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

Twelfth Session
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GENETIC RESOURCES: LIST OF OPTIONS

Document prepared by the Secretariat

CONTEXT

1. At its tenth session, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') requested the preparation of (i) a document listing options for continuing or further work, including work in the areas of the disclosure requirement and alternative proposals for dealing with the relationship between intellectual property and genetic resources; the interface between the patent system and genetic resources; and the intellectual property aspects of access and benefit-sharing contracts; and (ii) a factual update of international developments relevant to the genetic resources agenda item. Document WIPO/GRTKF/IC/11/8 (a) provided the required list of options, and a companion document, WIPO/GRTKF/IC/11/8 (b) provided the required factual update of international developments.

2. At its eleventh session, the Committee decided concerning its agenda item on genetic resources that:

“the Secretariat should prepare a further update of international developments based on document WIPO/GRTKF/IC/11/8(b) which would include omissions

identified in the current session, more recent developments, and any other relevant developments reported to the Committee, and

“document WIPO/GRTKF/IC/11/8 (a) remains on the table in its existing form and comments made in relation to it are noted.”

The present document includes for reference by the Committee the text of document WIPO/GRTKF/IC/11/8 (a) on “Genetic Resources: List of Options” without amendment, in the light of the Committee’s decision. The companion document, WIPO/GRTKF/IC/12/8 (b), contains the required further update of international developments.

LIST OF OPTIONS

3. Following is a brief list of options for continuing or further work identified in this process, covering the areas of “the disclosure requirement and alternative proposals for dealing with the relationship between intellectual property and genetic resources; the interface between the patent system and genetic resources; and the intellectual property aspects of access and benefit-sharing contracts,” as required by the Committee’s decision. Further details are provided in the discussion set out in Annex I, which is an update of the summary earlier provided to the Committee in document WIPO/GRTKF/IC/8/9.

Options for continuing or further work

4. The options listed below are derived exclusively from proposals put to the Committee by Member States and other Committee participants, including national and regional submissions, proposals by other participants, and the Committee’s working documents. Each option would be subject to the overarching requirement in the current mandate of the Committee that its work should not prejudice the work of other fora, both within and beyond WIPO. In some instances, however, this work corresponds to direct invitations or encouragements of other fora, in particular the Conference of Parties of the Convention on Biological Diversity (see document WIPO/GRTKF/IC/11/8(b)).

(i) Development of a mandatory disclosure requirement such as has been tabled in the Committee;

(ii) Further examination of issues relating to disclosure requirements, such as the questions addressed or identified in earlier studies and invitations;

(iii) Related analysis of patent disclosure issues making use of the information submitted by Committee Members in the context of questionnaire WIPO/GRTKF/Q.5.;

(iv) Guidelines or recommendations concerning the interaction between patent disclosure and access and benefit-sharing frameworks for genetic resources;

(v) 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;

- (vi) 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;
- (vii) Recommendations or guidelines for search and examination procedures for patent applications to ensure that they better take into account disclosed genetic resources;
- (viii) 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;
- (ix) Considering options for stakeholder consultations on and further elaboration of the draft guidelines for contractual practices contained the Annex of document WIPO/GRTKF/IC/7/9; and
- (x) Development 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.

5. As a response to the Committee's decisions at the tenth and eleventh sessions, this document is intended to set out, objectively and succinctly, the range of options for the Committee's work on genetic resources that have been discussed in the past ten sessions of the Committee. These options have not been listed according to the three categories established in the Committee's decision, as there is some overlap between the categories and no prejudgement was made as to the appropriate categorization. Further background and more extensive references are available in Annex I (a description of the past work and issues discussed) and Annex II (a summary of the Committee's materials on genetic resources issues).

6. The Intergovernmental Committee is invited to review and draw on this document as appropriate in its discussions under agenda item 10 on genetic resources.

[Annexes follow]

ANNEX I

I. SUBSTANTIVE ISSUES CONSIDERED BY THE COMMITTEE

1. This Annex provides an overview of the Committee's work on genetic resources issues. 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. In conclusion, the document catalogues certain technical measures or activities, which have been identified by Committee participants at past sessions to partially address these issues. Committee members may wish to consider these possible options in order to provide guidance on the Committee's further work regarding IP and genetic resources, without prejudice to the work of other fora.

