

Council for Trade-Related Aspects
of Intellectual Property Rights
Committee on Trade and Environment

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REVIEW OF THE PROVISIONS OF ARTICLE 27.3(b), RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY AND PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

Information from Intergovernmental Organizations

Addendum

Convention on Biological Diversity (CBD)

As agreed by the TRIPS Council, at its meeting of 5 to 7 March 2002, the Secretariat contacted the secretariats of the CBD, CGIAR, FAO, UNCTAD, UNEP, UPOV, WIPO and the World Bank, to request them to provide updated information on their activities in relation to the agenda items on review of the provisions of Article 27.3(b), relationship between the TRIPS Agreement and the Convention on Biological Diversity and protection of traditional knowledge and folklore.

The present document reproduces the information that the Secretariat has received from the Executive Secretary of the CBD. This document is being circulated to Members of the TRIPS Council and of the Committee on Trade and Environment.

I. INTRODUCTION

Intellectual property rights (IPRs) have a direct bearing on a number of issues under discussion in the framework of the Convention on Biological Diversity. At its third meeting, in November 1996, the Conference of the Parties recognized that *"further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity (see Decision III/17).*

Section two of the present note provides background information on relevant provisions of the Convention and bodies established by the Conference of the Parties to address the issues of access and benefit-sharing and traditional knowledge, as well as relevant decisions adopted by the Conference of the Parties. Section III presents an overview of recent developments regarding the role of intellectual property rights in access and benefit-sharing arrangements. Section IV examines developments with respect to intellectual property rights and the protection of traditional knowledge. Finally, section IV reviews recent developments under the Convention regarding the relationship between the CBD and the TRIPS Agreement.

II. BACKGROUND INFORMATION

A. RELEVANT PROVISIONS OF THE CONVENTION

Provisions of the Convention of relevance when considering issues related to intellectual property rights include:

- Article 15 on Access to genetic resources;
- Article 8(j) on Traditional knowledge, innovations and practices;
- Article 16 on Access to and transfer of technology;
- Article 19 on Handling biotechnology and distribution of its benefits.

As set out in Article 1 of the Convention, one of the three objectives of the Convention is *"the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."*

Article 15 of the Convention recognizes the sovereign rights of States over their natural resources. It also stipulates that *"each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties"*. It further provides that access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources and shall be granted on mutually agreed terms, and that benefits arising from the commercial or other utilization of genetic resources shall be shared upon mutually agreed terms.

The principal provision of the Convention on traditional knowledge is Articles 8(j) although other provisions also address this issue (articles 10(c), 17.2 and 18.4). Article 8(j) stipulates that, as far as possible and as appropriate, Parties shall *"[s]ubject to [their] national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices."*

Thus, the Convention recognizes, in Article 8(j), that indigenous and local communities should share in the benefits arising from the use of their knowledge. It also recognizes in Article 18, paragraph 4, that scientific and technical cooperation includes the use of traditional technologies in pursuance of the objectives of the Convention in which Contracting Parties shall also promote cooperation in the training of personnel and exchange of experts.

Access to and transfer of technology (Article 16) will be one of the themes for in depth consideration by the Conference of the Parties at its seventh meeting, to be held in Malaysia, in the first quarter of 2004. As for the handling of biotechnology, this is addressed under the Cartagena Protocol on Biosafety.

B. RELEVANT BODIES OF THE CONVENTION

The bodies established by the Conference of the Parties to address respectively the issues of access to genetic resources and benefit-sharing and the issue of the protection of traditional knowledge, innovations and practices of indigenous and local communities are the following:

Panel of Experts on Access and Benefit-sharing

A Panel of Experts was established by the Conference of the Parties in 1998 with the mandate to develop a common understanding of basic concepts and to explore all options for access and benefit-sharing on mutually agreed terms. The Panel met twice, in October 1999 and in March 2001.

One of the issues addressed by the Panel was the role of intellectual property rights in access and benefit-sharing arrangements. It identified specific issues that required further study (UNEP/CBD/COP/5/8), namely: the role of intellectual property rights in prior informed consent, intellectual property and traditional knowledge related to genetic resources, intellectual property rights and access and benefit-sharing agreements, scope, prior art and monitoring. At the request of the Conference of the Parties the Executive Secretary prepared a report on these specific issues, in consultation with the Secretariat of the World Intellectual Property Organization. The report is available on the CBD web site as document UNEP/CBD/WG-ABS/1/4.

