

WIPO



WIPO/GRTKF/IC/8/9

ORIGINAL: English

DATE: April 20, 2005

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

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

Eighth Session
Geneva, June 6 to 10, 2005

OVERVIEW OF THE COMMITTEE'S WORK ON GENETIC RESOURCES

Document prepared by the Secretariat

SUMMARY

1. This document is intended to provide a background information resource for the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') on the issue of genetic resources. It provides general information on the Committee's past activities relating to genetic resources and intellectual property (IP), and work in related fora.
2. The document describes the background of work on IP and genetic resources before the Committee was created, and provides an overview of the Committee's own work. 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.
3. 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.

I. PAST WORK ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES

4. The discussions which led to the creation of the Committee originated in questions related to genetic resources. However WIPO's activities on IP and genetic resources began prior to, and extends beyond the activities of, the Committee itself. This Section describes past WIPO work on IP and genetic resources; considers these activities in the context of other committees inside WIPO and beyond it; and traces certain lines of development in that work.

UNEP/WIPO Study on the Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources (1998-1999)

5. In line with the approval of a new program area, activities on genetic resources began in 1998 with a cooperative initiative with the United Nations Environment Programme (UNEP). Jointly with UNEP, WIPO commissioned a study on the role of IP rights in the sharing of benefits arising from the use of biological resources and associated traditional knowledge (TK). The study resulted in three case studies, which provide lessons as to how intellectual property (IP) may support the sharing of benefits arising from the use of genetic resources. The Study is available today as WIPO publication no. 769 (E).

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

Third Session of the Standing Committee on the Law of Patents (September 1999)

6. Issues related to IP and genetic resources were also discussed by Member States at the third session of the Standing Committee on the Law of Patents (SCP) in September 1999. The SCP requested the International Bureau to include the issue of protection of biological and genetic resources on the agenda of a Working Group on Biotechnological Inventions, to be convened in November 1999. The SCP further invited the International Bureau to take steps to convene a separate meeting involving a larger number of Member States early in 2000, in order to consider that issue.²

WIPO Working Group on Biotechnology (November 1999)

7. The Working Group on Biotechnology, at its meeting in November 1999, recommended the establishment of nine projects related to IP and biotechnology. The Working Group decided to establish a questionnaire for the purpose of gathering information about the protection of biotechnological inventions, including certain aspects regarding intellectual property and genetic resources, in the Member States of WIPO. The Secretariat sent a questionnaire to the Member States and has compiled information from the responses received in reply to the questionnaire. This was submitted to the Committee at its first session (document WIPO/GRTKF/IC/1/6).

Meeting on Intellectual Property and Genetic Resources (April 2000)

8. In response to the invitation issued by the SCP, WIPO organized a Meeting on Intellectual Property and Genetic Resources in April 2000. The Meeting addressed issues that generally are raised in the context of access to, and *in-situ* preservation of, genetic resources in their direct or indirect relationship with intellectual property. The Chairman's Conclusions from the Meeting state that the exchange of views that took place at the Meeting produced a clear consensus that:

“WIPO should facilitate the continuation of consultations among Member States in coordination with the other concerned international organizations, through the conduct of appropriate legal and technical studies, and through the setting up of an appropriate forum within WIPO for future work.”

Diplomatic Conference on the Adoption of the Patent Law Treaty (May/June 2000)

9. Before the Diplomatic Conference for the Adoption of the Patent Law Treaty in May and June 2000, informal consultations were held on the question of genetic resources. The consultations produced an agreed statement which said, *inter alia*, that

“Member State discussions concerning genetic resources will continue at WIPO. The format of such discussions will be left to the Director General's discretion, in consultation with WIPO Member States.”

10. Following the Diplomatic Conference, consultations with Member States were held to determine the format and content of such discussions. As a result of the consultations, it was

² See document SCP/3/11, paragraph 208.

proposed that a distinct body should be established within WIPO to facilitate such discussions.

