of technical issues raised in previous studies would be useful and discussion of these points as part of option B.2 would allow the Committee to proceed with disclosure on firm grounds. It highlighted the Swiss, EU and Norwegian proposals on disclosure, and any proposal tabled by other Delegations, as an important part of this task. It suggested that the various proposals be considered closely by the IWG on GR issues.

The representative of the AECG questioned what benefits indigenous peoples could expect to derive from disclosure. It proposed to study further the issue of disclosure. The representative of the AECG considered that the points raised at the Committee's eighth session held in 2005 (see document WIPO/GRTKF/IC/8/11) formed the basis for defining a disclosure procedure. The Committee could then propose model clauses to be adapted by national laws.

*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 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<sup>34</sup>.*

*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 and updated in document WIPO/GRTKF/IC/17/INF/12<sup>35</sup>, 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<sup>36</sup>.*

<sup>34</sup> See WIPO/GRTKF/IC/2/12; WIPO/GRTKF/IC/2/16

<sup>35</sup> See WIPO/GRTKF/IC/5/9; WIPO/GRTKF/IC/6/5; WIPO/GRTKF/IC/7/9; WIPO/GRTKF/IC/17/INF/12

<sup>36</sup> See WIPO/GRTKF/IC/6/14 paras. 102, 103: A Global Public License approach was proposed in the sixth session of the Committee to avoid that, on the one hand, the new sui generis regimes for the protection of traditional knowledge resources could be implemented in a way that leads to barriers to scientific progress or innovation, while on the other hand acknowledging and sharing concerns that there is inadequate benefit sharing when products that rely upon traditional knowledge resources are commercialized. The approach was compared with the European Union biotechnology directive which, for genetically modified crops, provided for a mandatory cross license between patents and sui generis plant breeder rights, when both rights apply to the same product. The patent owner would have a mandatory compulsory license to the traditional knowledge resource could commercialize the invention, subject to making royalty payments to the traditional knowledge resource owner, and the traditional knowledge owner could also commercialize the patented invention, subject to making royalty payments to the patent owner, similar in structure to the dependent patent provisions in TRIPS Article 31. The approach would combine "the equitable reallocation of benefits without constraining open access to know-how". The very relevant experience of the modern free software movement, which sought to protect the work of a global community of programmers against misappropriation, leading to an important and effective legal strategy for protecting community knowledge was mentioned in the context of a Global Public License in the copyright area

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.

## 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,”<sup>37</sup> 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),<sup>38</sup> as well as in the sharing of non-monetary benefits.<sup>39</sup> 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*”.<sup>40</sup> 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<sup>41</sup> has been updated with several new agreements, and has been increasingly used as a practical capacity building (non-normative) tool.
15. The latest updated draft on guide practices – “Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing: Updated Version”<sup>42</sup> – will be circulated as an information document for consideration for the Committee’s seventeenth session. These draft guidelines have been 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 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.*

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<sup>37</sup> Art. 15.4 CBD

<sup>38</sup> See Items 1(j) in the catalogue of Monetary Benefits listed in Appendix II of the Bonn Guidelines

<sup>39</sup> See item 2(q) of Appendix II, Bonn Guidelines

<sup>40</sup> See Decision VI/24 C, Convention on Biological Diversity, para. 9

<sup>41</sup> The database is available at <http://www.wipo.int/tk/en/databases/contracts/index.html>

<sup>42</sup> See WIPO/GRTKF/IC/17/INF/12

16. Additional principles put forward by Committee members included:
- the Guide Contractual Practices should be non-binding,<sup>43</sup> flexible<sup>44</sup> and simple;<sup>45</sup>
  - 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;<sup>46</sup>
  - 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;<sup>47</sup>
  - 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;<sup>48</sup> 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.<sup>49</sup>

### *Comments made and questions posed*

#### General

The Delegation of Sweden, on behalf of the European Union, favored giving the third cluster increased attention.

The Delegation of Colombia emphasized, in relation to cluster C, that the Committee should work on this keeping in mind the sovereignty of respective countries over their GR to establish the preconditions for access. This meant as well establishing IP clauses in mutually agreed terms (MAT) under which access to these resources could be considered.

The Delegation of New Zealand fully supported the options set out in C.1, C.2 and C.3.

The Delegation of the Russian Federation supported the examination of options for extending the use, scope and accessibility of the online database relating to IP provisions in mutually-agreed terms for access and fair and equitable benefit sharing proposed in C.1. On C.2, it supported the

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<sup>43</sup> 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)

<sup>44</sup> See Canada (WIPO/GRTKF/IC/2/16, para.77), USA (WIPO/GRTKF/IC/2/16, para.74)

<sup>45</sup> 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)

<sup>46</sup> 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)

<sup>47</sup> 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)

<sup>48</sup> 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)

<sup>49</sup> See INADEV (WIPO/GRTKF/IC/2/16, para. 88)

examination of options for devising the draft guiding principles on agreed practices on the basis of additionally available information and included in the online database.

The representative of IPO highlighted that, because of the issues raised above with regard to patent disclosure proposals, issues of access and benefit-sharing are better addressed at the time of access via mutually agreed terms. This approach ensured that users and providers negotiate an agreed approach for access and benefit-sharing, which may include conditions for access, specified uses of the genetic resource in question, reporting requirements, and either monetary or non-monetary benefits. Furthermore, because such an approach would not be contingent on IP protection, it would ensure benefit-sharing for uses of GR that did not result in eventual commercialization and for products that were commercialized in the absence of patent protection. Finally, reliance on mutually agreed terms ensured that prior informed consent was indeed prior in time to the access. IPO had previously stated its support for the WIPO database of existing access and benefit-sharing agreements. The contracts currently available via the database provided excellent examples of both monetary and non-monetary benefit-sharing, while also safeguarding the other two goals of the CBD – conservation and sustainable use of GR. Certain contracts available via the WIPO database also provided examples of mutually agreed terms aimed at addressing trans-boundary GR, which was an all-too-real issue that has not been sufficiently addressed. Guidelines for negotiating mutually agreed terms could assist both users and providers to ensure their rights and interests were protected.

The representative of BIO and IFPMA endorsed further work on Option C.1 and applauded the decision of the 16<sup>th</sup> session to have the Secretariat produce an updated version of that document. As recognized in document WIPO/GRTKF/IC/7/9, the development, and subsequent implementation of the draft guidelines for contractual practices would play both a capacity building and normative role in addressing issues relating to the relationship of patents and GR. This work program, as suggested in this document, should proceed on three levels: Developing the operational principles, Developing model intellectual property clauses which might be considered for inclusion in contractual arrangements; and Revising and further elaborating the text of the draft guidelines for contractual practices. The guidelines, if agreed, would represent a landmark international instrument that would help both providers and recipients of GR when engaging in decisions relating to intellectual property matters that were relevant to ability to come to mutually agreed terms as envisioned in the CBD. It believed that the Option C.1 might also be helpful in creating an additional informational mechanism for providers and users of GR. In addition, Option C.3, might be helpful in a general sense, but the option should be defined differently. There was no discernible reason to single out or focus on concepts of “distributive innovation” or “open source” in respect of licensing practices in the field of GR. Instead, it would be helpful to develop case studies on licensing practices in the field of GR that have developed over the years. By considering the different practices in use in ABS agreements, as well as tools such as the BIO Model Material Transfer Agreement (MMTA), the Committee could perhaps develop “best practices” that could be incorporated into an outcome for the relevant organizations– e.g., within the context of the draft guidelines for contractual practices.