Ad Hoc Open-ended Working Group on Access and Benefit-sharing

The Working Group on Access and Benefit-sharing was established by decision V/26 with the mandate to develop guidelines and other approaches for submission to the sixth meeting of the COP, to assist Parties and stakeholders with the implementation of access and benefit-sharing provisions of the Convention. At its meeting in Bonn, in October 2001, the Working Group adopted a set of guidelines on access and benefit-sharing, which were subsequently endorsed by the sixth meeting of the Conference of the Parties, in April 2002.

The Working Group also considered the role of intellectual property rights in access and benefit-sharing arrangements and adopted a series of recommendations, which are included in the report of the Working Group in document UNEP/CBD/COP/6/6 and were considered by the Conference of the Parties at its sixth meeting.

Ad Hoc Open-ended Working Group on Article 8(j) and related provisions

In May 1998, the Conference of the Parties established the Open-ended Working Group on Article 8(j) and Related Provisions. The Working Group has met twice, in March 2000 and in February 2002. At its first meeting, the Working Group discussed a number of issues concerning the application and development of legal and other forms of protection for traditional knowledge; proposed elements for a programme of work; the participation of indigenous and local communities in the work of the Convention; and strengthening cooperation among indigenous and local communities. At its second meeting, the Working Group considered *inter alia* an "Assessment of the effectiveness of existing subnational, national and international instruments, particularly intellectual property rights instruments, that may have implications for the protection of the knowledge, innovations and practices of indigenous and local communities". A series of recommendations, included in the report of the Working Group on Article 8(j) (UNEP/CBD/COP/6/7) were considered by the Conference of the Parties at its sixth meeting.

C. RELEVANT DECISIONS OF THE CONFERENCE OF THE PARTIES

Decision VI/24 on access and benefit-sharing addresses the role of intellectual property rights in access and benefit-sharing arrangements (section C) and the relationship between the CBD and TRIPS Agreement (section D). Decision VI/10 on Article 8 (j) (section F) provides an "Assessment of the effectiveness of existing sub-national, national and international instruments, particularly intellectual property rights instruments, that may have implications for the protection of the knowledge, innovations and practices of indigenous and local communities".

COP-6 adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilisation, which are annexed to decision VI/24A. These voluntary guidelines will assist Parties, Governments and other stakeholders in developing an overall access and benefit-sharing strategy, and in identifying the steps involved in the process of obtaining access to genetic resources and benefit-sharing. They are meant to support Parties, Governments and other stakeholders in establishing legislative, administrative or policy measures on access and benefit-sharing and/or in negotiating contractual arrangements for access and benefit-sharing. The guidelines are structured as follows:

- Section I on General Provisions covers key features, use of terms, scope, relationship with relevant international regimes and the objectives of the guidelines;
- Section II deals with the role of the national focal points and competent national authority(ies), and responsibilities of Parties and stakeholders that are users and providers of genetic resources;
- Section III addresses the participation of stakeholders in the development and implementation of access and benefit-sharing arrangements;
- Section IV covers steps in the process of access and benefit-sharing, including prior informed consent and mutually agreed terms;
- Section V covers other provisions, such as incentives, accountability, monitoring and reporting, verification, dispute settlement and remedies;
- Appendix I contains suggested elements for Material Transfer Agreements; and
- Appendix II provides an illustrative list of monetary and non-monetary benefits.

III. THE ROLE OF INTELLECTUAL PROPERTY RIGHTS IN ACCESS AND BENEFIT-SHARING ARRANGEMENTS

A. INTELLECTUAL PROPERTY RIGHTS AND BENEFIT-SHARING

It has been argued that intellectual property rights may be a means to ensure benefit-sharing. This could be achieved through different mechanisms such as: joint ownership, sharing of royalties arising from the exploitation of patents and others.