2. The document recalls that the mandate of the Committee indicates that its work is "without prejudice to work in other fora".¹ With particular relevance to genetic resources issues, the Committee itself has identified the principle that its work shall "be fully complementary with, and supportive of, the work of the CBD and FAO in particular." Recalling these principles, the present document provides background to Committee members in case they wish to discuss possible directions for continuing work on genetic resources issues.

II. SUBSTANTIVE ISSUES ARISING FROM RECENT DEVELOPMENTS

3. Following the decision of the Committee at its tenth session, this section provides information relevant to "continuing or further work, including work in the areas of the disclosure requirement and alternative proposals for dealing with the relationship between intellectual property and genetic resources; the interface between the patent system and genetic resources; and the intellectual property aspects of access and benefit-sharing contracts."

4. During the above-mentioned discussions and analyses in the Committee and other fora within and beyond WIPO, a number of substantive issues have emerged as ongoing concerns and themes that have been expressed by Committee participants. Some technical aspects of these substantive issues are briefly summarized here in three clusters: (i) defensive protection of genetic resources; (ii) disclosure requirements in patent applications for information related to genetic resources used in the claimed invention; and (iii) IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources.

¹ See Document WO/GA/30/8, paragraph 93.

Substantive IP issues concerning the interface between the patent system and genetic resources, particularly defensive protection of genetic resources.

5. 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 studies² 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.

6. 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.³ This complements extensive work undertaken in the first six sessions of the Committee to establish an array of defensive mechanisms to promote , and complements the development of patent examination guidelines for TK-related patents. Other UN agencies, such as the FAO, have requested WIPO to cooperate in analyzing and addressing similar concerns in specific sectors.⁴ International organizations working in the genetic resource 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 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

² See documents submitted by Peru (WIPO/GRTKF/IC/5/13, WIPO/GRTKF/IC/8/12, WIPO/GRTKF/IC/9/10)

³ WIPO/GRTKF/IC/9/13

⁴ See FAO document CGRFA-9/02/REP.

any country, in order to avoid the erroneous granting of patents for genetic resources and related traditional knowledge.”⁵.

Substantive IP issues concerning disclosure requirements and alternative proposals for dealing with the relationship between intellectual property and genetic resources

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

8. These discussions have focussed 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. A formal proposal⁶ has already been tabled in the Committee for a mandatory disclosure requirement.⁷ Some Committee participants argue for a mandatory requirement but have called for it to proceed in other fora, 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.⁸ Another perspective is that disclosure requirements can under certain circumstances relate to larger regulatory questions about access and benefit-sharing frameworks, in addition to the question of their compatibility with, and integration into, specific existing IP agreements. Several further points of view have been expressed by commentators, who have pointed out that these conceptual questions regarding the interrelation and synergies between patent disclosure requirements and access and

⁵ WIPO/GRTKF/IC/9/13, para 34

⁶ Document WIPO/GRTKF/IC/8/11, described further below.

⁷ Since the present document was drafted, a second submission has been made, by the Delegation of Switzerland, as document WIPO/GRTKF/IC/11/10.

⁸ 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)

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 analysed 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.⁹

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) 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?¹⁰
- what impact would a new disclosure requirement have on innovation?

⁹ Annex to document WIPO/GRTKF/IC/5/11, paras 205 and 206.

¹⁰ This and the following six questions were included in the comments of the United States of America on WIPO/IP/GR/05/01.

- 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?¹¹
- are national patent offices the appropriate bodies to enforce licences or contract-based interests of providers of genetic resources or associated TK?¹²

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;
- (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.”¹³

¹¹ This and the following question were included in comments of an observer, IFPMA, subsequent to the June 3, 2005 Ad Hoc Meeting.

¹² Annex to document WO/GA/32/8, paragraph 74.

¹³ Document WIPO/GRTKF/IC/8/11

Substantive issues concerning intellectual property aspects of access and benefit-sharing contracts

12. 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,”¹⁴ 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),¹⁵ as well as in the sharing of non-monetary benefits.¹⁶ 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.”¹⁷ 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 has been updated with several new agreements, and has been increasingly used as a practical capacity building (non-normative) tool.

