

WIPO



WIPO/GRTKF/IC/13/8(b)

ORIGINAL: English

DATE: September 8, 2008

E

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

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

Thirteenth Session
Geneva, October 13 to 17, 2008

**GENETIC RESOURCES:
FACTUAL UPDATE OF INTERNATIONAL DEVELOPMENTS**

Document prepared by the Secretariat

CONTENTS

I. WIPO ACTIVITIES	2
II. WORLD TRADE ORGANIZATION (WTO) TRIPS COUNCIL	10
III. FOOD AND AGRICULTURAL ORGANIZATION (FAO)	12
IV. CONVENTION ON BIOLOGICAL DIVERSITY (CBD)	15
V. INTERLAKEN DECLARATION ON ANIMAL GENETIC RESOURCES	19
VI. MARINE GENETIC RESOURCES	20

SUMMARY

1. At its tenth session, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“the Committee”) requested the preparation of a (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. At its twelfth session, the Committee requested a further update of international developments. The present document, WIPO/GRTKF/IC/13/8(b), provides the required update of international developments.

FACTUAL UPDATE OF INTERNATIONAL DEVELOPMENTS

2. This document updates the information on international developments provided to the Committee in documents WIPO/GRTKF/IC/8/9, WIPO/GRTKF/IC/11/8(b) and WIPO/GRTKF/IC/12/8(b). It covers relevant international developments before and after the creation of the Committee in chronological order, in order to provide a full account of international developments, given that 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 extend beyond the activities of, the Committee itself. Therefore, this document 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.

For ease of reference, in contrast to past versions of this document, the update is provided according to the main international processes concerned, namely WIPO itself, the World Trade Organization (WTO), the Convention on Biological Diversity and the Food and Agricultural Organization.

I. WIPO ACTIVITIES

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

3. 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).

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

4. 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.¹

WIPO Working Group on Biotechnology (November 1999)

5. 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)

6. 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)

7. 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.”

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

WIPO General Assembly (September 2000)

9. 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

¹ See document SCP/3/11, paragraph 208.

purpose of discussions on, *inter alia*, IP issues that arise in the context of access to genetic resources and benefit-sharing.

First session of the Intergovernmental Committee

10. 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, 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

11. 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.

12. 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].”²

13. 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 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.

14. 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.³

Third session of the Intergovernmental Committee

15. At its third session, the Committee received the requests of the COP through a document submitted to the Committee by the CBD Secretariat.⁴

16. 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

17. 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,

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

³ 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.

⁴ Document WIPO/GRTKF/IC/3/12.

the reports of its eighth, ninth and tenth sessions, documents SCP/8/9, SCP/9/8, and SCP/10/10 respectively).

Fourth session of the Intergovernmental Committee (December 2002)

18. 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.

Fifth session of the Intergovernmental Committee (July 2003)

19. At its fifth session, the Committee considered a document on Practical Mechanisms for the Defensive Protection of Genetic Resources within the Patent System,⁵ 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.

20. 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.⁶ The Secretariat of the Convention on Biological Diversity highlighted to the Intergovernmental Committee⁷ 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)

21. 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

⁵ WIPO/GRTKF/IC/5/6

⁶ WIPO/GRTKF/IC/5/15

⁷ WIPO/GRTKF/IC/5/15

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.

22. 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 Group⁸ and provided the basis for deliberations which led to the adoption of Recommendations to the COP on the issues addressed in the Study.⁹ The Preamble of the Recommendations reflects the positive reception by the Working Group of the Technical Study.¹⁰

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

23. 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).

Sixth session of the Intergovernmental Committee (March 2004)

24. 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.¹¹

25. At the same session, the Committee also reviewed Draft “Guide Contractual Practices” for Intellectual Property Aspects of Access and Benefit Sharing Arrangements Relating to

⁸ See document UNEP/CBD/COP/7/6, paragraphs 10 to 12, and 81.

⁹ See document UNEP/CBD/COP/7/6, paragraph 75 to 85.

¹⁰ 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.

¹¹ See WIPO/GRTKF/IC/6/14, paragraph 183.

Genetic Resources.¹² 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 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." These provisions were subsequently updated and reviewed by the Committee at its seventh session.

WIPO General Assembly (September 2004)

26. 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 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.

27. 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 Internet¹³ and have been circulated as a provisional collation.

28. 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.

¹² See document WIPO/GRTKF/IC/6/5.