WIPO General Assembly (September 2000)

11. At the Twenty-Sixth Session of the General Assembly of the Member States of WIPO, held in September and October 2000, the Member States established the Committee, for the purpose of discussions on, *inter alia*, IP issues that arise in the context of access to genetic resources and benefit-sharing.

FAO Commission on Genetic Resources for Food and Agriculture (CGRFA)

12. Prior to the creation of the Committee, governments were engaged in an important process of addressing the distinct characteristics of plant genetic resources for food and agriculture (PGRFA) by revising the International Undertaking on Plant Genetic Resources for Food and Agriculture (“the Undertaking”), and negotiating an internationally binding legal instrument which is today in force as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR). These negotiations were being facilitated by the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA). Within these negotiations, governments had raised several IP issues in the context of the draft provisions on facilitated access to PGRFA (Article 13) and on benefit-sharing (Article 14) of the Multilateral System of Access and Benefit-sharing which was established by the ITPGR.³ In particular, the Composite Draft Text of the ITPGR at the time included a provision for the sharing of benefits on commercialization, which provided for an IP-based benefit-sharing mechanism⁴ (Article 14.2(d)(iv)⁵). Since WIPO had been participating in the negotiations as an observer, it had provided, strictly upon request, technical IP information and advice, when required by the FAO in order to advance its negotiations. The development of more extensive analysis and advice, if required and requested by the FAO, was also left open as an option for the work of the Committee itself following its formation.

First session of the Intergovernmental Committee

13. The Intergovernmental Committee held its first session in May 2001. At the first session of the Intergovernmental Committee, WIPO Member States considered possible elements of a workprogram on IP and genetic resources, which comprised the following possible tasks:

- to consider the development of “guide contractual practices,” guidelines, and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing, taking into account the specific nature and needs of different stakeholders,

³ See document CGRFA/CG-6/01/2.

⁴ The concept of such a mechanism was first introduced into the Composite Draft Text following a private sector proposal from the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL) and was revised during the negotiations at subsequent meetings of the Contact Group of the CGRFA (See documents CGRFA-8/99/Inf.9; CGRFA/CG-3/00/2; CGRFA/CG-4/00/2, CGRFA/CG-5/01/2 and CGRFA/CG-6/01/2).

⁵ Four countries stated that they do not agree with the text of Article 14.2(d)(iv). See CGRFA/CG-6/01/2.

different genetic resources, and different transfers within different sectors of genetic resource policy;

- to consider the development of appropriate provisions or guidelines for national patent laws which facilitate consistency with measures of States concerning access to genetic resources and which are consistent with existing international intellectual property standards;
- to consider, subject to the conclusion of the revision of the International Undertaking, the desirability and feasibility of practical and low-cost mechanisms to implement intellectual property-based benefit-sharing arrangements under multilateral systems for access to genetic resources and benefit-sharing, which are consistent with international intellectual property standards and focus in particular on plant genetic resources for food and agriculture;
- to review, on the basis of information compiled in the summary of practices related to the protection of biotechnology inventions in Member States and recalling the work of the SCP, the application of legal standards concerning the availability and scope of patent protection to structures and compositions derived or isolated from naturally occurring living organisms and to early stage biotechnology inventions, with a view to producing guidelines on the application of such standards in the field of genetic resources;
- to consider if it is possible to improve the management of genetic resources by exploring methods by which the genetic resources in the form of protected varieties may be integrated into overall plans for effective conservation.

In conclusion of its discussions, the Committee decided to proceed immediately with the first possible task.

Second session of the Intergovernmental Committee

14. At its second session (in December 2001), the Committee received a report from the Secretariat of the Convention on Biological Diversity (CBD) and discussed possible activities for the implementation of the tasks of the workprogram adopted at the first session.

