Patents and Genetic Resources / Traditional Knowledge

AIPPI Forum Singapore 2007, Session II

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Chair AIPPI Special Committee Q166, “Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IP and GRTKF)”
Patents and Genetic Resources / Traditional Knowledge

Convention on Biological Diversity (CBD)

Interaction with Patents: Attempts for a solution in WIPO and WTO (TRIPS)

What is the definition of a Genetic Resource and of Traditional Knowledge in the context of the CBD?

Requirement of indicating the source (or country of origin) of genetic resources and traditional knowledge in patent applications: Questionnaire and Resolution Q166 taken at the Gothenburg Congress 2006
Background

The Convention on Biological Diversity (CBD), which grants sovereignty to their member states over genetic resources (GR) and traditional knowledge connected with it (TK), could be a source of income for developing countries, since the biological richness is rather located in the countries of the “South” than in industrialized countries.

Developing countries believe that their interests are not adequately met in this respect in the harmonisation discussions at WIPO, and would also like to see a TRIPS amendment.

Patent applications as a way to “police” implementation of the CBD requirements?
Patents and Genetic Resources / Traditional Knowledge

TRIPS

TRIPS Amendment

WIPO

WIPO PLT

WIPO PCT

WIPO Harmonisation

WIPO Development Agenda

WIPO GRTKF

CBD

CBD Bonn Guidelines

CBD ABS Certificate

FAO
Patents and Genetic Resources / Traditional Knowledge

(TRIPS) -> CBD

(WIPO) -> CBD

CBD -> Bonn Guidelines

CBD -> ABS Certificate

(FAO)
The Convention on Biological Diversity was actually set up to stop the erosion of biological diversity. Part of this aspect is the desire to give “value” to genetic resources and traditional knowledge connected with it in order to improve their protection.

Countries have sovereignty over their resources. They should respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities … and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices (Art. 8(j)).

Patents and other intellectual property rights may have an influence on the implementation of the CBD. Countries should ensure that such rights are supportive of and do not run counter to its objectives (Art. 16(5)).
The Bonn guidelines are non-binding rules for national authorities and for applicants for patents and set up best practices concerning getting prior informed consent before the start of bioprospecting, capacity building, technology transfer and benefit sharing based on GR and TK.

There is a CBD working group discussing access and benefit sharing (ABS) and e.g. certification of Origin/Source/Legal Provenance.
Biopiracy

There have been some cases of real or perceived biopiracy:

Reasons for these:

Relative novelty in patent laws of some countries: Prior use is regarded as novelty-destroying only if it occurred in the country of potential patent protection.

Difficulty to find prior knowledge ("traditional knowledge") by a patent examiner since it is buried in unusual publications or not published at all.

Some of these “biopiracy” case were also combined with a wrong interpretation of patent law. What has been used in the prior art cannot be taken away and made subject of a patent monopoly.
Definitions: Genetic Resources (GR)

Genetic Resources means genetic material of actual and potential value. In the CBD it is restricted to non-human genetic resources.

Examples of Genetic Resources are
- genetic material from plants, animals and microorganisms containing functional units of heredity
- plants (including fruits, flowers, tea and spices), animals and microorganisms
- food or other natural products isolated from plants, animals and microorganisms as long as they contain functional units of heredity

Whenever rules are set up for genetic resources, one should also think of genetic resources from humans and the special problems connected with (privacy, ownership)

Biological Resources means genetic resources and other biotic components of actual and potential value.
Definitions: Traditional Knowledge (TK)

Traditional Knowledge in the CBD: Knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.

Traditional knowledge connected with genetic resources, natural products, crop plants, technical matter, arts, handicraft ...

In many indigenous societies, traditional knowledge connected with natural products is sacred and not available for other users.

In the understanding of patent law, knowledge available through publications (including public registers) and unrestricted use is in the public domain and cannot be subject to royalties or other payments.

A *sui generis* protection scheme (including an international agreement) for traditional knowledge not in the public domain could in principle be set up, but many questions still remain unsolved.
According to the CBD sovereignty over genetic resources and traditional knowledge connected with it lies with states (countries). Member states of the CBD interested in proper compensation for use of genetic resources and traditional knowledge connected with it therefore would like to know who uses such resources or knowledge.

Users of genetic resources very often cannot trace the resource back to the country of origin. Genetic resources are not bound to state borders, and many resources have been and still are transported from one country to another.

Users of genetic resources could at least indicate the source, if they do not know the real country of origin, i.e. where the resource was bought (food market, collecting company ...) or found (botanical garden, sewer facility, microorganism collection ...)
GR and TK as a Source of Income

The “blockbuster biotech pharmaceutical drug” based on genetic resources from a developing country is far from reality and, as science and product development patterns evolve, gets less and less probable. Reliance upon naturally occurring genetic resources within the pharmaceutical industry is giving way to science and technology that enable “drug design” at the molecular level.

Onerous requirements in laws for access to genetic resources in some countries just add to this development, and many of the major pharmaceutical and agrochemical companies have reduced or terminated natural product research in recent years.

