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

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PATENT DISCLOSURE REQUIREMENTS RELATING TO GENETIC RESOURCES
AND TRADITIONAL KNOWLEDGE: UPDATE

Document prepared by the Secretariat

EXECUTIVE SUMMARY

1. This document provides an update for the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC) on the question of patent disclosure requirements relating to genetic resources (GR) and traditional knowledge (TK). It addresses two distinct aspects of this issue:

(a) It provides an update on work within WIPO in the context of the decision, at the sixth session of the Committee, to refer an invitation by the Conference of Parties (COP) of the Conference on Biological Diversity (CBD) concerning this issue.

(b) It notes the existing proposals for continued work on this issue within the Committee.

PART A: CBD INVITATION

Background

2. The Secretariat of the CBD reported to the IGC at its second session (WIPO/GRTKF/IC/2/11) on the outcome of the first meeting of the CBD Ad-Hoc Open-ended Working Group on Access and Benefit-sharing (“the Working Group”). The report indicated that the Working Group had developed the draft Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From Their Use, and had recommended “that the Conference of the Parties [COP] at its sixth meeting invite [WIPO] to prepare a technical study on methods [for requiring disclosure within patent applications of certain information] which are consistent with obligations in treaties administered by [WIPO]” (WIPO/GRTKF/IC/2/11 and UNEP/CBD/COP/6/6).

3. The Working Group’s Report was considered by the COP at its sixth meeting (held from April 7 to 19, 2002), and as part of its decision on this matter (decision VI/24), the COP invited WIPO to:

“prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, *inter alia*:

- (a) Genetic resources utilized in the development of the claimed inventions;
 - (b) The country of origin of genetic resources utilized in the claimed inventions;
 - (c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;
 - (d) The source of associated traditional knowledge, innovations and practices;
- and,
- (e) Evidence of prior informed consent.”

4. This invitation was transmitted to the IGC at its third session (WIPO/GRTKF/IC/3/12), which agreed to respond positively and adopted a work schedule which would allow for the completion and transmission of the study in time for the seventh meeting of the COP, then scheduled to be held in Kuala Lumpur from March 9 to 20, 2004. Between the IGC’s third and fourth sessions, a questionnaire was developed in consultation with Member States (WIPO/GRTKF/IC/Q.3) and then circulated to Member States regarding the intellectual property issues identified for study in the invitation contained in Decision VI/24.

5. At its fourth session, the IGC considered and commented upon a draft technical study (WIPO/GRTKF/IC/4/11), which was based on questionnaire responses from WIPO Member States. The IGC invited further comments for incorporation into a revised version of the draft study, which was then prepared and submitted to the IGC at its fifth session (WIPO/GRTKF/IC/5/10). The IGC agreed to transmit this draft technical study to the WIPO General Assembly for consideration and possible transmission to the seventh meeting of the COP.

Transmission of the study to the CBD, and further steps

6. At its Thirtieth Session, the WIPO General Assembly adopted the draft revised technical study for transmission to the seventh meeting of the COP. This decision was subject to the following understanding:

“The [Study] has been prepared to contribute to international discussion and analysis of this general issue, and to help clarify some of the legal and policy matters it raises. It has not been prepared to advocate any particular approach nor to expound a definitive interpretation of any treaty. It is to be regarded as a technical input to facilitate policy discussion and analysis in the CBD and in other fora, and it should not be considered a formal paper expressing a policy position on the part of WIPO, its Secretariat or its Member States.”

Following the General Assembly decision, the Technical Study was transmitted to the Secretariat of the CBD together with this understanding.

7. The Technical Study was subsequently considered by the Working Group at its second meeting, held from December 1 to 5, 2003 (UNEP/CBD/COP/7/6, paragraphs 10 to 12, and 81). This led to the adoption of recommendations to the COP on the issues addressed in the Technical Study (UNEP/CBD/COP/7/6, paragraphs 75 to 85). The seventh COP met in Kuala Lumpur from February 9 to 20, 2004, and duly considered these recommendations. COP Decision VII/19 on ‘[a]ccess and benefit-sharing as related to genetic resources’ included a reference to the Study and invited further work on this issue. Among other things, this decision:

- noted the technical study with appreciation;
- requested the CBD Ad hoc Open-ended Working Group on Access and Benefit-Sharing to identify issues related to the disclosure of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights, including those raised by a proposed international certificate of origin/source/legal provenance, and transmit the results of this examination to WIPO and other relevant forums; and
- invited WIPO to examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the CBD, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, inter alia:
 - (a) Options for model provisions on proposed disclosure requirements;
 - (b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;
 - (c) Options for incentive measures for applicants;
 - (d) Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties;
 - (e) Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance;

and regularly provide reports to the CBD on its work, in particular on actions or steps proposed to address the above issues, in order for the CBD to provide additional information to WIPO for its consideration in the spirit of mutual supportiveness.

Sixth session of the IGC

8. The sixth session of the IGC was convened from March 15 to 19, 2004. Document WIPO/GRTKF/IC/6/9, prepared for this session, reported on the transmission of the Study and provided an update of developments elsewhere (as it was circulated on December 12, 2003, in advance of the seventh CBD COP, this document did not address the subsequent COP decision VII/19). This document also drew on proposals for further work on this issue which had been put to the fifth session of the IGC (WIPO/GRTKF/IC/5/10), and invited the IGC to “take note of the transmission of the Technical Study and of recent developments in other fora on this issue” and “in the light of such developments and other proposals to consider possible future work for the IGC on this issue, including the proposals in paragraph 12(ii) of WIPO/GRTKF/IC/5/10”, namely “continued exchange of national experience and case studies, and the development of guidelines and recommendations concerning the interaction between access to genetic resources and patent disclosure”.