15. The CBD Secretariat reported to the Committee (document 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 (“the Bonn Guidelines”), and had recommended “that the Conference of the Parties 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].”⁶

16. Regarding possible activities for the implementation of the genetic resource tasks adopted at the first session, the Committee adopted a two-step approach for the development of model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing. It decided that first a complete and systematic survey of IP clauses used in existing contracts should be undertaken, and, second, guide practices or model IP clauses should be developed, based on the existing practices and clauses. The Committee

⁶ See document WIPO/GRTKF/IC/2/11, Annex, and document UNEP/CBD/COP/6/6, Annex.

reached certain general conclusions concerning the guide practices and model clauses, including that:

- they would deal only with intellectual property-aspects;
- they would be non-binding;
- they would be without prejudice to, and consistent with, the work of the CBD and FAO;
- they would be developed with the full and effective participation of all stakeholders, in particular indigenous and local communities.

17. The Committee also considered certain specific issues, such as disclosure of the origin of genetic resources, prior informed consent, the sovereignty of states over their genetic resources, transfer of technology, the issue of applicable law, the safeguarding of basic scientific research, education and legal assistance to indigenous and local communities, the legal status of genetic resources under international law, definitions of terms, and a process-based approach for the guide contractual practices. The Committee specified that the development of an electronic database on contracts should be considered.⁷

Sixth Meeting of the Conference of the Parties (COP) to the CBD

18. From April 7 to 19, 2002, the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) held its sixth meeting in The Hague. In Decision VI/24A, the COP adopted the Bonn Guidelines on access to genetic resources and benefit-sharing. In section C of the same decision, it also considered the role of intellectual property rights in the implementation of access and benefit -sharing arrangements and invited Parties and Governments to encourage the disclosure of origin of the country of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources or associated traditional knowledge in its development.⁸ Recognising that further work was needed on this issue, 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,

⁷ The preparation of the Database format and early drafts of the guide practices were undertaken by a consultant with a background from a genetic resource conservation institution.

⁸ See Decision VI/24C, paragraphs 1 and 2.

(e) Evidence of prior informed consent.”

19. In the same decision the CBD-COP, in the context of the work of the Committee on IP aspects of mutually agreed terms, encouraged WIPO “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.”⁹

20. The same COP decision also “*recognizes* the importance of the work being undertaken by the World Intellectual Property Organization on international models and *encourages* the World Intellectual Property Organization to also consider means by which Parties could collaborate to protect traditional knowledge for further consideration by the Conference of the Parties”¹⁰

21. In the same decision the CBD-COP also requested the CBD Executive Secretary with the help of other intergovernmental organizations such as WIPO “to undertake further information gathering and analysis on:

(a) Impact of intellectual property regimes on access to and use of genetic resources and scientific research;

(b) Role of customary laws and practices in relation to the protection of genetic resources and traditional knowledge, innovations and practices, and their relationship with intellectual property rights;

(c) Consistency and applicability of requirements for disclosure of country of origin and prior informed consent in the context of international legal obligations;

(d) Efficacy of country of origin and prior informed consent disclosures in assisting the examination of intellectual property rights applications and the re-examination of intellectual property rights granted;

(e) Efficacy of country of origin and prior informed consent disclosures in monitoring compliance with access provisions;

(f) Feasibility of an internationally recognized certificate of origin system as evidence of prior informed consent and mutually agreed terms; and

(g) Role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights.”¹¹

22. Finally, the COP, in a request for close interagency collaboration between the CBD and WIPO, reiterated its request for a Memorandum of Understanding with WIPO and urged WIPO “to provide to the Conference of the Parties with the results of its deliberations of relevance to access to genetic resources and benefit-sharing related to traditional knowledge;”¹²

Third session of the Intergovernmental Committee

23. At its third session, the Committee received the requests of the COP through a document submitted to the Committee by the CBD Secretariat.¹³

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

¹⁰ See Decision VI/24C, Convention on Biological Diversity, para. 10.

¹¹ See Decision VI/24C, Convention on Biological Diversity, para. 3.

¹² See Decision VI/24C, Convention on Biological Diversity, para. 11.

¹³ Document WIPO/GRTKF/IC/3/12.

24. This invitation was considered by the Committee and the Committee agreed to respond positively to the CBD's request. It adopted a work schedule which would allow for the completion and transmission of the study in time for the seventh meeting of the COP. Between the Committee's third and fourth sessions, a questionnaire was developed in consultation with Member States and then circulated to Member States regarding the intellectual property issues identified for study in the invitation contained in Decision VI/24.