The latest draft on guide practices – ‘Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing’¹⁸ – was circulated for consideration at the Committee’s seventh session. This document noted that the terms of access to genetic resources may include a requirement not to take out IP at all on derivative research, or an obligation to consult with the resource provider in the event of potential IP activity, and may structure ownership and management of any agreed resultant IP in a range of different ways, including co-ownership between access provider and resource user and different mechanisms for ensuring access to technology and other equitable benefits. These draft guidelines were developed according to the principles set out and discussed by the Committee since its second session:

Principle 1: The IP-related rights and obligations set out in [the Guide Contractual Practices] should recognize, promote and protect all forms of formal and informal human creativity and innovation, based on, or related to, the transferred genetic resources.

Principle 2: The IP-related rights and obligations set out in [the Guide Contractual Practices] should take into account sectorial characteristics of genetic resources and genetic resource policy objectives and frameworks.

Principle 3: The IP-related rights and obligations set out in [the Guide Contractual Practices] should ensure the full and effective participation of all relevant stakeholders

¹⁴ Art. 15.4 CBD.

¹⁵ See Items 1(j) in the catalogue of Monetary Benefits listed in Appendix II of the Bonn Guidelines.

¹⁶ See item 2(q) of Appendix II, Bonn Guidelines.

¹⁷ See Decision VI/24C, Convention on Biological Diversity, para. 9.

¹⁸ WIPO/GRTKF/IC/7/9

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.

13. Additional principles put forward by Committee members included:

- the Guide Contractual Practices should be non-binding,¹⁹ flexible²⁰ and simple;²¹
- 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;²²
- 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;²³
- 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;²⁴ 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.²⁵

¹⁹ 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).

²⁰ See Canada (WIPO/GRTKF/IC/2/3, para.77), USA (WIPO/GRTKF/IC/2/3, para.74).

²¹ 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).

²² 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).

²³ See (WIPO/GRTKF/IC/1/13, para. 106), Ecuador (WIPO/GRTKF/IC/2/3, para. 55), Bolivia, Cuba, Dominican Republic, Ecuador, Panama, Nicaragua, Peru, and Venezuela (WIPO/GRTKF/IC/2/3, para. 56).

²⁴ Algeria (WIPO/GRTKF/IC/2/3, para. 78), Bolivia, Cuba, Dominican Republic, Ecuador, Panama, Nicaragua, Peru, and Venezuela (WIPO/GRTKF/IC/2/3, para. 56), Venezuela (WIPO/GRTKF/IC/2/3, para. 57).

²⁵ See INADEV (WIPO/GRTKF/IC/2/16, para. 88).

III. POSSIBLE OPTIONS FOR CONTINUING OR FURTHER WORK OF THE COMMITTEE

14. In the course of its work on genetic resources in its past sessions, the Committee has considered various options for possible activities that could partially address the substantive issues which have been described above in Section II. The concern has been expressed, and the current mandate of the Committee underscores, that its work should not prejudice work of other fora, both within WIPO and elsewhere. This appears to be pertinent to the issue of genetic resources, given the array of activity only partially surveyed in the present document. Committee participants may wish to identify substantive issues which have been identified as requiring action at the international level, and to indicate how this work could be done by the Committee in such a way as to support and not prejudice the work of other fora, including key partners such as the CBD, CGIAR, FAO and UNEP.

15. As possible facilitative input to any such consideration of the issues, this Section briefly recapitulates options put before the Committee, noting the Committee session at which the option was identified. Each option is then followed by a footnote containing references to Committee documents which contain more details or additional information about that option. This is not intended to prompt or pre-empt consideration of any particular approach, but to provide a distillation of past more voluminous documentation in more readily accessible form, in case this will be of use to Committee participants.

Questions for guidance on the interface between the patent system and genetic resources, particularly defensive protection

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

A.1 (*second session*): 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;²⁶

A.2 (*third session*): The Online Portal of Registries and Databases which was 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).²⁷ A concrete proposal for such a system was presented at the ninth session and proposed that "a new system has to be a one-stop system where genetic resources ... can be 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

²⁶ This has already been successfully accomplished for periodicals concerning disclosed TK, as foreseen in WIPO/GRTKF/IC/2/6, paras 41 to 45.