The representative of the AECG emphasized that under some national laws an author of an invention must be identified in order to benefit from protection under IP legislation. This would be the case in New Caledonia under French legislation. In order to preserve collective rights, contracts could be concluded combining several laws. The need for further discussion on the principles of prior informed consent and benefit-sharing was highlighted. It was asked whether this could lead to a proposed model contract. The representative awaited the outcome of the work being done by the Secretariat on the sharing of national experiences, as mentioned in document WIPO/GRTKF/IC/16/6 (Annex I, page 25).

The representative of the SIPC raised concerns regarding devoting resources of indigenous peoples/nations to develop a Guide on Contractual Practices regarding GR if this guide pretends that UN Member Nations have sovereignty over indigenous peoples, lands, culture, and resources, such as TK, TCE/EoF, or GR.

#### Practical questions on protection of GR and ABS

The Delegation of Australia asked:

- 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?

The Delegation of the United States of America indicated that 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. It also asked:

- Why prioritize the third cluster before the others?
- Would an patent application again be considered to determine whether the proof of prior informed consent (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

The Delegation of South Africa 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

The Delegations of Indonesia and Senegal each 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

The Delegation of the United States of America 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.

The Delegation of Brazil 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.

The Delegation of Australia 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.

The Delegation of Peru informed the Committee that 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 contractual practices and model IP clauses

The Delegation of Sweden, on behalf of the European Union and its Member States, 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.

The Delegation of Spain, on behalf of the European Union and its Member States, emphasized that document WIPO/GRTKF/IC/7/9 might also be relevant for further discussions on cluster C containing draft IP guidelines for access and equitable benefit-sharing and ensuring important coherence with the work carried out under the CBD.

The representative of Indian Movement "*Tupaj Amaru*" (Tupaj Amaru) reminded that 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.

The Delegation of New Zealand, on Option C.2, considered that further elaboration and finalisation of the draft guidelines for contractual practices was an essential task to ensure that indigenous and local communities could have the benefit of this resource. The Delegation favoured stakeholder consultations.

The Delegation of Mexico said the Secretariat should continue to perfect the draft guidelines on contractual practices featuring in Annex of document WIPO/GRTKF/IC/7/9. The Secretariat could also continue its study on the practices of granting of licenses in the area of GR.

#### Online database of IP clauses and MAT on access and benefit-sharing

The Delegation of Canada emphasized the extended use and accessibility of the online database on IP clauses in MAT for access and equitable benefit-sharing. It believed the IWGs should work on those options in order to enrich the discussion on GR at the seventeenth session of the Committee.

The Delegation of Spain, on behalf of the European Union and its Member States, recommended the Secretariat to update the online database of IP clauses and MAT on access and benefit-sharing under option C.1. These updates would form useful discussions for a draft on guidelines for contractual practices in ABS contracts referred to in option C.2. In continuing this work the EU and its Member States suggested that the Secretariat provide a glossary of terms to be defined and *inter alia* what GR actually are we referring to. This glossary would greatly facilitate interpretation of the scope of the options agreed.

The Delegation of New Zealand was increasingly receiving requests for assistance from Maori indigenous organisations for guidance on how to proceed in contractual arrangements with research or other organisations. It had referred certain organisations to the online database of IP clauses, and their feedback was that the database could be more user-friendly. The option C.1 suggesting expanding the online database would be very useful.

The Delegation of Mexico highlighted that it was very important to continue integrating the experience on licenses practices on GR. It proposed that the Secretariat continue to integrate and analyze the online databases for IP clauses featuring MAT upon conditions governing access and benefit sharing on GR.

#### Licensing practices

The Delegation of the Russian Federation supported the collection of information characterizing the practice of licensing as it related to GR.

#### Open sources and distributive innovation

The Delegation of New Zealand proposed case studies on licensing practices in the field of GR as suggested in option C.3, in particular those that extended the concepts of distributive innovation and open source. It attributed great merit to exploring alternative approaches, including those outside traditional IP.

#### Link to other organizations

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

The representative of the Tulalip Tribes 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.

The Delegation of the Islamic Republic of Iran highlighted the importance of GR in particular as regards food security. The Islamic Republic of Iran while facing challenges in gene banking and plant engineering had approved an act for plant variety registration, control and certification of seed and plant material. This Act which comprised 14 articles and 14 notes had been certified by the Islamic Consultative Assembly endorsed and certified by the Consul of the Guardians on July 2003. In addition, the Islamic Republic of Iran was preparing an Act on protection and utilization of agricultural GR as a national system. Therefore, equitable attention should be given to these three elements, TK, TCE and GR and particularly GR. Given the crucial role of GR in eradication of hunger and poverty alleviation for present and future generations, it urged the Committee to give equitable balance to these three elements. It reiterated the necessity of establishing international binding instruments and *sui generis* systems for the protection of GR, through strengthening the work of the IWGs and the collaboration with the FAO International Treaty and the CBD and also through encouraging involvement of all stakeholders in this international process. This would help alleviate poverty and hunger worldwide. Finally, the Committee should consider new IP issues that were arising in the work on plant genomic and its relation to ABS systems for food crops. Given the importance of these issues, they should be analyzed in collaboration with the CBD and the FAO International Treaty.

The Delegation of India highlighted that not all issues inherent to the nature of GR and associated TK could be subsumed in a single organization. Members should be aware of discussions taking place in the CBD and the WTO on these issues. The proposal before TRIPS called for an amendment to include a mandatory provision for disclosure, evidence of PIC and ABS. The proposal enjoyed support of over two thirds of WTO membership from both developed and developing countries including the European Union and Switzerland. Considering the discussion in the WTO and the CBD, norm setting in WIPO needed to be cognizant of developments in these fora. Concerning the proposal of Objectives and Principles presented by Australia at the present session, it stressed the need to examine in detail the proposal and would comment on it in another session of the Committee. It asserted that for constructive progress in the session, discussion should be on documents that had already been circulated by the Secretariat according to the agenda of the meeting. The earlier proposal of Switzerland making disclosure mandatory under the PCT had evolved and had been reflected in the proposal TN/C/W/52 in WTO calling for an amendment in the TRIPS agreement incorporating a disclosure requirement. The Delegation supported this proposal as useful to productive discussions on GR. In addition, the issue of mandatory PIC and access ABS needed to be addressed simultaneously.

The Delegation of Argentina suggested taking into account work carried out by the CBD hoping to reach the conclusion of an international system for ABS for the COP 10 to be held in October, 2010.

