

Summary Report

Questionnaire February 2010

Special Committee Q94 WTO/TRIPS
Special Committee Q166 Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

The requirement of indicating in patent applications the source or country of origin of genetic resources and traditional knowledge involved in the making of the invention

Background

The discussion on what can be termed “special disclosure requirements for patent applications involving genetic resources” is now ongoing since the 1990’s.

Proponents of such special disclosure requirements present different arguments as to why such special disclosure requirements should be introduced. The present Summary is not the place to go into detail on those arguments. Suffice it to say that a main argument is to counteract misappropriation, “biopiracy”, of genetic resources, especially in developing countries rich in genetic resources.

On the multilateral level, this discussion takes place in different fora, notably in the WTO/TRIPS Council, in WIPO, especially in its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, IGC GRTKF, and in the framework of the Convention on Biological Diversity, CBD.

Over the last couple of years the work on the subject in the WTO, in WIPO, as well as under the CBD has intensified. In the WTO there is a two-way procedure: the ordinary work in the TRIPS Council on the one hand, and the special consultations carried out by the WTO Director General on the other hand. In WIPO, the discussions in the IGC GRTKF have been revived recently. And in the CBD, the aim is to implement the International Regime on Access and Benefit Sharing (ABS), the Nagoya Protocol.

In parallel with these discussions in multilateral organizations, a growing number of individual countries have introduced, or are considering to introduce, special disclosure requirements for patent applications in their national legislation.

AIPPI work

In the context of its Gothenburg Congress 2006, AIPPI collected information and opinions from its National Groups concerning national legal requirements for indicating the country of origin, or the source, for genetic resources and traditional knowledge in patent applications involving genetic resources. This was done through a Questionnaire prepared by AIPPI Special Committee Q166. The responses from the 37 national groups which responded are available on www.aippi.org under Questions/Committees, Special

Committee Q166. The AIPPI Gothenburg Congress passed a resolution Q166 on basis of the results from said questionnaire.

In view of the intensified discussion in WIPO, in the WTO, and in the CBD, it was decided between the AIPPI Special Committees Q94 and Q166 to make a joint effort aiming to establish current facts on national legislation on the topic. The present February 2010 Questionnaire was accordingly prepared and distributed to the AIPPI National Groups.

The main aim of said Questionnaire is twofold:

1. to make a factual update via the AIPPI National Groups on provisions in national legislations on such special disclosure requirements. Such requirements may be located in patent laws, in general IP laws, or in laws implementing the CBD dealing with access to genetic resources and associated traditional knowledge, prior informed consent and benefit-sharing.
2. to collect information on the practical experience with the application of such laws and regulations.

Outcomes of the February 2010 Questionnaire

1. **The Questionnaire**, including the questions taken up, is attached as Annex 1.

2. Which countries have responded to the 2010 Questionnaire?

Responses to the Questionnaire were obtained from 35 National Groups. These are listed in Annex 2.

The individual responses are available on www.aippi.org under Questions/Committees, Special Committee Q94 and Special Committee Q166.

3. What were the responses on specific questions, briefly summarized?

For an overview, the responses obtained are provided in abbreviated tabular format in Annex 3.

More information from the responses on some of the questions raised is provided below. For complete responses regarding an individual country, the individual AIPPI National Group response must be consulted.

4. Which countries have introduced special disclosure requirements for patent applications involving genetic resources?

In the Summary Report on the 2006 Questionnaire, it is noted that in addition to the countries listed below also the (then) Andean Community member states Colombia, Ecuador, Peru and Bolivia had introduced a disclosure requirement in regard to the source and geographical origin of biological material. Further, Venezuela has a

requirement for indicating the source if the invention relates to genetic resources or traditional knowledge of origin in Venezuela, but not from other countries.

The 2010 AIPPI Questionnaire has resulted in information that in addition to Colombia, Ecuador, Peru, Bolivia, and Venezuela, the 13 countries listed below have introduced a special disclosure requirement.