9. Following the seventh CBD COP, a subsequent update was prepared for the IGC, document WIPO/GRTKF/IC/6/11, which foreshadowed the aspects of the COP decision that were relevant to the IGC’s work. Then, immediately prior to the sixth session of the IGC, WIPO received from the Secretariat of the CBD a communication of the decision, and this was duly reported to the IGC in document WIPO/GRTKF/IC/6/13.

10. Since the invitation from the COP was potentially relevant to any future work by the IGC on the issue of disclosure mechanisms as a defensive protection measure relating to TK and genetic resources, the IGC considered the invitation. Various views were expressed as to how the invitation should be dealt with procedurally within WIPO, including by the IGC itself or by other WIPO fora (the discussion is recorded in full in the report of the sixth session, document WIPO/GRTKF/IC/6/14, from paragraphs 142 to 188); since there was no consensus on how to proceed, the IGC decided to refer the invitation to the WIPO General Assembly for consideration (WIPO/GRTKF/IC/6/14, paragraph 183).

Consideration by the WIPO General Assembly

11. This matter was accordingly submitted to the General Assembly for its consideration at its Thirty-First Session (document WO/GA/31/8). In view of the discussions and consultations undertaken during the meeting, the General Assembly adopted the following:

“Noting that Decision VII/19 of the Conference of the Parties of the Convention on Biological Diversity, *inter alia*,

“invited WIPO to examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the CBD, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, *inter alia*:

- (a) Options for model provisions on proposed disclosure requirements;

- (b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;
- (c) Options for incentive measures for applicants;
- (d) Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties;
- (e) Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance;

and regularly provide reports to the CBD on its work, in particular on actions or steps proposed to address the above issues, in order for the CBD to provide additional information to WIPO for its consideration in the spirit of mutual supportiveness.”

the WIPO General Assembly decided that WIPO should respond positively and that, for this purpose, the following timetable and modalities would be adopted:

- (i) the Director General will invite all Member States of WIPO to submit proposals and suggestions before December 15, 2004;
- (ii) a first draft of the examination (the draft) will be prepared by the International Bureau and published on the WIPO website and circulated by the end of January 2005 to all Member States of WIPO and observers accredited to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), Standing Committee on the Law of Patents (SCP) and Working Group on PCT Reform (PCT Reform WG) for observations and comments;
- (iii) all Member States and these accredited observers may submit observations and comments on the draft by the end of March 2005;
- (iv) all comments and observations received will be published on the WIPO website as and when received and in a consolidated document following the expiration of the time period for the submission of such comments and observations;
- (v) a one-day ad hoc intergovernmental meeting will be held in May 2005 to consider and discuss a revised version of the draft. The revised version of the draft will be made available at least 15 days before the Meeting. All Member States of WIPO and the accredited observers will be invited to attend the Meeting, which shall elect its chair and will be held under the General Rules of Procedure of WIPO. With respect to the scheduling of this meeting, the meeting shall be scheduled to occur on a date that will permit the participation of the maximum number of observer organizations of indigenous and aboriginal peoples;
- (vi) the International Bureau, shall prepare a further revised draft following the Meeting which shall be presented to the WIPO General Assembly at its ordinary session in September 2005 for consideration and decision.

12. Arrangements are under way for the initiation of this process as agreed by the WIPO General Assembly. This update on the steps to be taken in responding to the CBD invitation is accordingly provided for the information only of the IGC.

PART B: WORK BY THE COMMITTEE ON THE DISCLOSURE ISSUE

13. The current mandate of the Committee includes reference to the need for its work to continue “without prejudice to the work pursued in other fora” (see WO/GA/30/8, paragraph 93): the issue of patent disclosure requirements regarding TK and genetic resources, which is being considered in a number of other WIPO fora, and in other international fora, has been expressly mentioned in this regard (WIPO/GRTKF/IC/6/14, paragraph 172). The disclosure issue has been considered at previous IGC sessions. At the sixth session of the IGC, reflecting proposals circulated earlier for the Committee’s consideration, the following suggestion was tabled for possible continuing work in this area:

The Committee may wish to consider any further work that may be appropriate regarding the substantive intellectual property issues addressed in the Technical Study. In particular, document WIPO/GRTKF/IC/5/10 invited the Committee “to consider possible future work on this issue, including the continued exchange of national experience and case studies, and the development of guidelines and recommendations concerning the interaction between access to genetic resources and patent disclosure.” The range of such interaction considered by the Committee has included general disclosure requirements under patent law, specific requirements for genetic resources or traditional knowledge, and contractual obligations for disclosure linked to access to genetic resources. (Document WIPO/GRTKF/IC/6/9, paragraph 9).

14. Such future work, if agreed, could enhance the available background information available in general for continuing policy analysis of this issue. The Committee’s current mandate would indicate that any such work would need to be without prejudice to the work undertaken in other fora (including the specific process established by the General Assembly, and other fora within and beyond WIPO). It would be possible to develop additional background information, input on national experiences, and case studies, by drawing more extensively on the responses received to questionnaire WIPO/GRTKF/IC/Q.3 (which were not analyzed fully in the context of the initial Technical Study) and further reports of practical national experience, and by providing further material on the specific technical issues that were outlined in the conclusion of the Technical Study. It is suggested that any such work, if it were to proceed, should be undertaken with the clear understanding that it should have no legal status, it should not detract from work on this issue undertaken in other processes in WIPO or in other bodies, and it should not distract from other priorities underlined by WIPO Member States concerning the work of the Committee.

15. The Intergovernmental Committee is invited: (i) to note the update provided concerning the further invitation from the CBD COP, but to take no specific action in this regard; and (ii) to consider the proposal for continuing work on this issue within the Committee in accordance with paragraphs 13 and 14, above.

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