## GENERAL COMMENTS

### Need for principles and objectives

The Delegation of the United States of America 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 had 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 defined what to do and why. Once agreed, further work would be much easier.

The Delegation of Australia highlighted the importance of substantive discussions on GR and welcomed the significant number of submissions on this agenda item. It had developed some draft objectives and principles which had been informally discussed with a number of other Member States. This approach was supported by Canada, United States of America, Norway and New Zealand [and was issued as working document WIPO/GRTKF/IC/16/7]<sup>50</sup>. A number of those objectives and principles would draw on main areas to be considered by the Committee including other bodies of the Committee. The objectives and principles would be proposed for consideration and as a working document on GR for use by the Committee or its other bodies. The Delegation reiterated that they were without prejudice to any positions developed to promote discussion and debate. These objectives and underlying principles were to promote discussion and debate and as a good starting point for discussion accepting that not all members of the Committee had necessarily agreed with all those objectives and principles.

The Delegation of Spain, on behalf of the European Union and its Member States, Singapore and Switzerland, each welcomed the objectives and principles as an interesting proposal, providing very interesting data, and expressed the wish to look at it in detail in order to formulate a constructive approach to the debate.

The Delegation of New Zealand supported the objectives and principles suggested by Australia as a useful framework to guide ongoing work on GR. It also supported Canada's list of questions for referral to the IWGs.

The Delegation of the United States of America supported the creation of an objectives and principles document for GR and suggested that the second objective be rephrased to change "patents" to "intellectual property rights" so as to capture the objectives of the Committee - that no IP right would be granted on inventions that were not created by the inventor *i.e.* on GR or GR associated with TK that existed before an invention was made. It also suggested that the second principle, "patent" be changed to "IP" and proposed the addition of another objective that would prevent utility model applicants from receiving a monopoly on inventions that were not new. The Delegation stated it would be pleased to further discuss the proposal at the next session of the Committee and submit written comments in this regard. It endorsed the statement made by Colombia to the effect that the Committee had several options, and because these alternatives were not exclusive, the Committee should be able to continue its work without prejudging its approach. As such the Committee could explore a number of options without committing to the approaches articulated in the options. It noted that a single approach might not be effective to accomplish the Committee's goal of preventing misappropriation and misuse of GR. It said it would, however, be useful to focus the Committee's work on some of the core options. The Delegation also confirmed its endorsement of the list of issues proposed by Canada. The

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<sup>50</sup> This explanation was inserted by the Secretariat

Committee had heard that the work on GR was not as advanced as the work on TCEs and TK. However, after reviewing the work of the Committee, it was evident that considerable work had been done on GR. The Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing in document WIPO/GRTKF/IC/7/9 was one example. Since this document was not finalized, it was in agreement with the Delegations of Spain on behalf of the EU, New Zealand, Mexico, and the Russian Federation, that the said document would form a useful component of the Committee's further work on GR and requested that the document be updated. In this regard, as noted by the Delegation of New Zealand, the draft contractual provisions, although a useful database, could be more user-friendly and thus supported improvement and updating of the database. It encouraged the Secretariat to create an inventory of databases and information resources on GR. The Committee could contribute productively to the creation and development of such databases by communicating best practices, such as the one-click idea suggested by Japan so that such practices would prevent unauthorized addition of TK and GR in such databases. Also, the Committee could help communicate technical standards required to make the database more functional. This inventory could serve as a useful basis for answering the thoughtful questions posed by Mexico on databases. It appreciated the significant effort of many Member States in providing the informational documents for the Committee session on GR and said it would continue to study the information documents and would have a number of questions that it would like to ask in relation to the documents. The Delegation proposed an intersessional comment period wherein Member States could submit questions on these documents, and these questions could be answered.

The Delegation of Chile highlighted two objectives pointed out by Australia, which it thought were essential when looking at the relationship between GRs and IP, the proposed objectives number two and three. These proposed options would improve quality assessment ensuring that patents granted had an inventive level sufficient to warrant protection.

The representative of IFPMA and BIO welcomed the fact that the IGC discussions on GR appear to be reinvigorated as part of the "text-based" negotiations ongoing in the Committee on all three major topics. GR is a topic that is inseparable from TK and traditional cultural expressions and the WIPO IGC is uniquely situated to address these issues. In that light, they intended to continue their positive engagement in the IGC and its deliberations with respect to GR.

#### List of issues to discuss in the intersessional working group

The Delegation of Canada proposed the following list of issues on GRs which should be taken into consideration as a distillation from the most important and not entirely new issues in document WIPO/GRTKF/IC/16/6. It proposed to discuss under option 2, relating to disclosure requirements:

- National experiences on disclosure
- Alternative and complementary mechanisms
- Disclosure and relation to CBD
- Disclosure requirements and the FAO ITPGRFA
- Practical relevance of disclosure
- Disclosure and the public domain
- Disclosure and rights of indigenous peoples

A second issue would be drawn from option 6, the extension of already approved defensive protection mechanisms for TK to address GR, more specifically, including the review and greater recognition of further sources of already disclosed information about GR, including databases and digital libraries.

It emphasized under option 8, the expanded use and accessibility of the online database on IP clauses in MAT for access and equitable benefit-sharing.

### Three clusters

The Delegations of Sweden, on behalf of the European Union and its Member States, the United States of America, Canada, Mexico and Switzerland each stated that all three clusters should continue to be addressed. These three clusters would constitute a good basis for continuing this work.

The Delegation of Australia 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.

The Delegation of Senegal proposed: (1) To elaborate a series of options on various aspects of IP 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.

The Delegation of Germany stated that the list of options should not be exhaustive. The existing options should be not mutually exclusive and could be complementary. It 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.

The Delegation of Spain, on behalf of the European Union and its Member States, stated that the extensive information provided by countries on the different national and regional legislative measures applied to GR showed the high priority countries attached to this issue and it welcomed the revision and updating of the list of options provided in document WIPO/GRTKF/IC/16/6. Further consideration should be given to other documents prepared by the Committee as required and appropriate, for instance, document WIPO/GRTKF/IC/8/9 updated by document WIPO/GRTKF/IC/13/8(b) containing a historical inventory of all the activities taking place in this and other fora.

The Delegation of Sweden, on behalf of the European Union and its Member States, and the Delegation of New Zealand each 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.

The Delegation of Colombia emphasized in respect to the three major clusters of options with their subdivisions made available by the working document, that these would be alternative but not exclusive. As previously done, it should be worked harmoniously on the various options, without prejudging the work on other options.

The Delegation of Mexico highlighted that the options in cluster A, B and C presented in document WIPO/GRTKF/IC/16/6 complied with the mandate of this Committee to provide effective protection of GR including protection against misappropriation. These measures were not exclusive and could be complementary.