Standing Committee on the Law of Patents

25. Successive sessions of the Standing Committee on the Law of Patents (SCP) also considered issues relating to genetic resources, including the disclosure of origin of genetic resources, in the context of its work on a draft Substantive Patent Law Treaty (for example, the reports of its eighth, ninth and tenth sessions, documents SCP/8/9, SCP/9/8, and SCP/10/10 respectively).

Ninth Session of the FAO Commission on Genetic Resources for Food and Agriculture (October 2002)

26. At the ninth session of the CGRFA, held in October 2002, the Commission received a report from CIAT, on a granted patent relating to a field bean cultivar named 'enola'.¹⁴ This patent had been granted for a new cultivar of field bean (*Phaseolus vulgaris* L.) which produces a distinctly yellow seed with a yellow hilum that remains relatively unchanged over time. Having considered the report, "A number of countries expressed concern over cases involving the inappropriate granting of intellectual property rights over materials from the International Network, noting, however, that such cases had all been attended to." The CGRFA "requested the Director General of FAO to ... forward [certain FAO] documents ... to the World Intellectual Property Organization (WIPO) and its various Committees, with a request that WIPO cooperate with FAO in preparing a study on how intellectual property rights may affect the availability and use of material from the International Network and the International Treaty."¹⁵

Fourth session of the Intergovernmental Committee (December 2002)

27. At its fourth session, the Committee considered and commented upon a draft technical study, including a compilation of responses received from Committee members and a draft analysis of those responses. The Committee also invited further comments for incorporation into a revised version of the technical study. The Committee also agreed on the further development of the pilot database of contractual practices and clauses relating to IP, access to genetic resources and benefit-sharing as a practical tool in the provision of information in this area ("the Database"). The Committee also agreed that Questionnaire WIPO/GRTKF/IC/Q2 should continue to be disseminated as a means of promoting a wider range of material in the Database.

¹⁴ US patent 5,894,079.

¹⁵ See document CGRFA-9/02/REP Report of the Commission on Genetic Resources for Food and Agriculture, paragraphs 31 available at: <<ftp://ext-ftp.fao.org/ag/cgrfa9/r9repe.pdf>>.

Fifth session of the Intergovernmental Committee (July 2003)

28. At its fifth session, the Committee considered a document on Practical Mechanisms for the Defensive Protection of Genetic Resources within the Patent System,¹⁶ which raised the illustrative patent case forwarded by the FAO and summarized the products for the defensive protection of genetic resources which had been produced by the Committee. It considered a report on the updating of the Database to a more fully operational and comprehensive version, which also discussed the role of contractual arrangements in recently enacted legislation on access to genetic resources and associated TK, and provided an overview of the IP aspects of mutually agreed terms relating to biological material and associated TK.

29. The Committee also reviewed the “Draft Technical Study on Disclosure Requirements related to Genetic Resources and Traditional Knowledge,” which had been prepared on the basis of the questionnaire Q3 (see Annex I to document WIPO/GRTKF/IC/5/10). The Committee decided to transmit the draft technical study to the General Assembly with the recommendation that it be transmitted as a technical reference document to the Seventh Conference of Parties of the CBD.¹⁷ The Secretariat of the Convention on Biological Diversity highlighted to the Intergovernmental Committee¹⁸ the usefulness of the technical study not merely for the Conference of Parties meeting in the first quarter of 2004, but also for technical working groups of the CBD which were scheduled to meet in December 2003, and requested that this be taken into account in the possible transmission of the study to the CBD.

WIPO General Assembly (Twenty-Ninth Session, September 2003)

30. At its Twenty-Ninth 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 attached draft technical 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 Convention on Biological Diversity 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 (SCBD) with the above-mentioned understanding attached to the Study.