¹³ See www.wipo.int/tk/en/genetic/proposals/index.html#proposals

Seventh session of the Intergovernmental Committee (November 2004)

29. 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.

Ad hoc Intergovernmental Meeting on Genetic Resources and Disclosure Requirements (June, 2005) and WIPO General Assembly (September 2005)

30. In line with the procedure established by the General Assembly, a one-day *ad hoc* intergovernmental meeting was held on 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. Following this meeting, the draft examination of issues was revised in line with the comments of Member States and observers, and submitted to the General Assembly for its consideration. The General Assembly, in turn, approved the examination of issues for transmission to the CBD COP, and it was forwarded accordingly.

Latest developments at the IGC

31. At its eleventh session, the Committee considered two additional documents, a “List of options” (document WIPO/GRTKF/IC/11/8(a)) and the “Factual Update of International Developments” (document WIPO/GRTKF/IC/11/8(b)). Among the options listed in document WIPO/GRTKF/IC/11/8(a) are mandatory disclosure requirements as proposed by the European Union, databases, the development of case studies, recommendations or guidelines or mandatory requirements. The Secretariat was asked to prepare a further update of international developments based on document WIPO/GRTKF/IC/11/8(b) which would include more recent developments, and any other relevant developments reported to the Committee. Document WIPO/GRTKF/IC/11/8(a) remain on the table in its existing form and comments made in relation to it were noted.

32. At its twelfth session, the Committee reached a compromise agreement on steps for the future work. In relation to traditional cultural expressions/expressions of folklore (TCEs/EoF) and traditional knowledge (TK), it was agreed that the Secretariat will prepare for the next IGC a working document that will: (a) describe what obligations, provisions and possibilities already exist at the international level to provide protection for TCEs/EoFs; (b) describe what gaps exist at the international level, illustrating those gaps, to the extent possible, with specific examples; (c) set out considerations relevant to determining whether those gaps need to be addressed; (d) describe what options exist or might be developed to address any identified gaps, including legal and other options, whether at the international, regional or national level; (e) contain an annex with a matrix corresponding to the items mentioned in

sub-paragraphs (a) to (d) above. The Secretariat will also make explicit the working definitions or other bases upon which its analysis is conducted.

33. On Genetic Resources, the decision also mentioned that the Secretariat will also reissue document titled "Genetic Resources: List of Options" (document WIPO/GRTKF/IC/12/8(a)) and update document WIPO/GRTKF/IC/12/8(b) ("Genetic Resources: Factual Update of International Developments") for full in-depth discussion at the thirteenth session.

34. It was also agreed that at the next IGC, the Committee will consider taking a decision on the proposed modalities and terms of reference for the establishment of intersessional mechanisms or processes, as well as other possibilities, to continue and to build on the progress achieved so far, in a structured and focused manner, the technical work of the Committee on the three substantive items between its sessions, on the basis of proposals submitted.

II. WORLD TRADE ORGANIZATION (WTO) TRIPS COUNCIL

35. Prior to the 2001 Doha Declaration, the review of Article 27.3(b) on exclusion of patentability began in 1999 as required by the TRIPS Agreement. The topics raised in the TRIPS Council's discussions included among others how to deal with the commercial use of traditional knowledge and genetic material by those other than the communities or countries where these originate, especially when these are the subject of patent applications. Discussions also included how to ensure the TRIPS Agreement and the UN Convention on Biological Diversity (CBD) support each other.¹⁴

36. The 2001 Doha Declaration made it clear that work in the TRIPS Council should cover the protection of traditional knowledge and folklore and the relationship between the TRIPS Agreement and the CBD.

37. The discussion in the TRIPS Council has gone into considerable detail with a number of ideas and proposals for dealing with these complex subjects.

38. The ideas put forward include:

- Disclosure as a TRIPS obligation: A group represented by Brazil and India and including Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Peru, Thailand, and supported by the African group and some other developing countries, wants to amend the TRIPS Agreement so that patent applicants are required to disclose the country of origin of genetic resources and traditional knowledge used in the inventions, evidence that they received "prior informed consent", and evidence of "fair and equitable" benefit sharing.
- Disclosure through WIPO: Switzerland has proposed an amendment to the regulations of WIPO's Patent Cooperation Treaty (and, by reference, WIPO's Patent Law Treaty) so that domestic laws may ask inventors to disclose the source of genetic resources and traditional knowledge when they apply for patents. Failure to meet the requirement could hold up a patent being granted or, when done with fraudulent intent, could entail a granted patent being invalidated.