Flavours, fragrances and herbal remedies originating in developing countries are still exploited for large-scale commercial value, but they are usually not the subject matter of patents.
Patents and Genetic Resources / Traditional Knowledge

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(TRIPS)
(CBD)
(FAO)
World Intellectual Property Organisation (WIPO)

WIPO Patent Law Treaty: When negotiating this treaty on formal requirements of patent applications, the requirement of indicating the source / country of origin in patent applications was discussed, but then the treaty was finalized without such requirement.

There are proposals pending for amendment of PCT which would allow countries to require the indication of source / country of origin.

At present, discussions on substantive harmonisation (WIPO SPLT) are blocked since developing countries would like to have the question of indication of country of origin / prior informed consent and proof of benefit sharing agreement in patent applications discussed and included in such a treaty.

The Development Agenda looks at ways and means to better take into consideration the problems and options for developing countries.
The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC on GRTKF) discusses potential links between IP and Genetic Resources (GR falling under the CBD or the FAO treaty on plant GR for food and agriculture), Traditional Knowledge (TK as prior art, *sui generis* protection of TK) and Folklore (Traditional Cultural Expressions).

A lot of background work has been done by the WIPO secretariat, but the IGC (which met for its 11th session in July 2007) has not yet come close to any agreement on a treaty or any other binding conclusion on the points of discussion.
Patents and Genetic Resources / Traditional Knowledge

TRIPS

TRIPS Amendment

(CBD)

(WIPO)

(FAO)
Trade related aspects of intellectual property rights (TRIPS)

The CBD discussion in TRIPS has neither to do with the question of patentability of biological material (genes, plants and animals), Art. 27(3)b, nor with the question of sufficiency of description, Art. 29(1).

It deals with the fact that TRIPS requirements have to be fulfilled by all WTO members (with the risk of sanctions for non-compliance), but that there is no equivalent measure to make sure that the CBD requirements are followed.

TRIPS can be amended as shown by the Hong Kong ministerial conference (Art. 39a compulsory licences for pharmaceuticals).

Developing countries demand that TRIPS be amended to make a connection to the CBD:
New Art. 29bis: Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge (Document IP/C/W/474)
The answers to the questionnaire (37) show that the opinions, whether indications on source or country of origin of genetic resources and traditional knowledge should be indicated in patent applications, differ widely within the AIPPI national groups.

The following countries have a legal requirement to indicate the origin of genetic resources: Brazil, Colombia (actually all states of the Andean Community), Denmark, Egypt, Germany, India, Italy, Norway, Philippines, South Africa, Sweden, Venezuela. Corresponding bills are under discussion in Indonesia, Mexico, New Zealand and Switzerland.

Details see www.aippi.org
Most national groups of AIPPI are of the opinion that the patent applications are not the place to “police” the application of the CBD principles and are against a requirement to indicate the source or country of origin of GR and TK in patent applications.

Some national groups (15) are of the opinion that the source or even the country of origin of GR and TK should be indicated in patent applications.

Of these, some (8) are of the opinion that not only the country of origin should be indicated, but also prior informed consent and proof of a benefit sharing agreement for GR and TK should be provided in a patent application.
AIPPI Q166 Resolution

Observing the struggle of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore to come to final conclusions on the topics;

Noting that
- the Convention on Biological Diversity accepts the sovereignty of states over their genetic resources and traditional knowledge connected with it, and puts forward the concept of prior informed consent and access and benefit sharing when utilising such resources;
- many member countries of the Convention on Biological Diversity have not yet set up mechanisms how to access genetic resources under their control and how to get prior informed consent;
Mindful that
- the patent system is intended to encourage inventors to disclose their inventions to the public in return for a monopoly period in which patent owners may prevent others from practising the invention, and that an invention is a solution to a technical problem;
- patents should only be granted for inventions which are new, not obvious and capable of industrial application, and should contain disclosure of the invention sufficient to enable the skilled person in the art to work the invention;
- the patent system cannot prevent unlawful use of genetic material or traditional knowledge in research, development, marketing of products, or trade;

Supporting that users of genetic material and traditional knowledge connected with it comply with the requirements of the Convention on Biological Diversity and national laws in this respect.
AIPPI Q166 Resolution (3)

Resolves:
1) Traditional knowledge in the public domain should be treated as other information in the public domain for the assessment of patentability of inventions.
2) The patent system is not suitable to control whether the requirements of the Convention on Biological Diversity are met, in particular since research results and products in commerce and trade need not be covered by patents.
3) If national laws require a declaration of the source of genetic material and traditional knowledge in patent applications, such laws should:
   - only require that the patent applicant to the best of his knowledge identifies the source from which the inventor obtained the genetic material or the information based on traditional knowledge;
   - entitle the applicant to rectify any failure to indicate the source or add any later information obtained on the origin of the genetic material.
4) Ways and means other than patent applications should be developed to deal with prior informed consent and access and benefit sharing concerning genetic resources and traditional knowledge connected with it.