The legal basis for these requirements is:

Belgium: Patents Act Article 11, para 2 and Article 15 para 1, sub 6

Denmark: Implementing Regulations for the Danish Patent Law, §3 subsection 4

Germany: German Statute on Patents §34a

Italy: Article 5.2 of Law no. 78 of 22.02.2006, and Implementing Provisions of the Italian Industrial Property Code (C.P.I.): Law Decree no. 33 13.01.2010

Sweden: Section 5a of the Patents Decree (1967:838 as amended 2004:162)

Norway: Patents Act Section 8b

Switzerland: Patent Law Article 49a, Article 81a, Article 138, and Patent Ordinance Article 45a

Brazil: Provisional Measure (PM) 2186-16 of August 23, 2001

China: Third-amended Patent Law of China, Article 26(5) and Article 5(2)

Egypt: Article 13 of Law No. 82/2002 for the Protection of Intellectual Property Rights

The Philippines: Section 26.1 of the Joint DENR-DA-PSCD-NCIP Administrative Order No. 1, Series of 2005, and Rule VI, Section 15 of the implementing rules of Republic Act No. 8371, also known as Indigenous Peoples' Rights Act of 1997, "IPRA"

South Africa: Patents Amendment Act no. 20 of 2005 and Regulations under this Act put into effect December 14, 2007

India: Section 10(4)d of the Patent Act 1970, as amended in 2005, requires to "disclose the source and geographical origin of the biological material in the specification, when used in an invention".

A note is that EPC and PCT do not contain this type of disclosure requirements.

5. Which countries have indicated existence of a project of law introducing special disclosure requirements?

Indonesia: Draft of Law concerning the Intellectual Property Protection and Use/Development for Traditional Knowledge and Traditional Cultural Expressions/Folklore

New Zealand: Patents Bill in progress.

Turkey: Draft law of patent and utility model in progress

The Australian Group draws attention to the “contrary to law” section 51(1)(a) in the Australian patent law: *“The Commissioner may refuse to accept a patent request and specification, or grant a patent for an invention the use of which would be contrary to law.”* It is unclear whether the Environment Protection and Biodiversity Conservation Act, which implements the CBD, can be used under said “contrary to law” provision in the Patents Act. Further, IP Australia is reported to work on a reconciliation plan relating to the needs and interests of indigenous Australians, i.a. on IP issues.

The New Zealand Group draws attention to a Patents Bill in progress which i.a. will establish a Maori advisory committee to advise the Commissioner in relation to patent applications for inventions involving traditional knowledge or indigenous plants and animals.

In Thailand, the Plant Varieties Protection Act, B.E.2542 (1999), a sui generis system, requires applications to register a new plant variety to provide details of the origin of the new plant variety or the genetic material.

In Malaysia, a Bill on access to genetic resources and benefit sharing is being drafted.

6. What experiences with the application of legal requirements for special disclosure requirements when filing and prosecuting patent applications have been reported? Is statistical data available?

Very little national experience of existing legal provisions and no reliable statistical data have been reported.

India: Although no statistical data are available, it is the feeling that the legal requirements are strictly enforced. Furthermore the Traditional Knowledge Digital Library (TKDL) available for TK from India and focused on the Indian systems of medicines Ayurveda, Unani, Siddha and Yoga is used to alert patent examiners worldwide, if cases of potential "biopiracy" are identified in patent applications outside India.

7. Are administrative or judicial decisions on the topic available?

No such decisions have been reported.

8. Is the disclosure requirement limited to biological/genetic resources or traditional knowledge of the country in question only, or is it applicable also to biological/genetic resources or traditional knowledge obtained or obtainable from other countries and geographical areas?

Brazil: specifically limited to domestic resources only

South Africa: it seems clear that only domestic resources are covered

Denmark, Egypt, Germany, Italy, Norway, The Philippines, Switzerland: reported to be independent of country or geographical origin

Belgium: not clear

Sweden: not stated explicitly in the Patents Decree

China: not stated in the law, but likely not limited to domestic resources

New Zealand: The Maori advisory committee will only assess patent applications in which the invention is based on Maori traditional knowledge or plants/animals indigenous to New Zealand.

India: Not limited to biological material from India. For biological material from India the National Biodiversity Authority (based on the Biological Diversity Act 2002) has to grant permission before an application for patent can be made.

9. Is traditional knowledge to be indicated only if it is connected to genetic/biological resources, e.g. falling under the CBD, or in general?

Belgium, Germany, Denmark, Italy, Sweden: No requirements regarding traditional knowledge

Brazil, The Philippines: Yes, when associated with genetic resources

South Africa: yes, but probably only if associated with genetic/biological resources falling under the CBD

Switzerland: yes, if associated with the genetic resource and if the invention is directly based on such knowledge

Egypt: yes, and not only if connected to a genetic resource

New Zealand: not included in the Patents Bill in progress

Turkey: the draft law of patents and utility models requires disclosure of traditional knowledge whether it is connected to genetic/biological resources or in general.