¹⁴ WTO website.

- Disclosure, but outside patent law: The EU's position includes a proposal to examine a requirement that all patent applicants disclose the source of origin of genetic material, with legal consequences of not meeting this requirement lying outside the scope of patent law.
- Use of national legislation including contracts rather than a disclosure obligation: The United States has argued that the CBD's objectives on access to genetic resources, and on benefit sharing, could best be achieved through national legislation and contractual arrangements based on the legislation, which could include commitments on disclosing of any commercial application of genetic resources or traditional knowledge.

39. On the eve of the 21-29 July 2008 WTO Ministerial meeting, a coalition of developed and developing country members led by Brazil, the EU, India and Switzerland presented document TN/C/W/52 covering the three current intellectual property issues: the relationship between the TRIPS Agreement and the CBD, extension of the protection of geographical indications provided for under Article 23 to products other than wines and spirits, and the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits. According to this text, members would agree to include these issues as part of the horizontal modalities process in order to have modality texts that reflect Ministerial Agreement on the key parameters for negotiating final draft legal texts with respect to each of these issues as part of the single undertaking. With respect to the TRIPS-CBD issues it was proposed that text-based negotiations would be undertaken in order to agree to amend the TRIPS Agreement so that all patent applications would be required to disclose the country providing/source of genetic resources and/or associated traditional knowledge used in the product in question. Members would also agree to define the nature and extent of the requirement on prior informed consent and benefit-sharing and consider additional elements in members' proposals in these negotiations.

40. On the other hand, a number of other members believe that these issues should not be addressed in the context of the modalities decision. They have expressed their strong opposition to this proposal and their conviction that it would substantially set back efforts to arrive at a viable way forward for the Doha negotiations. They reject what they consider to be an artificial parallelism being made in the proposal between the TRIPS issues cited, saying that each has its own terms of reference and subject-matter, many technical issues remain, and the interest of members in each varies considerably. With respect to the TRIPS-CBD issue, these members believe that the case has not been made as to how disclosure requirements of the sort proposed would contribute towards meeting the commonly accepted objectives, which these delegations believe can be met without amending the TRIPS Agreement, for example through the establishment under WIPO of improved databases on traditional knowledge available to patent examiners and through contractual arrangements under national access and benefit-sharing laws. These members are willing to continue fact-based discussions under the present process of work as agreed in paragraph 39 of the Hong Kong Ministerial Declaration on issues related to the relationship between the TRIPS Agreement and the CBD, but without prejudice to the outcome and the positions of members.

41. The July meeting did not succeed in reaching agreement on certain other trade issues under negotiation. The future of talks within the WTO on a possible amendment of the TRIPS Agreement to include a requirement for disclosure of origin of genetic resources

and/or associated traditional knowledge in patent applications appears to remain linked to an agreement on these other issues. Discussion on Intellectual property issues by key delegations during the ministerial meeting were facilitated by the Norwegian Foreign Minister.

III. FOOD AND AGRICULTURAL ORGANIZATION (FAO)

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

42. 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.¹⁵ 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 mechanism¹⁶ (Article 14.2(d)(iv)¹⁷). 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.

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

43. 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’.¹⁸ 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

¹⁵ See document CGRFA/CG-6/01/2.

¹⁶ 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).

¹⁷ Four countries stated that they do not agree with the text of Article 14.2(d)(iv). See CGRFA/CG-6/01/2.

¹⁸ US patent 5,894,079.

rights may affect the availability and use of material from the International Network and the International Treaty.”¹⁹

FAO Commission on Genetic Resources for Food and Agriculture (CGRFA), and Governing Body of the International Treaty