The Delegation of Brazil expressed the opinion that the working paper WIPO/GRTKF/IC/16/6 presented a list of options on how best to deal with the inter-connected issues of lawful access to GR and of benefit-sharing resulting from such access. With the vast majority of WTO member countries, Brazil favored an amendment to the TRIPS agreement including a provision on a compulsory disclosure of origin of GR. It was of the opinion that this would be the most effective way to address the issue of misappropriation of GR. Key discussions on benefit-sharing were taking place at the CBD. Given that membership of WIPO was not the same as those of both the WTO and the CBD, it would be important that future revisions of working paper WIPO/GRTKF/IC/16/6 include updates on relevant developments on negotiations being conducted outside WIPO. It noted with satisfaction that several countries had presented papers on their legal systems and frameworks on the interface between IP and GR. Brazil's submission was contained in document WIPO/GRTKF/IC/16/INF/9. Its national legislation clearly established compulsory disclosure of origin as a pre-requisite for the granting of patents. Patent applicants were requested to inform the number of the access permit given by the relevant national authority. Non-compliance may result in either administrative or criminal penalties. Similar legal provisions on mandatory disclosure of origin could be found in the submissions by the European Union, Norway and Switzerland, for instance. It said this would be a good contribution to further work by the Committee on GR. It requested the Secretariat to update the revised list of options taking into account all comments made during the present session of the Committee, preserving the current format which was concise and objective.

The Delegation of the Russian Federation supported the format of the Revised List of Options proposed in document WIPO/GRTKF/IC/16/6 to examine possible alternative approaches to further work, broken down into three clusters.

The Delegation of Angola, on behalf of the African Group, appreciated the work being undertaken by WIPO within the new mandate and the substantive contributions of the Secretariat in the area of GR related to IP. It acknowledged the negotiating process of the International Regime on ABS within the CBD and recalled the request from CBD to the Committee for support of the work that was being undertaken with regard to the ABS Regime. With the aim to harmonize and systematize the work already in progress in other international and national fora, taking into account the proposals already submitted by the African Group and other Member States, the African Group was of the view that there were key linkages amongst the various international processes that needed to be harmonized in order to enhance better understanding and mutual support amongst these processes. It said future work within the Committee on GR should take into account substantial developments within other international fora. The African group proposed various initiatives for consideration, which included: the development of a range of options for IP related aspects of ABS arrangements that could ensure benefit-sharing and the development of a structured menu of options to guide custodians of GR to facilitate their decision making process; the development of disclosure requirements and alternative proposals on the

relationship between IP and GR as requested by the CBD; the development of guidelines and procedures that would effectively deal with IP aspects of ABS arrangements; the support of demand and needs driven capacity building initiatives in Africa in the area of IP and GR, as well as the strengthening of existing linkages amongst WIPO, CBD, FAO and WTO to encourage active interaction and participation within their respective mandates and to foster synergistic implementation of related activities. In respect to the proposal of draft objectives and principles presented by Canada, the Delegation noted that additional time for review and translation of the proposal in all the six UN was necessary and indicated it would submit comments in another session.

The representative of the Tulalip Tribes highlighted several issues relating to options in document WIPO/GRTKF/IC/16/6. With regard to multiple access levels in PIC, the representative did not dispute that national sovereigns had the right to control access to GR of their non indigenous citizens and to determine access to GR of indigenous communities. This right was limited to restricting and denying access at the national level. However, he disputed the right of States to determine access to the GR of indigenous peoples whether on or off their territories. Indigenous peoples were the only ones who had the right to determine access to their own GR and associated TK, to set the terms of access based on MAT, and only with their free prior informed consent. Another issue was the conception of TK and GR and how they were treated. In the CBD negotiations on the international regime on ABS, indigenous peoples had consistently used the phrases, TK and associated GR, and GR and associated TK for two reasons. One being that in indigenous cosmo vision TK and GR could not be separated, but were inherently and inalienably connected. Another less recognized reason was the issue of embodied TK. TK had been applied to modify the course of evolution of many species, breeds, and plant varieties. He said regimes should acknowledge and address IPRs relating to ABS when these GR were accessed either on or off territories of indigenous peoples. The case of migratory species raised the question of rights of indigenous peoples to migratory GR. On defensive protection of TK, he took issue with the related cost of participation of indigenous peoples in the IP system. Currently the major cost of participation in Western IP was the public domain. IP rights were grants of rights with limited duration. Protection for patents for example required disclosure, and upon exhaustion of the patent rights the knowledge and production of the patent fell into the public domain. In this case, the cost of indigenous participation in the system required that TK protected by customary law since time immemorial would in a short time span fall into the public domain. The representative said defensive protection required some kind of disclosure, and many nations had public disclosure and freedom of information laws related to disclosed knowledge including TK. For example, if TK was incorporated into a patent, the public could have the right under statutory law to acquire that knowledge. This raised several cases that needed to be taken into consideration, like undisclosed TK, for instance due to spiritual, cultural norms and customary laws that prohibited disclosure. For this reason, a necessary distinction between *ex ante* remedies based on registration systems and *ex post* approaches to protection was proposed. With regard to the protection of TK revealed in prior art documentation, he highlighted the immense cost on indigenous people of defeating a patent by the disclosure of their TK, which would eventually fall into the public domain. This raised various issues relating to the protection of TK revealed in patents, and their status upon expiry of IPRs. He believed rights granted under customary laws were permanent. With regard to the protection of *ex situ* GR and associated TK in collections, and for migratory species, the question of whether protection should be limited to only GR acquired on territories of indigenous people needed to be addressed. The protection of GR of migratory species of indigenous communities acquired in *ex situ* collections also required consideration. He stated that the world was not static and, if IPRs assumed a static state, it would lead to difficulties, for example with climate change and its current impacts of species-rain-shifts. When species shifted their range, they carried their GR with them. This led to the question of determination of IPRs and rights to GR in cases where species had been moved off through anthropogenic climate change. Also to be addressed was the protection of

unsourced GR and associated TK, for example where the material was recognized as TK but with no documentation of the source. In response to comments made by the Delegation of Mexico on licenses, a discussion on licenses versus contracts would be necessary. He said in the CBD there had been proposals for a licensing model for access to GR. The representative further noted that the difference between a license and a contract was that a contract was an in person transaction, where one had control over the MAT and the forms of benefit-sharing. While a license was a pre-written contract which allowed the user to make the decision on compliance. Caution with licenses was required since in a traditional system where knowledge was shared or passed among the indigenous people, the person receiving the knowledge needed to be evaluated. This was a face to face interaction. However, the licensing system removed the elders and the TK holders from that process. Therefore, further discussion, probably in the IWGs, was required.