References to intellectual property rights are included in Section IV of the Bonn guidelines which deal with intellectual property rights in the context of benefits to be shared under mutually agreed terms, Section V and the two appendices. They include the following:

Basic requirements for mutually agreed terms or guiding parameters in contractual agreements, in paragraph 43, include:

"(c) Provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained and to provide licenses by common consent"

"(d) The possibility of joint ownership of intellectual property rights according to the degree of contribution"

Under national monitoring and reporting, in paragraph 55, it is provided that depending on the terms of access and benefit-sharing, national monitoring may include *"applications for intellectual property rights relating to the material supplied"*.

Under suggested elements for material transfer agreements, in appendix 1 of the Guidelines, it is suggested that access and benefit-sharing provisions may include *"whether intellectual property*

rights may be sought and if so under what conditions". The legal provisions of the material transfer agreement may address the "Assignment, transfer or exclusion of right to claim any property right, including intellectual property rights, over the genetic resources received through the material transfer agreement".

Appendix II includes in its list of possible monetary and non-monetary benefits: the payment of royalties, license fees in case of commercialization and joint ownership of relevant intellectual property rights.

B. DISCLOSURE OF ORIGIN OF GENETIC RESOURCES IN INTELLECTUAL PROPERTY RIGHTS APPLICATIONS

It has been argued that intellectual property rights could encourage access and benefit-sharing, if applications for such rights required: (i) identification of the source of genetic material used in the development of subject matter which is to be protected by intellectual property rights; and (ii) proof of the prior informed consent of the competent national authority of the provider country, if the genetic resource was acquired after the entry into force of the Convention on Biological Diversity and does not fall within the scope of the multilateral system set up by the International Treaty on Plant Genetic Resources for Food and Agriculture, once it has entered into force.

In paragraph 1 of decision VI/24 B, the Conference of the Parties made a statement on "the role of intellectual property rights in access and benefit-sharing arrangements", which may be of particular relevance in examining the relationship between the Convention on Biological Diversity and the TRIPS Agreement. The Conference of the Parties:

"invites Parties and Governments to encourage the disclosure of the country of origin of genetic resources in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted".

However, the Conference of the Parties has also recognized the need for further work on this topic and identified a list of issues which require further information gathering and analysis, in collaboration with a number of relevant organizations, including the WTO, as set out in paragraphs 3, 4 and 8 of section C.

In paragraph 3 of section C, the Conference of the Parties *"requests the Executive Secretary, with the help of other international and intergovernmental organizations such as the World Intellectual Property Organization and through the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention, where appropriate, to undertake further information gathering and analysis with regard to"* a number of issues, including:

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

...

(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..."*

In paragraph 4, the Conference of the Parties *"invites the World Intellectual Property Organization to prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, inter alia:*

(a) *Genetic resources utilized in the development of the claimed inventions;*

(b) *The country of origin of genetic resources utilized in the claimed inventions;*

(c) *Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;*

(d) *The source of associated traditional knowledge, innovations and practices;*
and

(e) *Evidence of prior informed consent;"*

In paragraph 8, the Conference of the Parties *"invites other relevant international organizations (such as the Food and Agriculture Organization of the United Nations, the United Nations Conference on Trade and Development, the World Intellectual Property Organization, the World Trade Organization, and the United Nations Commission on Human Rights), as well as regional organizations, Parties and Governments to contribute to the further study and analysis of the issues specified in paragraphs 3 and 4;"*

IV. INTELLECTUAL PROPERTY RIGHTS AND THE PROTECTION OF TRADITIONAL KNOWLEDGE

The relationship between intellectual property rights and the implementation of Article 8(j) and related provisions has been the subject of much discussion among Parties to the Convention. The main questions under examination by the Parties to the Convention are whether current intellectual property rights systems can or should be adapted so as to protect and reward the biodiversity-related traditional knowledge of indigenous and local communities, and/or what kind of *sui generis* approaches or alternative systems should be envisaged.