44. At its ninth session, the CGRFA requested “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”.²⁰ In response to this request, WIPO and FAO have cooperated to analyze how IP rights might affect the availability and use of plant genetic resources for food and agriculture. WIPO provided a first progress report on its work regarding this request at the Second Meeting of the CGRFA acting as Interim Committee for the International Treaty, in November 2004, entitled *Preliminary report on work towards the assessment of patent data relevant to availability and use of material from the International Network of Ex-Situ Collections under the Auspices of FAO and the International Treaty*.²¹ To commence work towards the request, this progress report only considered patents, rather than intellectual property more generally. One initial pathway to gaining insights on this question was to build up an information base on relevant patents and patent applications. To initiate this process, using existing patent search algorithms, sample searches were conducted in order to test the methods and broadly illustrate the type of information that could be generated, and on that basis to pose questions about how such information could be refined and used to clarify understanding about the effects on availability and use. The main insight from these preliminary sample searches was to illustrate the choices involved in developing a search method, and the *type* of data that might be obtained through its use. It illustrated the limitations of the conclusions that can be drawn from broad-brush patent searching, and underscored the need for careful analysis of the content, scope and implications of specific patents before any substantive assessments can be made. Above all, the exercise illustrated the need for more extensive examination of the patent landscape, and the broader legal context that surrounds particular crops, before any practical assessment could be made about the effect on availability and use of material that may be covered by patents. The document ended by identifying options for such follow-up work. The CGRFA acting as the Interim Committee “welcomed this Preliminary Report, which was of significant value to the agricultural community, and the continuing cooperation with WIPO”.²² In its Report, the Interim Committee “looked forward to receiving the report of the next stage of this work, in line with the follow-up activities identified in the preliminary report”.²³

45. In 2006, WIPO provided a second progress report on the follow-up work identified in its first findings to the first session of the Governing Body of the International Treaty, entitled *Progress Report on Work Towards the Assessment of Patent Data Relevant to Agricultural Biotechnology and the Availability and Use of Material from the International Network of Ex-Situ Collections Under the Auspices of FAO and the International Treaty: A Draft Patent*

¹⁹ 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>>.

²⁰ CGRFA-9/02/REP, paragraph 31.

²¹ CGRFA/MIC-2/04/Inf.5, <ftp://ftp.fao.org/ag/cgrfa/mic2/m2i5e.pdf>

²² CGRFA/MIC-2/04/REP, Report of the Commission on Genetic Resources for Food and Agriculture, paragraph 31; available at:

²³ Ibid.

*Landscape Surrounding Gene Promoters Relevant to Rice.*²⁴ This Progress Report contained a factual description of the international patent landscape surrounding gene promoters relevant to rice. Rice had been selected by FAO and WIPO for the draft patent landscape because of its crucial importance for food security. FAO selected gene promoters as an illustrative technology for the initial set of patent searches and analysis. Gene promoters regulate the transcription of genetic information from DNA (gene expression), and are therefore key tools in agricultural biotechnology and in the use of plant genetic resources for food and agriculture in research and development. Some initial observations that arose from this progress report included a first review of trends in research and development on these key research tools, including the comparative degree of public and private sector activity, the emergence of research collaborations, and the genes and the traits they express that are of interest to the research community. The Progress Report noted that similar searches would be conducted for maize, potato and soybean, and would subsequently be added to the Report.

46. WIPO participated as an observer, in the meetings of the CGRFA acting as Interim Committee for the International Treaty on Plant Genetic Resources for Food and Agriculture and in meetings of the Interim Committee's Contact Group for the Drafting of the Standard Material Transfer Agreement. At its First Session, held in June 2006 in Madrid, the Governing Body addressed and resolved a number of major questions, which now make the Treaty fully operative.

47. The Governing Body adopted, in particular, the Standard Material Transfer Agreement, which is the legal instrument by which plant genetic resources for food and agriculture under the Treaty's Multilateral System of Access and Benefit-sharing may be accessed, and which makes provision for the fair and equitable sharing of the commercial benefits resulting from the use of such resources. The Standard Material Transfer Agreement provides for payment to the Treaty's Funding Strategy of 1.1% of the sales of a commercialized product, such as a new crop variety, which incorporates material accessed from the Multilateral System, when there are restrictions such as patent protection, that result in the product not being freely available to others for research and breeding. Users of the Multilateral System can also opt for a crop-based payment system, whereby they pay at a lower rate (0.5%), on all their commercialized products of a particular crop, regardless of whether material from the Multilateral System is incorporated in those products, and whether or not they are freely available to others for research and breeding. The Governing Body invited FAO to act as the Third Party Beneficiary, which has the role of representing the Governing Body in any dispute settlement procedures that may be necessary.