31. The Study was subsequently issued by the SCBD as document UNEP/CBD/WG-ABS/2/INF/4 for the second meeting of the Working Group, which took place in Montreal from December 1 to 5, 2003. The Study and the above-mentioned qualification were introduced to the Working Group¹⁹ and provided the basis for deliberations which led to the

¹⁶ WIPO/GRTKF/IC/5/6

¹⁷ WIPO/GRTKF/IC/5/15

¹⁸ WIPO/GRTKF/IC/5/15

¹⁹ See document UNEP/CBD/COP/7/6, paragraphs 10 to 12, and 81.

adoption of Recommendations to the COP on the issues addressed in the Study.²⁰ The Preamble of the Recommendations reflects the positive reception by the Working Group of the Technical Study.²¹

Working Group on Reform of the Patent Cooperation Treaty (PCT)

31. At the fourth session of the Working Group on Reform of the Patent Cooperation Treaty (May 19 to 23, 2003), Switzerland submitted proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications (document PCT/R/WG/4/13). The proposals were discussed by the Working Group at its fifth session (November 17 to 21, 2003; document PCT/R/WG/5/11 Rev.) and its sixth session (May 3 to 7, 2004), when Switzerland submitted additional comments on its proposals (document PCT/R/WG/6/11).

Seventh meeting of the COP to the CBD

32. At its seventh meeting, held in Kuala Lumpur from 9 to 20 February 2004, the COP of the CBD received the Technical Study produced by WIPO at its request. COP Decision VII/19E:

“Not[es] with appreciation the Technical Study on Disclosure Requirements Concerning Genetic Resources and Traditional Knowledge prepared by World Intellectual Property Organization at the request of the Conference of the Parties in decision VI/24 C and considering the contents of the Technical Study to be helpful in the consideration of intellectual property-related aspects of user measures.”

33. In the same Decision the COP further invited WIPO, as a follow up to the previous invitation, 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;

²⁰ See document UNEP/CBD/COP/7/6, paragraph 75 to 85.

²¹ The Preamble specifically states that the Working Group issues its Recommendations while: *“Noting with appreciation the Technical Study on Disclosure Requirements Concerning Genetic Resources and Traditional Knowledge prepared by World Intellectual Property Organization at the request of the Conference of the Parties in decision VI/24 C and considering the contents of the Technical Study to be helpful in the consideration of intellectual property-related aspects of user measures.”* See document UNEP/CBD/COP/7/6, Annex, page 27.

(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 Intergovernmental Committee (March 2004)

34. The additional invitation was formally communicated to WIPO by the CBD Secretariat and was received immediately prior to the Committee’s sixth session in March 2004. In view of the possible relevance of the invitation to the Committee’s own work on defensive protection measures (in particular disclosure mechanisms relating to genetic resources and TK), the Committee was advised of the invitation and was invited to consider it in the context of its ongoing work (WIPO/GRTKF/IC/6/11 and WIPO/GRTKF/IC/6/13). The Committee considered the invitation, but in view of the relevance of the invitation to other WIPO bodies, the invitation was referred to the WIPO General Assembly for consideration.²²

35. At the same session, the Committee also reviewed Draft “Guide Contractual Practices” for Intellectual Property Aspects of Access and Benefit Sharing Arrangements Relating to Genetic Resources.²³ This took forward the work initiated by the Committee at its first meeting. The draft was prepared on the basis of the input from the approved questionnaire (Questionnaire of Contractual Practices and Clauses relating to Intellectual Property, Access to Genetic Resources and Benefit-Sharing, WIPO/GRTKF/IC/Q.2) and the contributions made to the capacity-building database, with expert input from a consultant with experience in access and benefit-sharing arrangements. This draft was provided in line with the an initial draft as required by the Committee’s decision taken at its first session. The draft bore the note “These are draft materials only, to serve as the basis for discussion and development, based on the operational principles already established by the Committee. Further improvements could include a series of practical steps, specific examples and case studies, model or illustrative contractual provisions, and graphic representations of key issues and basic practical steps. The evolution of this draft would also need to take account of developments in other international forums.” The Committee “took note of the statements and the observations made [concerning the draft] and decided to invite further comments and input relating to the issue by June 30, 2004, whereupon a revised version of the document would be published for the next session of the Committee.”

