

Subregional Seminar on the Legal Protection of Biotechnology and Genetic Resources

Banska Bystrica, May 2 and 3, 2007

Access and Benefit Sharing

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Overview

- The Context
- The Patent system
- Developments on the International Level



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The Context

- **Convention on Biological Diversity (CBD)**
 - **Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization**
 - **International Regime on Access to Genetic Resources and Benefit Sharing**
- **Food and Agriculture Organization of the United Nations (FAO)**
 - **International Treaty on Plant Genetic Resources for Food and Agriculture**



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Convention on Biological Diversity

- **1992 Earth Summit in Rio de Janeiro**
- **3 main goals:**
 - the conservation of biological diversity
 - the sustainable use of its components
 - and the fair and equitable sharing of the benefits from the use of genetic resources.
- **entered into force on 29 December 1993**
- **190 Parties** (<http://biodiv.org/world/parties.asp>)



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Convention on Biological Diversity

Article 1. Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are 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**, 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.



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Convention on Biological Diversity

Article 15. Access to Genetic Resources

1. Recognizing the **sovereign rights of States** over their natural resources, the authority to **determine access to genetic resources** rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavour to create **conditions** to facilitate **access** to genetic resources for **environmentally sound uses by other Contracting Parties** and not to impose restrictions that run counter to the objectives of this Convention.



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Convention on Biological Diversity

Article 15. Access to Genetic Resources

3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on **mutually agreed terms** and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to **prior informed consent** of the Contracting Party providing such resources, unless otherwise determined by that Party.



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Convention on Biological Diversity

Article 15. Access to Genetic Resources

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
7. Each Contracting Party shall take legislative, administrative or policy **measures**, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of **sharing** in a **fair** and **equitable** way the **results of research and development** and the **benefits arising from** the commercial and other **utilization of genetic resources with the Contracting Party** providing such resources. Such sharing shall be **upon mutually agreed terms**.



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Convention on Biological Diversity

Article 8. In-situ Conservation

[...]

(j) Subject to its 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 the benefits** arising from the **utilization** of such knowledge, innovations and practices;



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Convention on Biological Diversity

Article 16. Access to and Transfer of technology

1.- 4. [...]

5. The Contracting Parties, recognizing that patents and other **intellectual property rights** may have an **influence on the implementation of** this Convention, shall cooperate in this regard subject to national legislation and international law in order to **ensure** that such rights are **supportive** of and do not run counter to its objectives.



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Bonn Guidelines and International Regime

- **6th Conference of the Parties 2002 (COP, Decision VI/24)**
 - voluntary guidelines to assist Parties, Governments and other stakeholders
 - establishing legislative, administrative or policy measures
 - negotiating contractual arrangements
- **7th Conference of the Parties 2004 (Decision VII/19)**
 - negotiation of an international regime on access to genetic resources and benefit sharing
 - mandate to the Ad Hoc Open-ended Working Group on Access and benefit-sharing.
- **8th Conference of the Parties 2006 (Decision VIII/4)**
 - complete the work on the international regime at the earliest possible time before the 10th meeting of the Conference of the Parties (2010)



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Food and Agriculture Organization of the United Nations

- **International Treaty on Plant Genetic Resources for Food and Agriculture**
 - adopted in November 2001
 - entered into force on June 29, 2004, 112 parties (<http://www.fao.org/Legal/TREATIES/033s-e.htm>)
- **Definition: "any genetic material of plant origin of actual or potential value for food and agriculture".**
- **objectives**
 - **conservation** and **sustainable use** of plant genetic resources for food and agriculture
 - the fair and equitable **sharing of benefits** derived from their use, in harmony with the CBD, for sustainable agriculture and food security



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International Treaty on Plant Genetic Resources for Food and Agriculture

- **Multilateral System to facilitate access to plant genetic resources for food and agriculture (Article 12):**
 - over 64 major crops and forages
 - access for utilization and conservation in research, breeding and training
- **Share the benefits in a fair and equitable way (Article 13):**
 - facilitated access itself
 - information-exchange
 - access to and the transfer of technology
 - capacity-building
 - sharing of monetary and other benefits of commercialization
- **Material Transfer Agreements**



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The Patent System

- **Andean Community**
- **European Community**
- **National Patent Law**



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Andean Community

DECISION 486

Common Intellectual Property Regime

- Article 26 **Applications** for patents [...] shall contain:
 - h) a **copy of the contract for access**, if the products or processes for which a patent application is being filed were obtained or developed from **genetic resources** or by products **originating** in one of the **Member Countries**
- **Sanction**: Invalidation Article 75 g)



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European Community

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

– Recital 26

Whereas if an invention is based on **biological material of human origin** or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing **free and informed consent** thereto, in accordance with national law;

– Recital 27

Whereas if an invention is based on **biological material of plant or animal origin** or if it uses such material, the **patent application** should, where appropriate, **include information on the geographical origin** of such material, **if known**; whereas this is **without prejudice** to the processing of patent applications or the validity of rights arising from granted patents;



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National Patent Law

- **Disclosure requirement:**
invention to be fully disclosed
- **some European countries have implemented recital 27 of Directive 98/44/EC, e.g.**
 - **Germany, **sanction:**** without prejudice to the processing of patent applications or the validity of rights arising from granted patents, (§ 34a Patentgesetz)
 - **Italy, **sanction:**** in the patent procedure: nullity (LEGGE 22 febbraio 2006 n. 78)
 - **Norway, **sanction:**** penalty (Section 8b of the Patents Act)



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Developments on the International Level