Second session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR), Rome, Italy, October 29-November 2, 2007

48. The Governing Body considered: financial rules, the funding strategy, including the recommendations of the Ad Hoc Advisory Committee regarding priorities, eligibility criteria and operational procedures for the allocation of funds under the direct control of the Governing Body, the relationship with the Global Crop Diversity Trust, implementation of the Multilateral System (MLS) for access and benefit-sharing, including procedures for the Third Party Beneficiary; the material transfer agreement (MTA) for non-Annex I crops acquired prior to the Treaty's entry into force, implementation of Article 6 (Sustainable use of plant genetic resources) and Article 9 (Farmer's rights); relationship between the Governing Body

²⁴ IT/GB-1/06/Inf.17.

and the Commission on Genetic Resources for Food and Agriculture (CGRFA); cooperation with other international organizations and the possible establishment of a permanent technical advisory committee.

49. The meeting also adopted a resolution on farmers' rights, and a statement of intent to organize and strengthen collaboration with the CGRFA. However, the financial rules for the Governing Body remain pending, and discussions on compliance were also deferred, despite the GB-1 decision that the Governing Body was to consider and approve procedures for compliance at its second session.

FAO-WIPO cooperation on Patent Landscaping

50. The FAO and WIPO cooperated on the undertaking of a Symposium on Public Policy Patent Landscaping in the Life Sciences at WIPO, on April 7 and 8, 2008, within the context of a cooperation program between the FAO and WIPO on patent landscaping for policymakers. The Symposium included a preliminary technical consultation on patent landscapes commissioned by the FAO and WIPO, for close expert review, and a full peer review of the WIPO FAO patent landscapes and review of future directions in using patent information mechanisms for policymakers in relation to plant genetic resources.

IV. CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

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

51. 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.²⁵ Recognizing 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;

²⁵ See Decision VI/24C, paragraphs 1 and 2.

- (d) The source of associated traditional knowledge, innovations and practices; and,
- (e) Evidence of prior informed consent.”

52. 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.”²⁶

53. 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”²⁷

54. 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:

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

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;

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

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;

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

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

Role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights.”²⁸

55. 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;”²⁹

²⁶ See Decision VI/24C, Convention on Biological Diversity, para. 9.

²⁷ See Decision VI/24C, Convention on Biological Diversity, para. 10.

²⁸ See Decision VI/24C, Convention on Biological Diversity, para. 3.

²⁹ See Decision VI/24C, Convention on Biological Diversity, para. 11.

Seventh meeting of the COP to the CBD

56. 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.”

57. 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;
- (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.”

58. On the recommendation of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), the COP adopted a Programme of Work on Technology Transfer and Technological and Scientific Cooperation for the CBD. Several elements in this Programme of Work pertain *inter alia* to WIPO, such as Activities 2.1.1 and 2.1.2 (Information Systems) and a specific invitation to WIPO and other agencies to prepare technical studies that further explore and analyze the role of IP rights in technology transfer in the context of the CBD (Activity 3.1.1 under Creating Enabling Environments). The WIPO Secretariat has worked actively with the SCBD and the Secretariat of UNCTAD to prepare draft technical materials that could form the basis of the study on the role of IP rights in technology transfer. This draft, which does not reflect an official WIPO position, has been finalized following a peer review. WIPO has undertaken other, related work, in partnership with the SCBD and in line with the joint MoU. This work draws on past WIPO analysis of the role of IP rights in technology transfer under other Multilateral Environmental Agreements (MEAs).

Information Systems - Programme Element 2 of the CBD Work programme on Technology Transfer

59. Activity 2.1.3 (on Information Systems) of this work programme foresees the “development of advice and guidance on the use of new information exchange formats,

protocols and standards to enable interoperability among relevant existing systems of national and international information exchange, including technology and patent databases.” WIPO has held informal discussions with the SCBD with a view to further cooperation to enhance interoperability among relevant existing systems, in particular patent databases, so as to promote access to this technological information and the more effective use of this information as a means of promoting and analyzing patterns in technology transfer relevant to the CBD. The recent launch of PatentScope, a new portal on patents and the international patent system, and enhanced patent information resources by WIPO, can be expected to provide a useful platform for expanded cooperation in this area.

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

60. 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, 2005³⁰

Eighth meeting of the Conference of the Parties to the Convention on Biological Diversity, Curitiba, Brazil, March 20 to 31, 2006.

