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WIPO GENERAL ASSEMBLY

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MATTERS CONCERNING THE INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURES, TRADITIONAL KNOWLEDGE AND FOLKLORE: INVITATION FROM THE CONFERENCE OF PARTIES OF THE CONVENTION ON BIOLOGICAL DIVERSITY

Document prepared by the Secretariat

Background: technical study on patent disclosure

- 1. The Secretariat of the Convention on Biological Diversity (CBD) reported to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (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).
- 2. 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."
- 3. 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.
- 4. 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

5. 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.

- 6. 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

7. 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"

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experience and case studies, and the development of guidelines and recommendations concerning the interaction between access to genetic resources and patent disclosure."

- 8. 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.
- 9. 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). The present document has accordingly been prepared to convey the background to the General Assembly for its consideration.

Further information exchange with the CBD

- 10. Consideration of the practicalities and time-frame for possible responses to the invitation by the COP may be facilitated by information on the planned future work program of the COP. In particular, the eighth session of the CBD COP is tentatively scheduled to be held on May 8 to 19, 2006. The third and fourth meetings of the Working Group are tentatively scheduled for February 21 to 25, 2005 and March 15 to 19, 2006 respectively. Also relevant, to the extent that disclosure requirements concern traditional knowledge, may be the fourth meeting of the Ad Hoc Open-ended Working Group on Article 8(j), tentatively scheduled from March 20 to 24, 2006; and a series of regional workshops on the "Composite Report on Traditional Knowledge," tentatively scheduled from April to July, 2005.
- Accordingly, should the Assembly decide to respond positively to this invitation, it may also be appropriate to consider a time frame and methodology for developing the requested material, which specifically includes: options for model provisions on proposed disclosure requirements; practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements; options for incentive measures for applicants; identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties; and intellectual property-related issuesraised by a proposed international certificate of origin/source/legal provenance. Some of this material has been developed in part in the existing Technical Study, but would need to be further advanced and developed to meet the specific terms of the invitation, if the decision were taken to respond accordingly to the invitation. The request to report in particular on 'actions or steps proposed' may touch on several processes within WIPO. Other aspects of the invitation may need continuing updated information from the CBD, for instance on the development of a proposed 'international certificate of origin/source/legal provenance,' which may take further shape in the context of ongoing work within the CBD on the proposed international regime.

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- 12. If, in line with the invitation, a first report is to be submitted to the CBD through the General Assembly itself, with a view to elicit additional information from the CBD for the further consideration of WIPO, as proposed by the CBD, then timing factors would suggest that a draft report should be prepared in time for the General Assembly to consider at its thirty-second session in 2005, and thus would need to be ready for submission to Member States by July, 2005. This timing would ensure that at least an initial report was available for consideration by the next, eighth meeting of the CBD COP, and would enable the envisaged feedback to WIPO to occur. The General Assembly may wish to consider this practical aspect in the context of any possible response to the COP's invitation.
 - 13. The General Assembly is invited to consider possible responses to the invitation contained in decision VII/19 of the Conference of Parties of the Convention on Biological Diversity, and to specify the methodology for developing the substance of any response.

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