A. ARE INTELLECTUAL PROPERTY RIGHTS ADEQUATE FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE?

A number of Governments have expressed the view that intellectual property rights systems and more particularly patent systems are inappropriate for the protection of traditional knowledge, innovations and practices because such knowledge associated with biological resources may not meet all the conditions required for the granting of certain intellectual property rights under existing regimes, such as the conditions of novelty, inventive step and industrial applicability, which are required for the granting of patents. The following arguments are put forward as evidence of the inadequacy of intellectual property rights for the protection of traditional knowledge:

- Intellectual property rights are based on the protection of individual property rights whereas traditional knowledge is generally created, improved and transmitted collectively;
- Traditional knowledge is generally developed over a period of time and either codified in texts or retained in oral traditions over generations. The conditions of novelty and innovative steps necessary for the granting of patents may therefore be questionable;
- Knowledge is often held by different independent communities;
- Patents grant protection for a limited period of time whereas traditional knowledge is passed on from generation to generation.

However, genetic resources and traditional knowledge may contribute to the obtaining of patents by the biotechnology industry, which has based certain of its inventions on these resources and/or their related knowledge. It has been suggested that possible means may exist to ensure that intellectual property rights, in particular patents, provide for an equitable sharing of benefits arising from genetic resources, including the protection of traditional knowledge. In this regard, existing intellectual property rights regimes could be flexible enough or adapted to accommodate such knowledge.

In decision VI/24C, paragraph 2, and in decision VI/10, paragraph 46, the Conference of the Parties:

"... invites Parties and Governments to encourage the disclosure of the origin of relevant traditional knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity in applications for intellectual property rights, where the subject matter of the application concerns or makes use of such knowledge in its development."

In Paragraph 48 of decision VI/10, the Conference of the Parties also invited *"Parties and Governments, with the assistance of the World Intellectual Property Organisation, to take into account traditional knowledge in the examination of novelty and inventive step in patent applications"* and in paragraph 31 invited *"the WIPO Intergovernmental Committee to examine and consider mechanisms to protect traditional knowledge, such as the disclosure of the origin of relevant traditional knowledge in applications for intellectual property rights"*.

Following work carried out on the effectiveness and feasibility of various approaches to the protection of traditional knowledge (see document UNEP/CBD/WG8J/2/7), the emphasis in decision VI/10 is placed on developing and implementing practical solutions for the protection of traditional knowledge.

In the preamble to its decision VI/10, the Conference of the Parties took note of paragraph 19 of the Declaration of the Doha Ministerial Meeting of the World Trade Organization related to the examination by TRIPS Council of the relationship between the TRIPS Agreement and the Convention on Biological Diversity as well as the protection of traditional knowledge.

The Conference of the Parties also recognizes, in the preamble to its decision VI/10, that the Convention on Biological Diversity is the primary international instrument with the mandate to address issues regarding the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biological diversity.

In paragraph 33 of section F of its decision VI/10, the Conference of the Parties invites Parties and Governments, *"with the approval and involvement of indigenous and local communities representatives, to develop and implement strategies to protect traditional knowledge, innovations and practices based on a combination of appropriate approaches, respecting customary laws and practices, including the use of existing intellectual property mechanisms, sui generis systems, customary law, the use of contractual arrangements, registers of traditional knowledge, and guidelines and codes of practice, with the support of relevant intergovernmental organizations..."*. In paragraph 41, the Conference of the Parties also invites Parties and Governments, *"with the approval and involvement of indigenous and local communities to examine the feasibility of establishing mechanisms to protect the traditional knowledge, innovations and practices of these communities relevant to the conservation and sustainable use of biological diversity, taking into consideration customary laws and practices, and subject to national legislation."*

In order to better coordinate and institute measures to protect their traditional knowledge, innovations and practices, the COP, in paragraph 39, also encourages Parties and Governments to take measures to establish or improve operational links between their national governmental intellectual property bodies, national focal points of the Convention on Biological Diversity and indigenous and local communities and their organizations, particularly with regard to traditional-knowledge documentation initiatives and community-based registries of traditional knowledge.

In paragraph 40, Parties and Governments are also encouraged to undertake pilot projects in order to evaluate the effectiveness of existing intellectual property rights regimes, contractual methods and new systems being developed as a means of protection of traditional knowledge.

B. *SUI GENERIS* SYSTEMS FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE

In decision V/26 paragraph 1, the Conference of the Parties at its fifth meeting reaffirmed *"the importance of systems such as sui generis and others for the protection of traditional knowledge of indigenous and local communities and the equitable sharing of benefits arising from its use to meet the provisions of the Convention, taking into account the ongoing work on Article 8(j) and related provisions"*.

