



CBD Request to WIPO on the Interrelation of Access to Genetic Resources and Disclosure Requirements

Establishing an adequate framework for a WIPO Response¹

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¹ This note has been prepared under the South Centre and Center for International Environmental Law (CIEL) joint project aimed at improving the participation of developing countries in international intellectual property standard-setting.

I. Introduction

1. In October 2004, the Assemblies of the World Intellectual Property Organization (WIPO) decided to respond positively to the invitation of the Convention on Biological Diversity (CBD) for WIPO “to examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the CBD, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications” and established a procedure for preparing the response.² The CBD invitation had elicited a number concerns, even prior to its discussion in the Assemblies. First, there were concerns that the request would be addressed only in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (IGC), thus negatively impacting developing country and non-governmental organization (NGO) efforts to advance the protection of genetic resources and traditional knowledge in a simultaneous and coherent manner across all relevant WIPO bodies. The modalities established by the Assemblies to address the CBD request, which establish a cross-cutting procedure open to all WIPO Members and to observers accredited to the IGC, Standing Committee on the Law of Patents (SCP) and Working Group on PCT Reform (PCT Reform WG), are, in this regard, a positive development. A second set of concerns related to ensuring WIPO’s response adequately reflect the context of the invitation – the CBD objectives and process – as well as the state of discussions in its own bodies. Again, the modalities established present an important opportunity for developing countries and NGOs to indicate the fundamental principles and concepts that an adequate WIPO response should incorporate. In particular, the December 15, 2004, deadline for Member States of WIPO to submit proposals and suggestions is crucial in influencing the process from its very beginning.

2. The objective of the present note is to suggest several principles that would provide an essential framework for WIPO’s examination of the interrelation of access to genetic resources and disclosure requirements in patent applications. These principles arise from the invitation of

² See Decision on Item 10 – Invitation addressed to WIPO by the Contracting Parties of the Convention on Biological Diversity. The following modalities and timetable were adopted:

(i) the Director General will invite all Member States of WIPO to submit proposals and suggestions before December 15, 2004;

(ii) a first draft of the examination (the draft) will be prepared by the International Bureau and published on the WIPO website and circulated by the end of January 2005 to all Member States of WIPO and observers accredited to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), Standing Committee on the Law of Patents (SCP) and Working Group on PCT Reform (PCT Reform WG) for observations and comments;

(iii) all Member States and these accredited observers may submit observations and comments on the draft by the end of March 2005;

(iv) all comments and observations received will be published on the WIPO website as and when received and in a consolidated document following the expiration of the time period for the submission of such comments and observations;

(v) a one-day ad hoc intergovernmental meeting will be held in May 2005 to consider and discuss a revised version of the draft. The revised version of the draft will be made available at least 15 days before the Meeting. All Member States of WIPO and the accredited observers will be invited to attend the Meeting, which shall elect its chair and will be held under the General Rules of Procedure of WIPO. With respect to the scheduling of this meeting, the meeting shall be scheduled to occur on a date that will permit the participation of the maximum number of observer organizations of indigenous and aboriginal peoples;

(vi) the International Bureau, shall prepare a further revised draft following the Meeting which shall be presented to the WIPO General Assembly at its ordinary session in September 2005 for consideration and decision.

the CBD, from the CBD decision within which the invitation was made, and from other decisions made by WIPO at its Assemblies. They include the need to support and not run counter to the objectives of the CBD; the recognition of the leading role of the CBD in biodiversity-related issues; the integration of the development dimension; and the need to, only where appropriate, address the issues proposed by the CBD request. Consideration of these principles by WIPO would ensure that its response is adequately placed in the context of the CBD objectives, reflects an appropriate cooperation between the CBD, WIPO, and other relevant international organizations, and effectively incorporates development concerns. In addition, these principles would direct the response towards accurately portraying ongoing discussions and negotiations on these issues in the different WIPO bodies.