The representative of the Secretariat of the ITPGRFA of the FAO expressed its appreciation to the Committee and the Secretariat for the excellent work it had done on the three areas. The representative updated the Committee on recent developments under the ITPGRFA of the FAO of the UN and also on recent developments in FAOs Commission for GR food and agriculture. He reported that it had just completed the information technology systems which would operate the multilateral system of ABS and were currently being installed in Geneva at the UN Information and Computing Centre following extensive consultations which it conducted amongst contracting parties of the Treaty and Gene bank managers. Following a few initial and final tests this system was expected to go on-line within the next two months in the form of two main components. First the server would serve unique and permanent identifiers to users of the multilateral system so as to simplify, standardize and streamline their use of the SMTA. Second, global data store would receive the data on all the SMTAs entered into and would be accessed by the third party beneficiary of the SMTA for the resolution of any possible disputes which might arise from SMTAs. Part of this data store would be public and part of it would remain undisclosed under industry standard security protection. Disclosure of SMTA data in the public part of the data store was optional and the public data so far contained mostly data disclosed by the CGIAR. The public part of the Treaty and data store might very well interface with several options of the Committee's work on GR, identified in document WIPO/GRTKF/IC/16/6. In particular, under option A.1 the public part of the data store could be considered by international search authorities of the PCT for integration into the minimum documentation list under the PCT rules. Under option A.3 the public part of the database could in principle be integrated into the search and examination procedures in particular integration in international type searches again under the PCT. And finally the publicly disclosed SMTA data of the data store of the Treaty's multilateral system could in principle potentially be hyperlinked to the one-step database for GR defensive protection that had been proposed under option A.2. All of these options would have to be more closely examined but could in principle be considered by the treaty community. In response to statements by Canada in relation to Cluster B regarding disclosure requirements for GR in patent applications relating to material received from the multilateral system of ABS of the Treaty, he noted that it would be useful if any such disclosure requirements, were it to be considered or developed, take into account that when genetic material is received from the multilateral system of the Treaty, the multilateral system would be identified as the source of the genetic material utilized in the invention that is claimed in an application. He also reported on Resolution 6/2009 adopted by the Governing Body of the Treaty on the implementation of farmers rights under Article 9 of the Treaty. The implementation of Article 9 was subject to national legislation. He noted that this was relevant to the work of the Committee as farmers' rights included *inter alia* the protection of TK relevant to plant GR for food and agriculture. In the resolution, the governing body encouraged relevant organizations to submit views and experiences on the implementation of farmers' rights as set out in Article 9. In line with this and in the spirit of the provision of policy objective IX of document WIPO/GRTKF/IC/16/5, he invited the Secretariat to submit a progress report to possible consultations on farmers rights' on the work of the Committee to the governing

body of the Treaty which will meet for its 4<sup>th</sup> session in 2011 in Bali. This would allow the work under the Treaty to take into account as appropriate the work of the Committee.

The representative of IPCB noted that the interrelationship and consistency with international human rights laws regarding the rights of indigenous peoples to GR and associated TK was essential and needed to be examined in the current document, particularly those laws that required parties to recognize and protect Indigenous peoples' rights to the GR originating from their lands and territories, and their right to permanent sovereignty over natural resources. She said this body of law had been numerous times mentioned in written and oral interventions by indigenous peoples and should be reflected in the working documents as a substantive issue that required further examination. Many Indigenous peoples did not wish to use registers or databases for various reasons. There were concerns related to the security of the data in these databases, or concerns about the public release of knowledge they did not want to share, or that the registers might become a one stop shop for bio-prospectors. She said if this instrument was to serve the purpose of preventing misuse or misappropriation of GR, it must also contain options that recognized the rights of indigenous peoples to implement their own customary and codified systems of biological protection and management. It should not be assumed that all Indigenous people were interested in participating in the commercialization of their biological resources. In fact, the majority of indigenous people did not want to alienate their knowledge or biological resources through IP regime. The proposed instrument must also protect outside of the IP system giving due consideration to the integrity of the indigenous people.

The representative of CISA said biocolonialism still existed and property rights of indigenous peoples continued to be violated. Currently national laws were discriminatory and failed to protect indigenous people. GR were being extracted without the consent of indigenous peoples. Corporations were using institutions set up by States that had no right to consent to these patents. For example, the United States of America had never allowed the Alaska peoples or other internationally recognized people to give consent without employing the fully informed consent principle under the United Nations decolonization process. That particular principle was being violated. The permanent sovereignty over natural resources principles needed to be adhered to. It must be recognized that indigenous people could develop their own GR if they so desired without it being extracted from them and developed without their consent. This was in line with the right to development of indigenous peoples as provided for in Declaration and the existing obligations on national states. A working paper on on-going processes at the CBD and other negotiations outside WIPO should be presented. As the work of the Committee progressed there was need for a broader level of participation and uniformity in the consent process to text proposed by indigenous peoples.

The representative of Indigenous Peoples (Bethechilokono) of Saint Lucia Governing Council (BGC) welcomed the provisions in document WIPO/GRTKF/IC/16/6. He said GR, TK and TCEs went right across borders, were international in nature, and affected the lives of indigenous peoples all over the world.

The representative of the Comisión Jurídica para el Autodesarrollo de los Pueblos Originarios Andinos (CAPAJ) said comments made by representatives of the indigenous delegation led one to believe that the existing databases like the American, the European and the Japanese databases were sufficient to combat bio-piracy. He said efforts towards the establishment of an indigenous database that transcended national borders should be made, where indigenous communities would also be able to provide data and information on existing GR and TK in their territories. The database would be accessible to regional communities and peoples. This would in effect protect products of the indigenous peoples from bio-piracy. He said disclosure of origin of resources was highly necessary and should be done not only by countries but also by indigenous communities, in particular the cross border indigenous communities. For instance,

the community he represented was found in the Northern part of Chile, South Peru, the East of the Plurinational State of Bolivia and the North of Argentina. These were cross border peoples recognized as such by Article 32 of the Declaration on the Rights of Indigenous Peoples and Article 36 of the ILO Convention (No. 169) concerning Indigenous and Tribal Peoples in Independent Countries.

The representative of the Eurasian Patent Organization said that given that the rules governing access to GR and TK were intended to serve as an effective means of protection from misappropriation and misuse, he considered the new requirements for disclosure of an invention relating to GR or TK, namely compulsory reference to the country and/or other source of origin in patent application materials as being superfluous and would not help to achieve the stated aims. Patent laws in many countries in the world contained exhaustive rules for the compulsory disclosure of an invention in a patent application such that it could be carried out by a person skilled in the art. These rules undoubtedly also extended to inventions which related to the field of biology and biotechnology, in particular to the product containing or consisting of biological material or to the means of producing biological material, acting on it or using it. It was therefore appropriate to make amendments to existing rules regarding the examination of patent applications, *i.e.* to include therein the requirement for a special reference to the origin of TK or GR, since such a reference should in principle be given for all applications concerning biological material. Document WIPO/GRTKF/IC/16/6 was a good basis for further work and the Delegation considered that the strengthening of protection of TK and GR from the unlawful granting of patents and the devising of an agreed system for the fair and equitable joint sharing of benefits, resulting from the use of TK or GR, should be prioritized. He thanked the Secretariat for the highly professional work it had done and the materials prepared for the sixteenth session of the Committee.