²⁷ See WIPO/GRTKF/IC/3/6, para 15.

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.’²⁸

- A.3 (*second session*): The Committee could discuss a possible development of recommendations or guidelines 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.²⁹

Questions for guidance on disclosure requirements and alternative proposals for dealing with the relationship between intellectual property and genetic resources

17. 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.1 (*first session, sixth session*): 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;³⁰
- B.2 (*fifth session*): 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;³¹

²⁸ See WIPO/GRTKF/IC/9/13, para 40

²⁹ This has already been for patent applications involving disclosed TK. See WIPO/GRTKF/IC/2/6, para 52.

³⁰ 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).

³¹ The Committee considered such proposals at its first and fifth sessions. See WIPO/GRTKF/IC/5/10, para 12(ii).

B.3 (*ninth session*): 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 it was submitted at the ninth session as an alternative proposal for dealing with the relationship between intellectual property and genetic resources;³²

Questions for guidance on IP aspects of access and benefit-sharing contracts

18. 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.1 (*second session*): 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;³³

C.2 (*fifth, sixth and seventh sessions*): Based on the additional information available and included in the Database, the Committee might wish to consider to further develop the guide contractual practices contained in the Annex of document WIPO/GRTKF/IC/7/9;³⁴ and

C.3 (*sixth session*): compile information, possibly in the form of case studies, that describes licensing practices in the field of genetic resources which extends 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.³⁵

19. 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.

20. Annex II of document WIPO/GRTKF/IC/8/9 identified the following past options for possible activities that have been mentioned at past sessions to address substantive issues identified by the Committee in the field of IP and genetic resources

³² WIPO/GRTKF/IC/9/13.

³³ See WIPO/GRTKF/IC/2/12; WIPO/GRTKF/IC/2/16.

³⁴ See WIPO/GRTKF/IC/5/9; WIPO/GRTKF/IC/6/5; WIPO/GRTKF/IC/7/9.

³⁵ See WIPO/GRTKF/IC/6/14.

A. Options for possible activities on defensive protection

- A.1 (*second session*): The Committee could compile an inventory of existing periodicals, databases and other information resources which, 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 (*third session*): The Online Portal of Registries and Databases which was 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 resources would be required to implement this option);
- A.3 (*second session*): The Committee could discuss a possible development of recommendations or guidelines 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 for possible activities on disclosure requirements

- B.1 (*first session, sixth session*): The Committee could consider the development of appropriate (model) provisions for national or regional patent laws which would facilitate consistency and synergy between access and benefit-sharing measures for genetic resources on the one hand and national and international patent law and practice on the other;
- B.2 (*fifth session*): The Committee could consider the development of guidelines or recommendations concerning the interaction between patent disclosure and access and benefit-sharing frameworks for genetic resource;

C. Options for possible activities on IP and mutually agreed terms for fair and equitable benefit-sharing

- C.1 (*second session*): 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 (*fifth, sixth and seventh session*): Based on the additional information available and included in the Database, the Committee could consider to further develop the guide contractual practices contained the Annex of document WIPO/GRTKF/IC/7/9;
- C.3 (*sixth session*): compile information, possibly in the form of case studies, that describes licensing practices in the field of genetic resources which extends 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.

IV. CONCLUSION

21. This Annex describes three clusters of substantive questions which have been identified in the course of the Committee's work, namely technical matters concerning (a) the interface between the patent system and genetic resources, particularly defensive protection; (b) IP issues concerning disclosure requirements and alternative proposals for dealing with the relationship between intellectual property and genetic resources; and (c) IP issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources. Finally, the document recalls certain technical measures or activities which have been identified in past sessions, which would partially address these substantive issues, noting the need to ensure no prejudice to the work of other fora. This material is provided to the Committee in view of its possible contribution to discussion of genetic resource issues.