II. Supporting and not running counter to the objectives of the CBD

3. Intellectual property is relevant in the context of the CBD as an instrument to support the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. Access to and sharing of the benefits arising out of the commercial and other utilization of genetic material is an important part of the biodiversity debate because products developed from genetic resources found in developing countries often, instead of fueling their economic and social development, are protected by patents or other intellectual property rights that do not recognize or equitably reward the provider countries.³ In this regard, Article 16, paragraph 5, of the CBD requires Contracting Parties, to ensure that intellectual property rights are supportive of and do not run counter to CBD objectives. At the same time, intellectual property rules can play an important role in supporting prior informed consent (PIC) and fair and equitable benefit sharing, the core requirements in the CBD access and benefit-sharing objectives.⁴ The importance of intellectual property and other legal measures in implementing access and benefit-sharing arrangements envisaged by the Convention is recognized in Article 15, paragraph 7, which calls upon each Contracting Party to take legislative, administrative or policy measures aiming to ensure benefits arising from the use of genetic resources are shared in a fair and equitable way with the Contracting Party providing the genetic resources.

4. Disclosure of origin in patent applications has thus been analyzed in the CBD context as an instrument to ensure the traceability of genetic resources and to support compliance with PIC and fair and equitable benefit sharing. The First Meeting of the Panel of Experts on Access to Genetic Resources and Benefit-sharing, convened by the COP in 1999, stated, for instance, that a system in which intellectual property applications required evidence of PIC would create an incentive for users to effectively comply with these CBD provisions.⁵ The Ad Hoc Open-ended Working Group on Access and Benefit-sharing recognized that disclosure of the use of genetic resources and traditional knowledge in applications for intellectual property rights may assist patent examiners in the identification of prior art and noted that disclosure of origin and evidence of PIC requirements already exist in a number of countries as a precondition for the granting of patents.⁶ Moreover, the Sixth Meeting of the COP in 2002 invited Parties and Governments to

³ CBD Secretariat, "Sustaining Life on Earth: How the Convention on Biological Diversity promotes nature and human well being," available at <http://www.biodiv.org/doc/publications/guide.asp>.

⁴ See, e.g., COP Decision II/12 and report of the first meeting of the CBD Working Group on Access and Benefit Sharing.

⁵ See Report of the Panel of Experts on Access and Benefit-sharing, document UNEP/CBD/COP/5/8, paragraph 127 (2 November 1999).

⁶ See Recommendations adopted by the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, document UNEP/CBD/COP/6/6, Annex (31 October 2001).

encourage the disclosure of the country of origin of the genetic resources and traditional knowledge in applications for intellectual property rights, where the subject matter of the applications concerns or makes use of genetic resources or such knowledge in its development, as a possible contribution to tracking compliance with PIC and the mutually agreed terms on which access to those resources and knowledge was granted.⁷

5. The CBD invitation to WIPO, and thus WIPO's response, must be understood and developed in this context.⁸ The need and value of the disclosure of origin requirement for the conservation and sustainable use of biodiversity have already been identified by the CBD. As a result, the response elaborated by WIPO should focus on ensuring these needs and concerns are adequately integrated into the international intellectual property system. As has been acknowledged by WIPO Member States, the aim of intellectual property discussions on the issue of biodiversity should be to prevent the misappropriation of genetic resources and traditional knowledge, ensure prior informed consent and equitable sharing of the benefits arising from the use of genetic resources and traditional knowledge, and promote the conservation and sustainable use of biodiversity.⁹

III. Recognizing the leading role of the CBD in international biological diversity issues

6. In this context, while WIPO as an institution has a significant role in terms of addressing these challenges within its own intellectual property rules, it should only provide peripheral input into the CBD process. Indeed, Decision VII/19 of the CBD, which invites WIPO to examine disclosure of origin requirements, also recalls the leading role of the CBD in international biological diversity issues. The comprehensive and balanced approach to the conservation and sustainable use of biodiversity, described above, as well as its broad membership and stakeholder participation, are among the factors that generate and support the prominence of the CBD on biodiversity issues. The disproportionate participation and influence of WIPO in the CBD process, therefore, has not only become increasingly controversial, but it may also prove detrimental to effectively achieving CBD objectives, as well as to maintaining the credibility and acceptance of the international intellectual property system.