The representative of IPO believed that certain options in each of Clusters A, B and C merited further discussion in the Committee, particularly those options relating to enhanced patent examination and improved tools for negotiation of mutually agreed terms. While IPO did not believe that proposals for patent disclosure will assist the objectives sought, such issues were appropriate for continued discussion, with concrete examples, in the IGC. It supported the ongoing work of the Committee on these matters, but without prejudging any outcome. It urged members to ensure that GR issues were allotted equal time to other issues currently being discussed in the IGC, as a means of ensuring complete discussion of all of these options.

The representative of IFPMA and BIO stated that, when considering the options presented in document 16/6, the IGC should seek to build on progress achieved to date, through the establishment of pragmatic, concrete outcomes in this area. This approach should facilitate discussion and resolution of the matters before the Committee. Further, to the extent that the proposals presented were not prejudicial to the views of delegations on other proposals, it envisioned that the Committee could begin more detailed work on one or more of the proposals, where there were consensus, and leave consideration of more contentious proposals for a later time. It agreed that the categorization of the three "clusters" set out in document 16/6 was a helpful structure for deliberations by the Committee.

[Annex II follows]

## ANNEX II

## FACTUAL UPDATE ON RELEVANT ACTIVITIES

## INTRODUCTION

1. At its sixteenth session, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“the Committee”) requested the preparation of a factual update of international developments relevant to the genetic resources agenda item. This Annex II provides the required update. According to the decision taken in the sixteenth session of the Committee, the update is provided on relevant developments in respect of the Convention on Biological Diversity (CBD), the Food and Agriculture Organization (FAO) and the World Trade Organization (WTO).
2. This Annex updates and complements the information on international developments previously provided to the Committee in documents WIPO/GRTKF/IC/8/9, WIPO/GRTKF/IC/11/8(b), WIPO/GRTKF/IC/12/8(b) and WIPO/GRTKF/IC/13/8(b). Accordingly, it covers relevant international developments that occurred after the thirteenth session of the Committee in October 2008. In preparing this Annex, the WIPO Secretariat made its best endeavors to gather and record relevant information as accurately as possible. The Secretariats of the various other Organizations involved could provide additional information should the Committee so wish.

## I. CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

3. COP 9 consolidated its work on a range of issues which may be of relevance to the IP system, especially the protection of TK and the interplay between regulation of genetic resources and the patent system. A comprehensive work program was set for the next two years, with the goals of adopting an international regime on access and benefit sharing (ABS) (referring both to genetic resources and TK), and carrying out further work on TK questions concerning Article 8(j) and related articles of the CBD. COP 9 adopted a roadmap for the negotiation of an international ABS regime, requiring that before the 2010 deadline for completion of negotiations, there should be three meetings of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing and three expert group meetings covering the following sets of issues:
  - (i) compliance;
  - (ii) concepts, terms, working definitions and sectoral approaches; and
  - (iii) TK associated with genetic resources.

The meeting of the group of legal and technical experts on concepts, terms, working definitions and sectoral approaches took place in Windhoek, Namibia, from December 2 to 5, 2008. The meeting of the group of legal and technical experts on compliance took place in Tokyo, Japan, from January 27 to 30, 2009. Furthermore, the meeting of the group of Technical and Legal Experts on Traditional Knowledge associated with Genetic Resources took place in Hyderabad, India, from June 16 to 19, 2009.

Seventh meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (WG ABS 7), Paris, France, April 2 to 8, 2009

4. At WG ABS 7, delegates addressed the objective and scope of the international regime, as well as the components of the regime dealing with access to genetic resources, benefit-sharing, and compliance. The purpose of WG ABS 7 was the negotiation of operational text on these issues.<sup>1</sup>

Sixth meeting of the Ad hoc Open-ended Working Group on Article 8 (j) and Related Provisions (WG-8(j) 6) in Montreal, Canada, November 2 to 6, 2009

5. At WG-8(j) 6, the Working Group expressed detailed views on the international regime on ABS concerning Article 8 (j) of the CBD, for transmission to WG ABS 8. According to Decision IX/12, COP 9 requested this working group to continue to collaborate and contribute to the fulfillment of the mandate of the working group on ABS, by providing detailed and focused views on the outcome of the technical expert groups on traditional knowledge associated with genetic resources and compliance. The purpose of WG 8(j) 6 was to deal with mechanisms to promote the effective participation of indigenous and local communities in matters related to the objectives of Article 8 (j) and related provisions of the CBD, the development of elements of *sui generis* systems for the protection of TK, innovations and practices, elements of a code of ethical conduct to ensure respect for the cultural and intellectual heritage of indigenous and local communities and the multi-year programme of work on the implementation of Article 8 (j) and related provisions of the CDB.<sup>2</sup>

WG ABS 8, Montreal, Canada, November 9 to 15, 2009

6. The purpose of WG ABS 8 was the negotiation of operational text on nature, TK associated with genetic resources, capacity-building, compliance, fair and equitable sharing, access. For the first time in this process, the Parties agreed on a single negotiating text, to focus their work at the ninth meeting of the Working Group.<sup>3</sup>

WG ABS 9, Cali, Colombia, March 23 to 28, 2010

7. At WG ABS 9, a draft protocol was tabled by the Co-Chairs and accepted by Parties as a basis for further negotiations. However, since it was not possible to finalize the negotiations on the text at this session, the Working Group decided to suspend and resume WG ABS 9 later. The Working Group agreed to forward the revised draft protocol to the resumed session, with the understanding that the draft was not negotiated and was

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<sup>1</sup> Further information available at: <http://www.cbd.int/wgabs7/>; press release of WG ABS on April 1, 2009, available at: <http://www.cbd.int/doc/press/2009/pr-2009-04-01-abs-en.pdf>; for additional information see document UNEP/CBD/WG-ABS/8/8, available at: <http://www.cbd.int/doc/?meeting=abswg-07>

<sup>2</sup> See document UNEP/CBD/COP/10/2, available at: <https://www.cbd.int/doc/meetings/cop/cop-10/official/cop-10-02-en.pdf>

<sup>3</sup> Further information available at: <http://www.cbd.int/wgabs8/>; press release of WG ABS on November 16, 2010, available at: <http://www.cbd.int/doc/press/2009/pr-2009-11-16-abs-en.pdf>; for additional information see document UNEP/CBD/WG-ABS/8/8, available at: <http://www.cbd.int/wgabs8/doc/>

without prejudice to the rights of parties to make further amendments and additions to the text.<sup>4</sup>

Resumed WG ABS 9 in Montreal, Canada, July 10 to 16, 2010

8. Resumed WG ABS 9 allowed Parties to make significant progress in the negotiation of the draft Protocol, but the Working Group was unable to finalize the text at this session. The Working Group, therefore, decided to continue negotiations in an Interregional Negotiating Group (ING) meeting in September 2010 and that the ninth meeting of the Working Group would resume on October 16, 2010 to endorse the work of the ING and report to COP 10 in October 2010.<sup>5</sup>