[Annex II follows]

ANNEX II

IGC RESOURCES RELEVANT TO WORK ON IP AND GENETIC RESOURCES

Overview of issues and activities

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

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

WIPO/GRTKF/IC/2/3 Operational principles for IP clauses of mutually agreed terms concerning access to genetic resources and benefit-sharing discussed and supported in WIPO/GRTKF/IC/2/16 (paragraphs 52 to 110)

WIPO/GRTKF/IC/2/13 Information document on contractual agreements concerning access to genetic resources and benefit-sharing (submitted by the Delegation of the United States of America)

WIPO/GRTKF/IC/3/4
WIPO/GRTKF/IC/5/9
WIPO/GRTKF/IC/6/5
WIPO/GRTKF/IC/7/9 Progressive development of draft guidelines on IP aspects of mutually agreed terms for access and equitable benefit-sharing

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

WIPO/GRTKF/IC/2/12 Proposal for establishment of the database (submitted by the Delegation of Australia)

WIPO/GRTKF/IC/3/3 Call for comments on the draft structure of the database

WIPO/GRTKF/IC/3/4 Proposed structure of the database

WIPO/GRTKF/IC/Q.2 Questionnaire and stakeholder responses on current practices and clauses

WIPO/GRTKF/IC/5/9 Analysis of stakeholder responses to the questionnaire on current practices and clauses

WIPO/GRTKF/IC/6/5 Draft IP guidelines, based on responses to the questionnaire and subsequent analysis, concerning IP aspects of mutually agreed terms for access and benefit-sharing

WIPO/GRTKF/IC/7/9 Draft IP guidelines, based on responses to the questionnaire and subsequent analysis - reissued version of document WIPO/GRTKF/IC/6/5, as requested by the Committee

WIPO/GRTKF/IC/4/10 Report on establishment of the database

URL of database: <http://www.wipo.int/tk/en/databases/contracts/index.html>

Disclosure requirements relating to genetic resources and TK

WIPO/GRTKF/IC/1/6 Information provided by Member States in response to a questionnaire on protection of biotechnological inventions, including questions on disclosure requirements

WIPO/GRTKF/IC/1/8 Directive 98/44/EC on the Legal Protection of Biotechnological Inventions and an Explanatory Note on Recital 27 of the Directive, which concerns the indication of the geographical origin of biotechnological inventions. Also contains a paper on the relationship between IP rights and biodiversity (submitted by the European Community and its Member States)

WIPO/GRTKF/IC/2/11 Report of the CBD Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing (submitted by the CBD Secretariat)

WIPO/GRTKF/IC/2/15 Survey of patents using biological material and mentioning of the country of origin of the material (submitted by the Delegation of Spain)

WIPO/GRTKF/IC/Q.3 Questionnaire and stakeholder responses on disclosure requirements

WIPO/GRTKF/IC/4/11 First report on technical study

WIPO/GRTKF/IC/5/10 Draft technical study

UNEP/CBD/COP/7/INF/17 Technical study on disclosure requirements related to Genetic resources and traditional knowledge. Submission by WIPO

WIPO/GRTKF/IC/6/9 Report on the transmission of the Technical Study to the CBD

WIPO Publication 786 Final text of the technical study

WIPO/GRTKF/IC/6/13 Decisions of the CBD-COP concerning access to genetic resources and benefit-sharing, including an invitation to WIPO to examine certain issues related to disclosure requirements (Submitted by the CBD Secretariat)

WIPO/GRTKF/IC/7/INF/5 Further Observations by Switzerland on its Proposals Regarding the Declaration of the Source of Genetic Resources and

Traditional Knowledge in Patent Applications (Submitted by the Government of Switzerland)

- WIPO/GRTKF/IC/7/10 Update on recent developments regarding disclosure requirements
- WIPO/GRTKF/IC/8/11 Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications (submitted by the European Community and its Member States)

Technical standards on databases and registries

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

Studies and texts on IP and equitable benefit-sharing

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

Other defensive protection measures

- WIPO/GRTKF/IC/5/6 Practical Mechanisms for the Defensive Protection of Traditional Knowledge and Genetic Resources within the Patent System (includes discussion of the Enola case referred by the FAO)
- WIPO/GRTKF/IC/6/8 Further update on defensive protection measures relating to intellectual property, genetic resources and traditional knowledge
- WIPO/GRTKF/IC/8/12 Patent System and the Fight against Biopiracy - The Peruvian Experience
- WIPO/GRTKF/IC/9/12 Analysis of Potential Cases of Biopiracy (submitted by the Delegation of Peru)

Further IGC resources

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

[End of Annex II and of document]