7. The request of the CBD should thus not be interpreted or received as a delegation or deference. It should be noted that Decision VII/19 also invites the United Nations Conference on Trade and Development (UNCTAD) and other organizations to examine these issues and to report their findings. The WIPO response should be considered one particular contribution to the discussion and analysis of disclosure requirements, but not interpreted as providing any definitive examination of such requirements, advocating any particular approach, or developing any guidelines or recommendations with respect to the implementation of the CBD.¹⁰ In this regard, it is the CBD, with the support of its specialized sub-bodies and working groups, which will integrate the information and technical analysis from different sources with various approaches and complementary expertise into a framework adequate to its process, principles, and objectives.

⁷ See Report of the Sixth COP, document UNEP/CBD/COP/6/20, page 274 (27 May 2002).

⁸ Indeed, the CBD extended the invitation to WIPO in the framework of discussion dealing with measures to support compliance with PIC and mutually agreed terms on which access was granted.

⁹ Submission by the African Group, "Objectives, principles and elements of an international instrument, or instruments, on intellectual property in relation to genetic resources and on the protection of traditional knowledge and folklore," document WIPO/GRTKF/IC/6/12, March 15, 2004.

¹⁰ Such was the approach adopted by the previous study prepared by WIPO to the CBD. See note prepared by WIPO Secretariat, "Draft Technical Study on Disclosure Requirements related to Genetic Resources and Traditional Knowledge," document WIPO/GRTKF/IC/5/10 (May 2, 2003).

IV. Integrating the development dimension into the WIPO response

8. In elaborating a response to the CBD invitation, WIPO should consider not only the objectives of the CBD, but also the broad development goals that the UN has set for itself. At the 2004 Assemblies in which the request by the CBD request was addressed, WIPO welcomed the initiative to incorporate a development dimension into all of its activities.¹¹ WIPO thus accepted the challenge of determining how intellectual property, as a tool for public policy, should address and support sustainable development needs. In this regard, WIPO acknowledged internationally agreed development goals, including those in the United Nations Millennium Declaration and the Johannesburg Declaration on Sustainable Development.¹²

9. The conservation and sustainable use of biodiversity, which plays a critical role in overall sustainable development and poverty eradication, has been recognized as essential in achieving these development goals. The Johannesburg Declaration acknowledged the importance of biodiversity to human well-being and the livelihood and cultural integrity of people, and stated the loss of biodiversity can only be reversed if local people benefit from the conservation and sustainable use of biological diversity, in particular in countries of origin of genetic resources, in accordance with article 15 of the CBD.¹³ Moreover, it called for actions at all levels to integrate the objectives of the CBD into global, regional, and national programs and policies, in particular in those of the economic sectors of countries.¹⁴ The Seventh Meeting of the CBD COP also noted that achievement of the Millennium Development Goals are dependent on the effective conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. It thus urged Parties, Governments, and relevant intergovernmental organizations, as a contribution towards the Millennium Development Goals, to implement their activities in ways that are consistent with, and do not compromise, the achievement of the objectives of the CBD.¹⁵ The WIPO response to the CBD request should bear in mind these instruments and adequately address the issue in light of development concerns.

V. Examining, and where appropriate addressing, the interrelation of access to genetic resources and disclosure requirements

10. As WIPO is not in a position to provide any definitive examination of disclosure requirements in intellectual property applications or advocate any particular approach to these issues in the context of the CBD, the focus of the response should be in transmitting the discussions taking place in different WIPO bodies to ensure access and benefit sharing needs and concerns are adequately integrated into the international intellectual property system. In this regard, the summary and explanation of the different proposals and positions taken by Member States in the Standing Committee on the Law of Patents (SCP), the Working Group on the Reform of the Patent Cooperation Treaty (PCT), and the Intergovernmental Committee on

¹¹ Decision on Item 12 - Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO.