COP 10, Nagoya, Japan, October 18 to 29, 2010

9. Pursuant to decision IX/35, the tenth meeting of the COP 10 will be held in Nagoya, Aichi Prefecture, Japan, from October 18 to 29, 2010. COP 10 will include a high-level ministerial segment organized by the host country in consultation with the Secretariat and the Bureau. The high-level segment will take place from October 27 to 29, 2010.<sup>6</sup>

II. FOOD AND AGRICULTURE ORGANIZATION (FAO)

Third Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), Tunis, Tunisia, June 1 to 5, 2009

10. The third session of the Governing Body of the International Treaty convened from June 1 to 5, 2009, in Tunis, Tunisia. Delegates agreed to a set of resolutions for implementation of the funding strategy, including a target of US\$116 million for the Benefit-sharing Fund between July 2009 and December 2014; a resolution on implementation of the Multilateral System (MLS) and the Standard Material Transfer Agreement (SMTA), including setting up an intersessional technical advisory committee on MLS and SMTA implementation issues; a resolution on farmers' rights; and the adoption of procedures for the Third Party Beneficiary for dispute settlement under the SMTA. The Contracting Parties also adopted the work programme and budget for the biennium, agreed on the urgent need to finalize the outstanding financial rules at the Fourth session of the Governing Body and established an intersessional working group to finalize the procedures and operational mechanisms to promote compliance and address issues of non-compliance.<sup>7</sup>
11. Following Resolution 2/2009 "Procedures and Operational Mechanisms to Promote Compliance and Address Issues of Non-Compliance", the Governing Body decided to establish and convene an Ad Hoc Working Group on Compliance to negotiate and

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<sup>4</sup> Further information available at: <http://www.cbd.int/wgabs9/>; press release of WG ABS on March 28, 2010, available at: <http://www.cbd.int/doc/press/2010/pr-2010-03-28-abs9-en.pdf>; for additional information see document UNEP/CBD/WG-ABS/9/3 including the text of the draft protocol, available at: <http://www.cbd.int/wgabs9/doc/>

<sup>5</sup> Further information available at: <http://www.cbd.int/wgabs9-resumed/>; press release of July 16, 2010, available at: <http://www.cbd.int/doc/press/2010/pr-2010-07-16-abs9-en.pdf>; for additional information see document UNEP/CBD/COP/10/5/ADD4 including the revised version of the draft protocol, available at: <http://www.cbd.int/wgabs9-resumed/doc/>

<sup>6</sup> Further information available at: <http://www.cbd.int/cop10/>

<sup>7</sup> See document IT/GB-3/09/Report, available at: [http://www.planttreaty.org/meetings/gb3\\_en.htm](http://www.planttreaty.org/meetings/gb3_en.htm)

finalize the procedures and operational mechanisms to promote compliance and address issues of non-compliance, with a view to their approval at the Fourth Session of the Governing Body. The Ad Hoc Working Group on Compliance is to carry out its mandate on the basis of the draft text contained in the Annex to Resolution 2/2009. In accordance with the request of the Governing Body, Contracting Parties and observers were invited to make submissions on the text for consideration by the Ad Hoc Working Group on Compliance.<sup>8</sup>

The technical advisory committee on MLS and SMTA met in January and September 2010. The Ad Hoc Working Group on Compliance held its first meeting in February 2010. Both the committees made substantial progress in fulfilling their respective mandates.

On May 19, 2010, the Secretary of the International Treaty invited Contracting Parties and other relevant organizations to submit views and experiences on the implementation of Farmers' Rights, as set out in Article 9 of the International Treaty by 31 July, 2010.<sup>9</sup>

Twelfth Regular Session of the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA), Rome, Italy, October 19 to 23, 2009

12. The Commission held its thirteenth regular session from October 19 to 23, 2009 in Rome, Italy. Delegates considered, *inter alia*, the issue of access and benefit-sharing for genetic resources for food and agriculture, including a set of comprehensive studies dealing with the use and exchange of plant, animal, forest, aquatic, microbial and invertebrate genetic resources relevant to food and agriculture. The Commission endorsed the "Second Report on the State of the World's Plant Genetic Resources for Food and Agriculture" identifying the most significant changes since 1996 and requested FAO to start updating the rolling Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture.<sup>10</sup> The Commission also considered and adopted a strategic plan for the implementation of its 10-year Multi-Year Programme of Work. As a follow-up to the International Technical Conference on Animal Genetic Resources for Food and Agriculture, held in 2007 in Interlaken, Switzerland, the Commission also adopted a funding strategic for the implementation of FAO's Global Plan of Action for Animal Genetic Resources.

Thirty-sixth Session of the Conference of the FAO, Rome, Italy, November 18 to 23, 2009

13. The FAO Conference adopted Resolution 18/2009 previously agreed prepared by the Commission at its Twelfth Regular Session. The resolution stresses the special nature of genetic resources for food and agriculture in the context of the negotiations of the International Regime on Access and Benefit-sharing of the CBD. The Conference also welcomed the outcomes of the Commission Twelfth Regular Session, including the Second Report on the State of the World's Plant Genetic Resources for Food and Agriculture, the Strategic Plan 2010-2017 for the implementation of the Multi-Year Programme of Work, and the Funding Strategy for the implementation of the Global Plan of Action for Animal Genetic Resources. In view of preparations of the State of the

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<sup>8</sup> See document NCP GB4 Compliance, notification of July 31, 2009, available at:

[ftp://ftp.fao.org/ag/agg/planttreaty/gb3/NCP\\_GB4\\_compliance\\_09%2007%2031\\_EN.pdf](ftp://ftp.fao.org/ag/agg/planttreaty/gb3/NCP_GB4_compliance_09%2007%2031_EN.pdf)

<sup>9</sup> See notification of May 19, 2010, available at: [http://www.planttreaty.org/noti\\_en.htm](http://www.planttreaty.org/noti_en.htm)

<sup>10</sup> See document CGRFA-12/09/Report, available at: <ftp://ftp.fao.org/docrep/fao/meeting/017/k6536e.pdf>

World's Forest Genetic Resources, the Commission established the Intergovernmental Technical Working Group on Forest Genetic Resources.<sup>11</sup>

Fourth Session of the Governing Body of the ITPGRFA, Bali, Indonesia, March 14 to 18, 2011

14. The fourth session of the Governing Body of the International Treaty will take place from March 14 to 18, 2011, in Bali, Indonesia<sup>12</sup>.

Thirteenth Regular Session of the CGRFA, Rome, Italy, July 18 to 22, 2011

15. The thirteenth regular session of the Commission on Genetic Resources for Food and Agriculture will take place from July 18 to 22, 2011, in Rome, Italy.

