Convention on
Biological Diversity

PRESENTATION BY

HAMDALLAH ZEDAN
EXECUTIVE SECRETARY

CONVENTION ON BIOLOGICAL DIVERSITY

TO

THE WIPO SEMINAR ON INTELLECTUAL PROPERTY AND DEVELOPMENT

Geneva, Switzerland, 2-3 MAY 2005

Theme Two: Intellectual Property and Development—Biodiversity and Traditional Knowledge

Biodiversity and Access to Genetic Resources

Distinguished Delegates, Ladies and Gentlemen,

I wish to thank WIPO for inviting me to participate in this important meeting. A broad range of issues are to be addressed by this meeting, ranging from public health, biodiversity, and copyright in the digital environment to competition policy and technology transfer, which all have in common important linkages to intellectual property and development.

I am grateful for this opportunity to speak on biodiversity and access to genetic resources and to brief you on some of the issues at the core of the Convention on Biological Diversity that are of relevance to the subjects under discussion.

Background

The Convention on Biological Diversity was adopted at the Rio Summit in 1992 and is the main international instrument that provides a comprehensive and holistic approach to the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits deriving from the use of genetic resources.

The Convention sets out general principles for action to achieve its main objectives: the conservation of biological diversity, the sustainable use of its components and the equitable sharing of benefits derived from the use of genetic resources. Over the years, the Conference of the Parties to the Convention—the body responsible for reviewing and guiding implementation—has adopted a number of programmes of work on a range of thematic and cross-cutting issues. The thematic issues focus on the biodiversity of particular biomes or ecosystem types, such as marine and coastal areas, agricultural lands, drylands, mountains, inland waters, and so forth. The cross-cutting issues are of a more general relevance and aim both to support the implementation of the thematic programmes of work or to implement specific articles of the Convention. The programmes of work on access to genetic resources and benefit-sharing and indigenous and traditional knowledge fall into the latter category. The Conference of the Parties has also a number of tools and mechanisms to advance implementation of the Convention, such as operational guidance and principles for using the ecosystem approach and guidelines for incorporating biodiversity considerations into environmental impact assessment.

Prior to the entry into force of the Convention, genetic resources, wherever located, were generally regarded as a heritage of humankind and could be freely accessed without restriction, without the authorization of the country in which they were found and with no obligation to share the benefits from their use.

One case often cited to illustrate this situation is the Rosy Periwinkle, a plant claimed to be indigenous to Madagascar.[1] The anti-cancer agents vincristine and vinblastine were derived from this plant, discovered by scientists from the pharmaceutical manufacturer Eli Lilly & Co. in the 1950s. Vincristine and vinblastine have since been used respectively for the treatment of leukemia and Hodgkin's disease. International pharmaceutical companies have earned millions of dollars per year from the production of these agents without any benefits going to Madagascar.

The Convention on Biological Diversity redefined the conditions under which the benefits arising from the use of genetic resources should be shared with the countries where the resources are geographically located. Indeed, the Convention recognized the sovereignty of States over their natural resources and the need to share fairly and equitably the benefits arising out of the use of genetic resources.

More specifically, Article 15 of the Convention, supplemented by Articles 16 and 19, addresses the terms and conditions for access to genetic resources and benefit-sharing. Article 15 affirms the sovereignty of States over their genetic resources and that access is subject to national legislation. This right, however, is not absolute, as Article 15 also requires Parties to endeavour to facilitate access to genetic resources for environmentally sound uses by other Parties and not to impose restrictions. Other key principles are:

- That access shall be on mutually agreed terms;
- That it shall be subject to the prior informed consent of the Party in whose territory the resource is located; and
- That access shall be encouraged only if the Party seeking access will put the genetic resources to environmentally sound uses.

In addition, under Article 8(j) of the Convention, Parties have undertaken to encourage the equitable sharing of benefits arising out of the utilization of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.

In order to assist Parties and relevant stakeholders with the implementation of the access and benefit-sharing provisions of the Convention, a set of guidelines known as "the Bonn Guidelines" were adopted by the Conference of the Parties to the Convention, in April 2002. The Guidelines bridge the gap between policy development and implementation by providing the elements of a transparent and predictable framework for both users and providers of genetic resources. They assist Parties in their efforts to establish administrative, legislative or policy measures on access and benefit-sharing.

[1] Although there a numerous references in the literature to the case of the Rosy Periwinkle from Madagascar, it has since been argued that this plant was found in a number of countries and that it is difficult to determine from which country it first originated. For further details see: Brown, Michael F., *Who Owns Native Culture?*, Harvard University Press, Cambridge, Massachusetts, London, England, 2003, pp. 136-1388.