- **World Trade Organization**
- **World Intellectual Property Organization**



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World Trade Organization

- Doha Ministerial Declaration, November 14, 2001
19. We **instruct** the **Council for TRIPS**, [...], to **examine**, inter alia, the **relationship** between the **TRIPS** Agreement and the **Convention on Biological Diversity**, [...]
- WTO document IP/C/W/368/Rev.1, February 8, 2006:
The Relationship between the TRIPS Agreement and the Convention on Biological Diversity
 - Disclosure and evidence as a **TRIPS obligation** (Brazil, India, Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Peru, Thailand, African group and some other developing countries)
 - Disclosure through **WIPO** Amendment to the regulations of the Patent Cooperation Treaty (Switzerland)
 - Disclosure with legal **consequences** of not meeting this requirement **outside the patent law** (European Union)
 - **National legislation** and **contractual arrangements** (United States of America)



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World Intellectual Property Organization

- **Patent Law Treaty / Substantive Patent Law Treaty**
- **Patent Cooperation Treaty**
- **Technical Studies**
- **Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore**



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Patent Law Treaty / Substantive Patent Law Treaty

- **Columbian Proposal (WIPO document SCP/3/10)**
 - the grant of patents or registrations that relate to biological and genetic heritage shall be subject to their having been acquired legally
 - specification of the registration number of the contract affording access to genetic resources and a copy thereof

- **Indian Proposal (WIPO document SCP/9/8, par. 114), WIPO document SCP/10/3:**

Rule 4(2) of Draft Regulations Under the Substantive Patent Law Treaty:

A Contracting Party may require the indication of the **source and geographical origin of the deposited biological material** in the description.



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Patent Cooperation Treaty

Swiss Proposal

(May 2003, now WIPO document PCT/R/WG/9/5)

Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications:

- **Amendment of Rules under the PCT**
 - **4.17 Declarations Relating to National Requirements Referred to in Rule 51*bis*.1(a)(i) to (v)**
 - **Rule 51*bis* Certain National Requirements Allowed Under Article 27**
- **PCT amendments applicable under the PLT by**
 - **reference under PLT Article 6(1)**
 - **use of a PCT Request Form under PLT Rule 3(2)**
 - **decision of the PLT Assembly under PLT Article 16(1)**



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WIPO - CBD Cooperation

- **Memorandum of Understanding**
 - 2002: approved by WIPO's Coordination Committee (WIPO document WO/CC/48/2)
 - upon request and subject to approval of the competent subsidiary bodies
 - undertake studies and provide other technical inputs in writing to the competent subsidiary bodies of the requesting party on issues within their areas of competence
- **Technical Studies**
 - technical input to facilitate policy discussion and analysis, not a formal paper expressing a policy position on the part of WIPO, its Secretariat or its Member States
 - Decision of WIPO's General Assembly on a request
 - Invitation to WIPO Member States for comments and proposals
 - consultation process
 - Approval of WIPO's General Assembly



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Technical Studies

- **CBD Request for Technical Studies**
 1. COP 6: Decision VI/24C
 2. COP 7: Decision VII/19
- **Documents:**
 1. **UNEP/CBD/COP/7/INF/17 = WIPO Publication Nr. 786 (E)**

Background: WIPO documents **WIPO/GA/30/7, WO/GA/30/7 ADD.1, WIPO/GRTKF/IC/5/10**
 2. **UNEP/CBD/COP/8/INF/7**

Background: WIPO documents **WIPO/GA/32/8**



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Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

- **Draft Intellectual Property Guidelines for Access and Equitable Benefit Sharing**
(WIPO document WIPO/GRTKF/IC/7/9)
- **Overview about WIPO's work on genetic resources**
(WIPO document WIPO/GRTKF/IC/8/9)
- **Proposal of the EU**
(WIPO document WIPO/GRTKF/IC/8/11)
- **Memorandum of Norway**
(WIPO document WIPO/GRTKF/IC/9/12)
- **Submission of Japan**
(WIPO document WIPO/GRTKF/IC/9/13)



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Proposal of the EU (WIPO document WIPO/GRTKF/IC/8/11)

- a mandatory disclosure requirement in patent applications;
- declare the country of origin or, if unknown, the source of the specific genetic resource;
- invention directly based on the specific genetic resources;
- possibly also disclosure requirement regarding the specific source of traditional knowledge associated with genetic resources; a further in-depth discussion of the concept of “traditional knowledge” is necessary;
- sanction for failure or refusal to declare the required information after being given the opportunity to remedy: the application should not be further processed;
- sanctions for incorrect or incomplete information: outside the field of patent law;
- notification by patent offices of a declaration to a central body, e.g. the Clearing House Mechanism of the CBD.



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Memorandum of Norway

Proposal of Japan

- **Norway: WIPO document WIPO/GRTKF/IC/9/12**
 - disclosure requirements in patent applications contribute to improving transparency and building trust in the patent system
 - possible implications for monitoring possible cases of misappropriation of TK/TCEs.
 - separate proposal announced
- **Japan: WIPO document WIPO/GRTKF/IC/9/13**
 - Art. 16 CBD does not require disclosure of origin
 - Indication not needed for patent examination
 - Database related to genetic resources and traditional knowledge to help avoiding erroneously granted patents



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Decisions of the Tenth Session of the IGC

December 8, 2006

9. Regarding agenda item 10 (genetic resources), on the basis of its discussions, the proposals made by a number of delegations, document WIPO/GRTKF/IC/8/9, and within the specific mandate of the Committee established by the WIPO General Assembly, the Committee requested the Secretariat to prepare for its **consideration at its eleventh session**: (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.



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