III. WORLD TRADE ORGANIZATION (WTO) TRIPS COUNCIL

*The TRIPS Council*

16. In 2009, the TRIPS Council continued its discussion of three agenda items, i.e. review of the provisions of Article 27.3(b), relationship between the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the CBD, and protection of TK, pursuant to the mandate given in paragraph 19 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1) and paragraph 44 of the Hong Kong Ministerial Declaration (WT/MIN(05)/DEC). In these discussions, some countries referred to a communication from Albania, Brazil, China, Colombia, Croatia, Ecuador, the European Communities, Georgia, Iceland, India, Indonesia, the Kyrgyz Republic, Liechtenstein, the Former Yugoslav Republic of Macedonia, Moldova, Pakistan, Peru, Sri Lanka, Switzerland, Thailand, Turkey, the ACP Group and the African Group to the Trade Negotiations Committee on "Draft Modalities for TRIPS Related Issues" circulated in July 2008 (document TN/C/W/52). No new submissions were made to the Council in 2009.<sup>13</sup>
17. In 2010, the TRIPS Council continued the discussion of the three agenda items referred to. At its meeting in March 2010, Bolivia introduced a new proposal (IP/C/W/545) for prohibiting patenting of all life forms and ensuring protection of plant varieties and traditional knowledge in the context of the review of Article 27.3(b) and paragraph 12 of the Doha Ministerial Declaration. The Bolivian proposal was discussed further in the June 2010 session of the TRIPS Council.<sup>14</sup>

*The Director-General Consultations*

18. Since early 2009, the Director-General (DG) of the WTO has re-activated and chaired technical consultations on the TRIPS/CBD issue in his capacity as DG according to

<sup>11</sup> See document C.2009/REP, available at: <http://www.fao.org/docrep/meeting/018/k6821E02.pdf>

<sup>12</sup> Further information available at: [http://www.planttreaty.org/gbnex\\_en.htm](http://www.planttreaty.org/gbnex_en.htm)

<sup>13</sup> See document IP/C/52, Annual Report (2009) of the Council for TRIPS; document IP/C/M/58, Minutes of the Meetings of the Council for TRIPS on March 2, 2009; document IP/C/M/59, Minutes of the Meetings of the Council for TRIPS from June 8 to 9, 2009; document IP/C/M/60, Minutes of the Meetings of the Council for TRIPS from October 27 to 28 and on November 6, 2009, available at: [http://www.wto.org/english/docs\\_e/docs\\_e.htm](http://www.wto.org/english/docs_e/docs_e.htm)

<sup>14</sup> See document IP/C/M/62 and IP/C/M/63 which will be issued soon

paragraph 39 of the Hong Kong Ministerial Declaration. So far, he has held seven consultations with key delegations and has informed the full membership of the content of the consultations in two open-ended meetings.

19. The first round of the consultations from March to June 2009 reviewed the practical implications and comparative merits of the proposals of disclosure requirements, database systems and national-based approaches, and how each of these proposals could help achieve the widely shared objectives of avoidance of erroneous patents, securing compliance with national benefit-sharing regimes, and ensuring patent offices have available the information needed to make proper decisions on patent grant.<sup>15</sup>
20. The second round of the consultations were held from July 2009 to March 2010. The consultations were focused on four clusters of issues, including the legal character of misappropriation, measures, other than the disclosure requirements, to address misappropriation and benefit sharing, the legal scope of the national based approach and administrative costs and burdens, and legal certainty, of a mandatory disclosure requirement.<sup>16</sup>

[Annex III follows]

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<sup>15</sup> Lamy briefs members on his intellectual property, available at [http://www.wto.org/english/news\\_e/news09\\_e/trip\\_27jul09\\_e.htm](http://www.wto.org/english/news_e/news09_e/trip_27jul09_e.htm)

<sup>16</sup> Intellectual property differences 'better illuminated' — Lamy reports, available at [http://www.wto.org/english/news\\_e/news10\\_e/trip\\_12mar10\\_e.htm](http://www.wto.org/english/news_e/news10_e/trip_12mar10_e.htm)

ANNEX III

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
WIPO/GRTKF/IC/17/6	Genetic Resources: Revised List of Options
WIPO/GRTKF/IC/16/7	DRAFT Genetic Resources Objectives and Principles (submitted by the Delegation of Australia, Canada, New Zealand, Norway and the United States America)
WIPO/GRTKF/IC/17/INF/13	Glossary on key terms related to IP and genetic resources

*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 WIPO/GRTKF/IC/17/INF/12	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/4/10	Report on establishment of the database
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/17/INF/12	Draft IP guidelines, updated on the basis of responses to the questionnaire and subsequent analysis - reissued version of document WIPO/GRTKF/IC/7/9, as requested by the Committee
WIPO/GRTKF/IC/Q.6	Questionnaire and stakeholder responses on current practices and clauses
WIPO/GRTKF/IC/17/INF/11	Note on updating of the database
URL of database:	<a href="http://www.wipo.int/tk/en/databases/contracts/index.html">http://www.wipo.int/tk/en/databases/contracts/index.html</a>

*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 Union 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)
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*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 <i>Lepidium Meyenii</i> (maca): Responses of Peru
WIPO/GRTKF/IC/13/8(C)	Genetic Resources: Comments Received

*Policies, measures and experiences regarding IP and GR*

WIPO/GRTKF/IC/16/INF/7	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by the Nigeria Natural Medicine Development Agency (NNMDA)
WIPO/GRTKF/IC/16/INF/8	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by Zambia
WIPO/GRTKF/IC/16/INF/9	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by Brazil
WIPO/GRTKF/IC/16/INF/10	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by Algeria
WIPO/GRTKF/IC/16/INF/11	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by Kyrgyzstan
WIPO/GRTKF/IC/16/INF/12	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by Norway
WIPO/GRTKF/IC/16/INF/13	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by the International Institute for Environment and Development (IIED)
WIPO/GRTKF/IC/16/INF/14	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by Switzerland
WIPO/GRTKF/IC/16/INF/15	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by the European Union and its Member States
WIPO/GRTKF/IC/16/INF/16	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by Mexico
WIPO/GRTKF/IC/16/INF/17	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by the Center for Peace Building and Poverty Reduction Among Indigenous African Peoples (CEPPER)
WIPO/GRTKF/IC/16/INF/18	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by Australia
WIPO/GRTKF/IC/16/INF/19	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by Turkey
WIPO/GRTKF/IC/16/INF/20	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by the Food and Agriculture Organization of the United Nations (FAO)

WIPO/GRTKF/IC/16/INF/21	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by the Biotechnology Industry Organization (BIO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
WIPO/GRTKF/IC/16/INF/22	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by Kenya
WIPO/GRTKF/IC/16/INF/23	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Communication by Colombia
WIPO/GRTKF/IC/16/INF/24	Submission of Botswana on Behalf of the Member States of the African Regional Intellectual Property Organization (ARIPO): The African Regional Intellectual Property Organization (ARIPO) Draft Protocol on the Protection of Traditional Knowledge and Expressions of Folklore
WIPO/GRTKF/IC/16/INF/25	Submission of Kenya: The National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, July 2009
WIPO/GRTKF/IC/16/INF/26	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by the Russian Federation
WIPO/GRTKF/IC/16/INF/27	Policies, Measures and Experiences Regarding Intellectual Property and Genetic Resources: Submission by China

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