61. The WIPO examination of issues was reviewed by the COP at its eighth meeting as document UNEP/CBD/COP/8/INF/7. The COP also reviewed the progress made in the Ad Hoc Open-ended Working Group on Access and Benefit-sharing to elaborate and negotiate an international regime on access and benefit sharing, and transmitted an annex, entitled *International Regime on Access and Benefit-Sharing* (reflecting the range of views held by Parties at the fourth meeting of the Ad Hoc Open-ended Working Group), to the fifth meeting of the Ad Hoc Open ended Working Group for the purposes of continuing to elaborate and negotiate the international regime in accordance with decision VII/19 D, as well as, inter alia, the following inputs for the elaboration and negotiation of an international regime: (a) the outcomes of the group of technical experts on the certificate of origin/source/legal provenance; (b) a progress report on the gap analysis, and the matrix, and (c) other inputs submitted by Parties relating to access and benefit-sharing.³¹

62. The COP also invited Parties, Governments, relevant international organizations, indigenous and local communities and all relevant stakeholders to submit their views and information to the CBD Executive Secretary; these views would be compiled together with the other information requested for the Ad Hoc Open-ended Working Group at its fifth meeting.

³⁰ 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.”

³¹ UNEP/CBD/COP/8/31 (15 June 2006)

Sixth meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (ABS), Geneva, Switzerland, January 21 to 25, 2008

63. In a continuation of the fifth meeting of the Working Group, held in October 2007, the Working Group proceeded with the elaboration and negotiation of an international regime on ABS. Discussions focused on the main components of the international regime, including fair and equitable sharing of benefits, access to genetic resources, compliance, traditional knowledge and genetic resources, and capacity building. The Working Group made considerable progress in producing a new, short and concise working document on the international regime, consisting of sections on the main components and list of items “to be further elaborated with the aim of incorporating them in the international regime” in cases where there was agreement in principle, or “further consideration” in cases of disagreement or need for further clarification. The outcome of the deliberations will be submitted for consideration by the Conference of the Parties to the CBD at its ninth meeting, to be held from 19-30 May 2008, in Bonn, Germany, where critical decisions will need to be taken on the future of the ABS negotiations, with the 2010 deadline for completion rapidly approaching.

Ninth Conference of the Parties, Convention on Biological Diversity (CBD COP 9), Bonn, Germany, May 19 to 30, 2008

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

- (i) compliance;
- (ii) concepts, terms, working definitions and sectoral approaches; and
- (iii) traditional knowledge associated with genetic resources.

V. INTERLAKEN DECLARATION ON ANIMAL GENETIC RESOURCES

65. In recognition of the need to develop an effective framework for the management of animal genetic resources and to address the threat of genetic erosion, 109 countries came together in September 2007 at the first International Technical Conference on Animal Genetic Resources for Food and Agriculture held in Interlaken, Switzerland. The Conference adopted the Global Plan of Action for Animal Genetic Resources - which includes 23 strategic priorities for action to promote the wise management of these vital resources. The Global Plan of Action is the outcome of a country-driven process of reporting, analysis and discussion, which also resulted in the preparation of The State of the World's Animal Genetic Resources for Food and Agriculture, the first comprehensive global assessment of livestock diversity and its management. The Conference also adopted the Interlaken Declaration on

Animal Genetic Resources, which affirms countries' commitment to the implementation of the Global Plan of Action and to ensuring that the world's livestock biodiversity is utilized to promote global food security and remains available to future generations.

66. The Interlaken Declaration on Animal Genetic Resources "affirm[s] the desirability, as appropriate, subject to national legislation, of respecting, preserving and maintaining traditional knowledge relevant to animal breeding and production as a contribution to sustainable livelihoods[.]" The Global Plan of Action for Animal Genetic Resources aims, among other things, "to promote a fair and equitable sharing of the benefits arising from the use of animal genetic resources for food and agriculture, and recognize the role of traditional knowledge, innovations and practices relevant to the conservation of animal genetic resources and their sustainable use, and, where appropriate, put in place effective policies and legislative measures."

VI. MARINE GENETIC RESOURCES

67. The eighth meeting of the UN Open ended Informal Consultative Process on Oceans and the Law of the Sea, held from 25 to 29 June 2007, focused its discussions on the topic "marine GR". The in depth consideration of the topic took place in a discussion panel as well as in plenary sessions. The report of the Secretary General on oceans and law of the sea (contained in document A/62/66) and in particular its chapter on marine GR provided background information for the meeting. Panel discussions covered activities related to marine GR in particular experiences in collection and in commercialization, and international cooperation and coordination on issues related to marine GR, including current activities at the global and regional levels, as well as current and future challenges. IP rights in relation to marine GR was further raised in the ensuing discussions and the need for a better understanding of several aspects of IP regimes in relation to marine GR was highlighted.

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

[End of document]