India: Section 3(p) of the Patent Act 1970, as amended in 2005, states that "an invention which in effect is traditional knowledge or a duplication of known properties of traditionally known component or components" is not patentable, irrespective whether it is connected with biological resources or not.

10. What “triggers” the disclosure requirement, i.e. how close must the relationship of the invention to the biological/genetic resource be?

Belgium: The wording in the statute is “on the basis of which the invention has been developed”. No implementing regulations have been passed.

Brazil: the Law requires that the number and date of the corresponding Authorization for accessing samples of material deemed to be part of the national genetic resources is declared to the Brazilian Patent and Trademark Office.

China: Under the new Patent Law, “an invention achieved relying on genetic resources” refers to an invention the achievement of which utilizes the genetic function of genetic resources, and in more details, means that genetic function units are isolated, analyzed, treated and so on, so as to complete the invention and realize the value of the genetic resources.

Switzerland: If the invention is “directly based” on the genetic resource or the traditional knowledge.

Germany: The provision is triggered if biological material relating to plants or animals is the subject matter of the invention or is used by the invention.

Denmark: Not clear.

Egypt: There is no clear definition in the legislations mentioned in the response how close the relationship of the invention should be to the biological/genetic resource to require disclosure.

Italy: The disclosure requirement is compulsory in all cases under Art. 5.2 of Italian Law No. 78 of 22.02.2006, where the claimed invention is based on biological material of animal or vegetal derivation. Although there is no specific definition of this expression, the provision should apply to all cases where the biological material of animal or vegetal origin is the object or is used to carry out the object of the invention. However other interpretations may be possible.

Norway: The disclosure is required for inventions which directly concern or use biological material or traditional knowledge. Methods used on biological material are not concerned. The obligation to disclose information applies also in cases where the inventor has altered the structure of the received material.

The Philippines: Even indirect connection to the biological/genetic resource requires disclosure.

Sweden: Not explained in the preparatory comments on the relevant Section 5a in the Patents Decree.

South Africa: If the invention is “based on or derived from” an indigenous biological or genetic resource, the knowledge that an indigenous community has regarding the use of an indigenous biological or genetic resource, or the way in which, or the purpose for which, an indigenous community has used an indigenous biological or genetic resource, the applicant must mark the affirmative statement on these points on the relevant Form P.26.

India: Not clear based on the present statute.

11. Does the law/regulation indicate that access to a genetic/biological resource would not mandate a disclosure in the patent application if such access had occurred prior to a particular date, e.g. from prior to the date of entry into force of the CBD?

Belgium: the provisions apply from the date of entering into force of the patent law amendment April 28, 2005

Brazil: the date after which disclosure is mandatory is June 30, 2000

Denmark, Germany, Italy, Norway, Sweden, The Philippines: No

Egypt: the provisions apply from the entry into force of the IP law amendment in June, 2002

South Africa: No, the relevant statutory provision does not provide for a cut-off date.

Switzerland: the disclosure requirement is not dependent on the date on which the inventor/applicant had access to the resource or the traditional knowledge.

India: No date mentioned. The revocation provision (section 64, see below) clearly provides that a patent may be revoked, irrespective of whether it had been granted before or after the commencement of the Patent Act 2005. Implicitly this applies also for biological resources collected before the CBD went into effect.

12. Are sanctions foreseen for non-compliance, e.g. patent invalidation, revocation or lack of enforceability, patent transfer to the owner of the resource, fines, criminal sanctions etc.?

Belgium, Germany, Sweden: No sanctions have been foreseen

Brazil: yes, different sanctions including cancellation of the IP rights, warning, fine, seizure of samples of genetic resources and instruments used in their collection or processing or the products obtained, suspension of sale of products derived from genetic resources or associated traditional knowledge, partial or complete interdiction of activities or the intervention in the establishment, suspension of registration, patent

licence or authorization, loss or restriction of tax incentives granted by the government, suspension of eligibility for subsidized financing from official development agencies, and prohibition to contract with the government for up to five years.

Switzerland: fine up to SFR 100 000 for wrongful provision of false information, but no patent invalidation, it being specified that the fact that the applicant confirms in writing that he does not know the source could potentially trigger his criminal liability to the extent that this could be deemed as a wrongful provision of false information. In addition, the court can order the publication of its decision.