However, during the final negotiations of the Bonn Guidelines, developing countries felt that more needed to be done in order to ensure that users of genetic resources met their obligations under the Convention as set out in Articles 15, 16 and 19. It was felt that the guidelines did not sufficiently address the obligations of users of genetic resources.

In other words, developing countries were concerned about what they felt was the continued misappropriation of their genetic resources and associated traditional knowledge, and were concerned that Governments with users under their jurisdiction had not taken adequate measures to prevent unauthorized access and use of their genetic resources. This situation may have been aggravated by a number of cases of activities commonly referred to as "biopiracy" and unauthorized access and use of genetic resources and associated traditional knowledge, which have been the subject of media attention in recent years.

Following the adoption of the Bonn Guidelines, a group called "the Like-Minded Megadiverse Countries"[2] (LMMC), who hold a great majority of the world's biological diversity, declared that there was a need to go a step further to ensure the fair and equitable sharing of benefits. Under their impetus, the World Summit on Sustainable Development, in September 2002, called for the negotiation within the framework of the Convention on Biological Diversity of "an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources".[3] This call for action was later endorsed by the United Nations General Assembly.

In February 2004, the Conference of the Parties to the Convention mandated the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, the subsidiary body established in 2000 which developed the Bonn Guidelines, to undertake these negotiations.[4]

Current situation

There is currently a degree of uncertainty as to the rules governing access. There is also a perceived lack of trust between users and providers. To a large extent, this is due to the absence of adequate national measures taken by countries, both as users and providers of genetic resources. As advocated by a number of developing countries, it may also be due to the fact that no international instruments have been developed to address situations of non-compliance with national access requirements and access and benefit-sharing arrangements once genetic resources have left the provider country.

[2] The Group of Like Minded Megadiverse Countries includes Bolivia, Brazil, China, Colombia, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa and Venezuela. It was created by the Cancun Declaration of February 2002 as a mechanism to promote a common agenda relating to the conservation and sustainable use of biological diversity.

[3] Paragraph 44(o) of the WSSD Plan of Implementation.

[4] The mandate of the Working Group on Access and Benefit-sharing is set out in paragraph 1 of decision VII/19 D of the Conference of the Parties.

The first negotiating meeting for the international regime was held in Bangkok in February 2005[5]. At this meeting, discussions focused on the nature, scope, potential objectives and elements to be considered for inclusion in the regime.

No agreement was reached regarding the nature of the regime, i.e., whether it should be composed of one or more instruments within a set of principles, norms, rules and decision-making procedures, legally binding and/or non-binding. A series of options were put forward with respect to the scope and potential objectives of the regime for further consideration at the next meeting of the Working Group, to be held in Spain in January 2006. There is general agreement that the regime should cover access to genetic resources, the fair and equitable sharing of benefits arising out of the utilization of genetic resources and the protection of traditional knowledge associated with genetic resources.

Potential elements for inclusion in the international regime have also been identified and are to be considered by the negotiating body. They relate to: access to genetic resources, ensuring and promoting benefit-sharing, prior informed consent, mutually agreed terms for access, capacity-building, collaborative scientific research, recognizing and protecting the rights of indigenous and local communities, ensuring compliance with access and benefit-sharing requirements, enforcement mechanisms, dispute settlement, the issue of derivatives, the functioning of the international regime, and relevant elements drawn from existing instruments and processes.

The disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights has also been included as one of the elements for further consideration.

The role of intellectual property rights in access and benefit-sharing arrangements and the protection of traditional knowledge

The relationship between intellectual property rights and access and benefit-sharing arrangements

Prior to the discussion on an international regime and in order to prevent the unauthorized access to genetic resources, the Conference of the Parties invited countries to encourage the disclosure 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, in an effort to ensure compliance with prior informed consent and the mutually agreed terms on which access to those resources and related traditional knowledge was granted.[6]

[5] Mandate set out in decision VII/19 D, paragraph 1. The terms of reference for the negotiating body are set out in the annex to the same decision.
[6] See decision VI/24 C, paragraphs 1 and 2.

Further to this invitation, analytical work has been carried out under the Convention and the World Intellectual Property Organization (WIPO). The issue has also been discussed in a number of international forums, such as the WTO Council on Trade-Related Aspects of Intellectual Property Rights (TRIPS), relevant WIPO bodies and the Convention on Biological Diversity, in order to further examine the possibility of including the disclosure requirement in appropriate international agreements.

The relationship between the TRIPS Agreement and the Convention on Biological Diversity is also under discussion in the TRIPS Council, with a view to ensuring their mutual supportiveness.