General Assembly (September 2004)

36. At its Thirty-First Session, the WIPO General Assembly decided on a process to respond to the COP invitation (document WO/GA/31/8). Briefly, this included (i) an invitation by WIPO Member States to submit comments and proposals by December 15, 2004; (ii) the preparation of a draft examination and its circulation for comments by the end of January 2005; (iii) observations and comments on the draft to be submitted by Member

²² See WIPO/GRTKF/IC/6/14, paragraph 183.

²³ See document WIPO/GRTKF/IC/6/5.

States and accredited observers by the end of March 2005; (iv) publication on the website and in a consolidated document of all comments and observations received; (v) convening of a one-day *ad hoc* intergovernmental meeting to consider and discuss a revised version of the draft which would be available at least 15 days before the Meeting; (vi) preparation of a further revised draft to be presented to the WIPO General Assembly at its ordinary session in September 2005 for consideration and decision.

37. The first step in the procedure agreed by the WIPO General Assembly was for the Director General to invite all Member States ‘to submit proposals and suggestions before December 15, 2004.’ The invitation was accordingly circulated (C.7092 and C. 7093, November 10, 2004). By December 15, 2004, submissions had been received from the following Member States and groups of Member States: African Group, Australia, Belize, Brazil, Colombia, the European Community and its Member States, Ghana, the Islamic Republic of Iran, Japan, the Kyrgyz Republic, Peru on behalf of the Andean Community, the Russian Federation, Switzerland, Turkey, and the United States of America. These were posted on the Internet²⁴ and have been circulated as a provisional collation.

38. As provided in the agreed process, an initial draft examination of the issues was prepared on the basis of the suggestions and proposals of the Member States, which is intended to provide only an initial and preliminary basis for the continuing dialogue foreseen by the WIPO General Assembly.

Seventh session of the Intergovernmental Committee (November 2004)

39. In its work on genetic resources at its seventh session, the Committee considered a revised “Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing” (document WIPO/GRTKF/IC/7/9). This was a minor redraft of the previous document (WIPO/GRTKF/IC/6/5), based on comments received by the deadline set by the Committee and on comments made at the sixth session. The Committee also considered an update on the question of patent disclosure requirements relating to genetic resources (WIPO/GRTKF/IC/7/10). The update addressed two distinct matters: (a) it provided a factual on work within WIPO concerning the disclosure issue; and (b) it noted the existing proposals for possible further work on this issue within the Committee. The Committee considered, but did not reach a conclusion, on how to proceed further on the items concerning genetic resources that are currently on its agenda.

CBD Working Group on Access and Benefit-sharing (February, 2005).

40. A factual update on progress with the preparation of a draft examination on the issues was provided has also been provided to the third session of the CBD Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, which met in Bangkok, from February 14 to 18, 2005²⁵

²⁴ See www.wipo.int/tk/en/genetic/proposals/index.html#proposals

²⁵ See UNEP/CBD/WG-ABS/3/7, para 25 (‘Report of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing on the Work of its Third Meeting’), which states that: “The representative of WIPO described in detail activities that had been undertaken in response to requests from the seventh meeting of the Conference of the Parties, including a request for regular reports on the activities of his Organization with respect to access and benefit-sharing and on cooperative activities that it had undertaken with the Conference of the Parties.”

Ad hoc Intergovernmental Meeting on Genetic Resources and Disclosure Requirements
(June, 2005)

41. In line with the procedure established by the General Assembly, a one-day *ad hoc* intergovernmental meeting is scheduled for June 3, 2005, to consider and discuss a revised version of the draft revised draft examination of issues relating to the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications.

II. SUBSTANTIVE ISSUES ARISING FROM RECENT DEVELOPMENTS

42. 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.