China: Non-compliance of Article 5(2) of the new Patent Law, the patent could be either rejected during substantive examination or invalidated after issuance.

Denmark: No specific sanctions are indicated, but it is clear that a violation of the regulation will have no effect on the patentability of the invention or the validity of the patent. A violation of the regulation would be adjudicated under the rules of providing false information to a governmental administrative body which could, most likely, result in a fine, if the applicant knew the information was false.

Egypt: the patent application will be cancelled for non-compliance with the provisions of art. 3.3 of the Executive Regulations.

Italy: Law no. 78 does not provide sanctions for the patent application regarding an invention based on biological/genetic resources in case the prescribed declarations regarding the source and the country of origin of the biological material and/or the informed consent are not filed. The Implementing provision refers only to an annotation of the omitted act. However, according to Law no. 99 of 23.07.2009 the government has been delegated to enact provisions defining sanctions against violations of the rules regarding the juridical protection of biotechnological inventions.

Norway: Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code §166. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

New Zealand: There is no direct disclosure requirement and therefore no sanctions for failing to comply. In addition, it remains to be seen how the Maori advisory committee will function, it is unclear whether there is scope under the Bill for the Commissioner to refuse an application if it is contrary to Maori values, but an application can be refused for lacking novelty or inventive step, e.g. if the invention based on traditional knowledge is part of the prior art.

The Philippines: yes, sanctions are foreseen.

South Africa: A sanction (revocation) is provided for the lodging of a false declaration: section 61 of the Patents Act, 1978 provides that any person may apply for the revocation of a patent on a number of grounds; one such ground is set out in section 61(1)(g) namely that the disclosure statement contains a false statement or

representation that the patentee knew or reasonably ought to have known to be false. The disclosure statement, Form P.26, is a formal requirement to be met for acceptance of the application. Accordingly, non-compliance will prevent the application to be accepted and the patent to be granted.

India: Section 64(1)p of the Patent Act 1970, as amended in 2005, relating to Revocation of Patents provides that any person interested may ask for revocation on the grounds "that the specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention".

13. Are human genetic resources treated differently or the same way as animal or plant genetic resources falling under the CBD?

Belgium, Brazil: it is clearly stated that human genetic resources are not included

Denmark: Differently. The Implementing Regulations of the Danish Patent Law states in §3, subsection 5, that: if an invention relates to or uses biological material of human origin, the patent application must disclose if the person from whom the material originates has consented to the filing of the application. The information on consent does not have any effect on the prosecution of the application or the validity of any of the rights attached to the issued patent.

Germany: Human genetic resources are not addressed in the referenced provision. There is no specific requirement to indicate a country/place of origin with respect to human genetic resources. Among others, there was the argument that this would violate data protection and personality rights of concerned individuals.

Italy: Human genetic resources are treated in a different way than resources of animal or vegetal origin in so far as filing a prior informed express consent to the drawing and the use of the biological material from the person it has been drawn is required.

Norway: If an invention concerns or uses biological material from the human body, the patent application shall include information on whether the person from whom the material has been derived has given his/her consent to the use of the biological material.

Switzerland: Human genetic resources are perhaps also subject to the new Art. 49a. There is no formal limitation to genetic resources according to the CBD, although the legislative message mentions the definition of genetic resources in the CBD (which does not cover human genetic resources).

Sweden: Human genetic resources are not included in the relevant Section 5a of the Patents Decree.

Egypt: Human genetic resources are not patentable at all according to Article 2 of law 82/2002 for the Protection of Intellectual Property.

New Zealand: The patentability of human genetic resources, whether from indigenous peoples or others, will be regulated by other clauses in the Patents Bill.

The Philippines: unclear

Turkey: For human genetic resources there are different provisions.

South Africa: The South African Environmental Management Biodiversity Act, 2004, expressly excludes human genetic material from "indigenous biological resource". The Patents Act defines "indigenous biological resource" with reference to the Biodiversity Act, but then has a separate definition of "genetic resource". It will be noted that human genetic material is not expressly referred to, i.e. not expressly excluded.

India: The Biological Diversity Act, 2002 states that the definition of the term "biological resources" does not include human genetic material.

Three Annexes:

Annex 1: 2010 Questionnaire

Annex 2: AIPPI National Groups which have responded

Annex 3: Summary table with assembled responses

(document complemented February 2012)