According to some Governments, there is an inherent conflict between the Convention and the TRIPS Agreement, and the latter should be amended so as to exclude from patentability living organisms, including plants, animals and microorganisms. According to others, there is considerable overlap between the two agreements and, in order to avoid potential conflicts, the TRIPS Agreement should be amended to accommodate some essential elements of the Convention on Biological Diversity. More specifically, it has been proposed that the TRIPS Agreement be amended in order to provide that WTO Members require that an applicant for a patent relating to biological materials or traditional knowledge provide, as a condition to acquiring patent rights: (i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention; (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes; (iii) evidence of fair and equitable benefit-sharing under the relevant national regimes.[7] A third approach suggests that there is no conflict between the two agreements, but that measures should be taken at the national level to ensure that they are implemented in a mutually supportive manner.

Some have suggested the inclusion of the disclosure requirement in the Patent Cooperation Treaty, while others still do not support the requirement for disclosure of origin of genetic resources and associated traditional knowledge and are in favour of the *status quo*.

Different views have also been expressed with respect to the characteristics of such a disclosure requirement. For example, no consensus has been reached with respect to the nature of such a disclosure requirement, whether voluntary or mandatory, or with respect to the consequences of failure to comply with such a requirement.

The practical implications and potential characteristics of such a disclosure requirement are being examined by the TRIPs Council,[8] WIPO and under the Convention on Biological Diversity [9] in the context of the negotiations for the international regime.

[7] See WTO documents IP/C/W/356, IP/C/W/403. In the submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand and Venezuela, available in WTO document IP/C/W/403, dated 24 June 2003, it is stated that: "Disclosure of the source and the country of origin and evidence of PIC and fair and equitable benefit sharing in a patent application would play a significant role in preventing biopiracy and misappropriation and in some cases, prevent the issue of "bad patents" awarded without due regard to the prior use and knowledge with regard to the resource."

[8] See documents IP/C/W/420, IP/C/W/429/Rev.1, IP/C/W/438, IP/C/W/442.

In parallel to discussions at the international level, a number of countries have already included different variations of this disclosure requirement in their national patent law (e.g. Denmark, Sweden, Norway)[10].

In addition, as set out in the Bonn Guidelines, intellectual property rights may also be a means to ensure benefit-sharing through different mechanisms such as joint ownership and the sharing of royalties arising from the exploitation of patents[11].

Protection of traditional knowledge

The protection of traditional knowledge is yet another issue that will deserve particular consideration in the negotiation of the international regime. As mentioned above with respect to the scope of the regime, it has been agreed that the regime should not only cover genetic resources but should also include the protection of traditional knowledge. Indeed, the unauthorized appropriation of traditional knowledge associated with genetic resources has also been an important source of concern among provider countries and indigenous and local communities.

It is not clear at this stage of the negotiations how the protection of traditional knowledge will be addressed in the international regime. Considerable work has been carried out under the Convention process and WIPO to examine various alternatives to maintain, protect and promote traditional knowledge. The disclosure of origin of genetic resources and associated traditional knowledge would provide defensive protection for indigenous and local communities from misappropriation of their traditional knowledge through patenting.

In addition, a number of alternatives are being examined to ensure the protection of traditional knowledge at the national and regional levels. Some experts are of the opinion that existing intellectual property rights regimes are not appropriate for the protection of traditional knowledge and that *sui generis* systems are needed. Suggested elements for such *sui generis* systems, which are being considered by the Convention's Working Group on Article 8(j) and Related Provisions, include: clarity with regard to ownership of traditional knowledge and traditionally-used biological resources; a process and set of requirements governing prior informed consent, mutually agreed terms and equitable sharing of benefits with respect to traditional knowledge and associated genetic resources; conditions for the grant of rights; the rights conferred; a system for the registration of indigenous/local knowledge; and, a competent authority to manage relevant procedural/administrative matters with regard to the protection of traditional knowledge and benefit-sharing arrangements.

---

[9] For further details, see paragraph 8 of decision VII/19 E of the Conference of the Parties to the Convention on Biological Diversity.

[10] For further information on national initiatives, see documents UNEP/CBD/WG-ABS/2/4 and UNEP/CBD/WG-ABS/3/5.

[11] For further details see section IV of the Bonn Guidelines, section V and the two appendices.

One of the challenges in the negotiation of the international regime will be to determine how it will address the protection of traditional knowledge, given that there is some reluctance on the part of indigenous and local communities to providing access to their genetic resources for commercial purposes.

It has been agreed that the negotiations of the regime should take into account measures to ensure compliance with the prior informed consent of indigenous and local communities custodians of traditional knowledge associated with genetic resources. Subject to the national legislation of the countries where indigenous and local communities are located, the recognition and protection of the rights of these communities over their traditional knowledge is also to be considered in the elaboration of the regime, while also taking into account the customary law and traditional cultural practices of indigenous and local communities.[12]

Thank you for your attention.

[12] See decision VII/19D, Annex, (d).