Substantive IP issues concerning defensive protection of genetic resources

43. 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). Detailed submissions illustrated specific cases of potential misappropriation of genetic material and put forward options for addressing such cases.²⁶ Other UN agencies, such as the FAO, have requested WIPO to cooperate in analyzing and addressing similar concerns in specific sectors.²⁷ 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; and improved disclosure mechanisms for genetic resources in patent applications.

Substantive IP issues concerning disclosure requirements

44. Discussions also covered questions surrounding specific disclosure requirements in patent applications for information relating to genetic resources which have been utilized in

²⁶ See document submitted by Peru (WIPO/GRTKF/IC/5/13)

²⁷ See FAO document CGRFA-9/02/REP.

the claimed invention. 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.

45. These discussions have focussed on the potential integration of new or expanded disclosure requirements into existing patent systems. The debate also raises conceptual and practical questions about the linkage and synergies between disclosure requirements 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. As the CBD Secretariat has pointed out to the Committee, disclosure requirements are thus linked to larger regulatory questions relating to access and benefit-sharing frameworks, in addition to the question of their compatibility with, and integration into, specific existing IP agreements. Commentators have pointed out that these conceptual questions regarding the interrelation and synergies between patent disclosure requirements and access and benefit-sharing regimes are not exhaustively addressed in the discussions on the compatibility of disclosure requirements with existing patent systems or their integration into the mechanics of existing systems.²⁸

Substantive IP issues concerning mutually agreed terms for fair and equitable benefit-sharing

46. 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,”²⁹ 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),³⁰ as well as in the sharing of non-monetary benefits.³¹ 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.³² 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

²⁸ See *User Measures. Options for Developing Measures in User Countries to Implement Access and Benefit-sharing Provisions of the Convention on Biological Diversity*. UNU/IAS, 2003.

²⁹ Art. 15.4 CBD.

³⁰ See Items 1(j) in the catalogue of Monetary Benefits listed in Appendix II of the Bonn Guidelines.

³¹ See item 2(q) of Appendix II, Bonn Guidelines.

³² See Decision VI/24C, Convention on Biological Diversity, para. 9.

prepared and circulated, and initial drafts of guide practices for access and benefit-sharing agreements were prepared. The Database has been recently updated with several new agreements, and the latest draft on guide practices was circulated for consideration at the Committee's last 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.

III. POSSIBLE OPTIONS FOR THE COMMITTEE

47. 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 and FAO.

48. 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 defensive protection

49. 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;³³

³³ This has already been successfully accomplished for periodicals concerning disclosed TK, as foreseen in WIPO/GRTKF/IC/2/6, paras 41 to 45.

- 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);³⁴
- 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.³⁵

Questions for guidance on disclosure requirements

50. 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 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, scheduled for June 3, 2005). 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 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;³⁶
- 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;³⁷

³⁴ See WIPO/GRTKF/IC/3/6, para 15.

³⁵ This has already been for patent applications involving disclosed TK. See WIPO/GRTKF/IC/2/6, para 52.

³⁶ 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).

³⁷ The Committee considered such proposals at the first and fifth session. See WIPO/GRTKF/IC/5/10, para 12(ii).

Questions for guidance on IP and mutually agreed terms for fair and equitable benefit-sharing

51. 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;³⁸

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 the Annex of document WIPO/GRTKF/IC/7/9;³⁹ 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.⁴⁰

52. 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.

IV. CONCLUSION

53. The present document narrates the past work on IP and genetic resources in WIPO and other relevant international fora with which the Committee has cooperated closely since its inception. The document describes 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. 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.

³⁸ See WIPO/GRTKF/IC/2/12; WIPO/GRTKF/IC/2/16.

³⁹ See WIPO/GRTKF/IC/5/9; WIPO/GRTKF/IC/6/5; WIPO/GRTKF/IC/7/9.

⁴⁰ See WIPO/GRTKF/IC/6/14

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

[Annex I follows]

WIPO/GRTKF/IC/8/9
ANNEX I

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

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)

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

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 Utilisation 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

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

[Annex II follows]

PAST OPTIONS FOR POSSIBLE ACTIVITIES

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

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.

[End of Annex II and of document]