In addition, in decision V/16, paragraph 14, on Article 8 (j) and related provisions, the Conference of the Parties recognized *"the potential importance of sui generis and other appropriate systems for the protection of traditional knowledge of indigenous and local communities and the equitable sharing of benefits from its use to meet the provisions of the Convention on Biological Diversity, taking into account the ongoing work on Article 8(j) and related provisions..."*

At its sixth meeting, the Conference of the Parties recognized the need for further work on *sui generis* systems and, in paragraph 34 of decision VI/10, requested the Ad Hoc Working Group on Article 8(j) to address the issue of *sui generis* systems for the protection of traditional knowledge and to focus on the following issues:

- (a) Clarification of relevant terminology;
- (b) Compiling and assessing existing indigenous, local, national and regional *sui generis* systems;
- (c) Making available this compilation and assessment through the clearing-house mechanism of the Convention;

- (d) Studying existing systems for handling and managing innovations at the local level and their relation to existing national and international systems of intellectual property rights, with a view to ensure their complementarity;
- (e) Assessing the need for further work on such systems at the local, national, regional and international levels;
- (f) Identifying the main elements to be taken into consideration in the development of *sui generis* systems;
- (g) The equitable sharing of benefits arising from the utilization of traditional knowledge, innovations and practices of indigenous and local communities.

In undertaking this work, the Ad Hoc Working Group on Article 8(j)4, is to take into account the work carried out by the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization with *"a view to promote mutual supportiveness, and existing regional, subregional, national and local initiatives"*.

In the same decision (paragraphs 35 and 36), the Conference of the Parties has also invited the World Trade Organization and the World Intellectual Property Organization to make available to the Executive Secretary of the Convention on Biological Diversity information referred to above provided through their respective notification systems. The Executive Secretary has also been requested to continue to compile information provided by Parties and Governments relating to existing national legislation and other measures for the protection of traditional knowledge, innovations and practices.

V. RELATIONSHIP BETWEEN THE CBD AND TRIPS

In Decision V/26, section B, paragraph 2, the Conference of the Parties invited *"... the WTO to acknowledge relevant provisions of the Convention and to take into account the fact that the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Convention on Biological Diversity are interrelated and to further explore this relationship."*

The Conference of the Parties, in paragraph 4, also renewed its request to the Executive Secretary of the Convention to apply for observer status on the Council for the Trade-Related Aspects of Intellectual Property Rights. Further to this request, in a letter dated 4 July 2000, the Executive Secretary informed the Director-General of the WTO of these recent developments and renewed its application for observer status in the Council for Trade-Related Aspects of Intellectual Property Rights.

In decision VI/24 D, the Conference of the Parties addressed specifically the relationship between the TRIPS Agreement and the Convention on Biological Diversity. In the preamble to this decision, the Conference of the Parties noted that the provisions of the TRIPS Agreement and the Convention on Biological Diversity are interrelated, and that the relationship between the TRIPS Agreement and the Convention is being examined by the Council for Trade-Related Aspects of Intellectual Property Rights, in conformity with Article 19 of the Doha WTO Ministerial Declaration, adopted in November 2001. In this connection, the Conference of the Parties noted further *"that the Convention Secretariat has still not been granted observer status on the Council for Trade-Related Aspects of Intellectual Property Rights, notwithstanding the official request of the Executive Secretary to the Director General of the World Trade Organization in a letter dated 4 July 2000"*.

The Conference of the Parties requested the Executive Secretary of the Convention to renew the application for observer status on the Council for Trade-Related Aspects of Intellectual Property

Rights, to report back to the Conference of Parties on his efforts, and to follow discussions and developments in the Committee on Trade and Environment of the World Trade Organization and the Council for Trade-Related Aspects of Intellectual Property Rights regarding the relationship between the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Convention.

Pursuant these and other decisions of the Conference of the Parties, a letter by the Executive Secretary of the Convention dated 23 May 2002 was addressed to the Director General of the WTO, providing *inter alia* information on decisions VI/10 and VI/24 and renewing the request for observer status in the Council for Trade-Related Aspects of Intellectual Property Rights. In this letter, the WTO was also invited to collaborate in the further work to be carried out under the Convention on Biological Diversity as it relates to the agenda of the WTO.