¹² *Id.*

¹³ Plan of Implementation of the World Summit on Sustainable Development, Chapter IV “Protecting and managing the natural resource base of economic and social development” paragraph 44.

¹⁴ *Id.*

¹⁵ See Decision VII/32 in Report of the Seventh Meeting of the COP of the CBD, document UNEP/CBD/COP/7/21 (13 April 2004).

Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore would be a valuable and balanced contribution that would not pre-judge the outcome of these discussions.

11. Discussion on the disclosure requirement in WIPO has indeed been generally limited to patents, which should be reflected in the response to the CBD. Nevertheless, within that context, a number of countries have expressed their positions as to the nature, triggers, elements, and effects of a potential requirement to disclose genetic resources and traditional knowledge in patent applications. For instance, the African Group proposed the requirement to disclose source and country of origin of the genetic resource in claimed inventions and of the associated traditional knowledge used in the invention, as well as evidence of compliance with national access and benefit sharing laws of the country of origin of genetic resources as disclosure requirement in patent laws, as one of the elements of an international instrument on intellectual property in relation to genetic resources and on the protection of traditional knowledge and folklore.¹⁶ A number of countries have addressed the scope for introducing a disclosure of origin requirement in Article 5 of the proposed Substantive Patent Law Treaty.¹⁷ Again, the WIPO response should only reflect the discussions that have taken place, and thus it would not be appropriate for it to address issues, such as the certificate of origin, which have not been the subject of debate among Member States.¹⁸

VI. Conclusion

12. Establishing an adequate framework for a WIPO response would ensure the work supports and not runs counter to the objectives of the CBD, recognizes the leading role of the CBD in international biological diversity issues, and fully integrates the development dimension. In this regard, the December 15th deadline for Member States of WIPO to submit proposals and suggestions was carefully negotiated and should be utilized as an essential opportunity for countries to establish the parameters of an appropriate response to the CBD request.

13. In addition, the adequate framework for a response from WIPO, as a Member-driven organization, should be limited to appropriate reflection of the discussions taking place in the different WIPO bodies. In this regard, it may be helpful, though not required, for Member States to re-state their main positions in their contributions to the CBD request process. Moreover, as many of developing countries' positions have been elaborated through broad consultation and collaboration, it may be valuable for Member States to jointly present their contributions. Even

¹⁶ See *supra* note 8.

¹⁷ In the Ninth Session of the SCP, for instance, the delegation of Argentina noted that, while paragraph (2)(a) prevented a Contracting Party from imposing further requirements, paragraph (1) did not appear to prevent a Contracting Party from requiring parts of an application additional to those listed, including information on the geographical origin of biological material. This view was supported by the delegation of India, which suggested that ambiguity be avoided by deleting paragraph (2) and clarifying the chapeau of paragraph (1) to make it clear that extra parts could be required. See the report of the Ninth Session, document SCP/9/8, at paragraph 78.

¹⁸ Issues mentioned in the CBD invitation include:

- (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;

more, WIPO should allow the sponsoring of the different positions by other Member States after December 15th. Such consideration would be necessary for many developing countries that may not have had the capacity to respond in time.

14. As the CBD request process at WIPO continues, participation will continue to be fundamental. A first draft of the examination will be circulated by the end of January 2005 to all Member States of WIPO and accredited observers, with a deadline in the end of March 2005 for observations and comments. A revised version of the draft will be considered and discussed during an ad hoc intergovernmental meeting in May 2005. Continuing contribution and monitoring of these developments will be essential to ensuring the process achieves a balanced and appropriate outcome that can be positively decided upon at the WIPO Assemblies in 2005.

15. Also important will be increasing coordination with the CBD delegates to ensure the CBD process continues playing leading role in the protection of biodiversity, while discussions in intellectual property fora focus on integrating biodiversity concerns into international intellectual property rules. In this regard, it should be noted that Decision VII/19 also requests the Ad hoc Open-ended Working Group on Access and Benefit-sharing to identify issues related to disclosure of origin requirements and transmit the results of this examination to WIPO. The third meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing is scheduled to meet in February 2005, in Bangkok, Thailand.