

National Group: AIPPI ITALY

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Special Committees Q 94 – WTO/TRIPS and Q166 – Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

on the

Requirement of indicating the source and/or country of origin of genetic resources and traditional knowledge in patent applications

Questions

1) Is there a legal requirement in your country that the source and/or country of origin of biological/genetic resources and traditional knowledge must be indicated in patent applications for inventions based on such biological/genetic resources or traditional knowledge? If yes, please quote the corresponding text from the law or regulations and reply to the following questions, if applicable:

- a) Are these regulations found in patent law, general IP laws or in legislation implementing the Convention on Biological Diversity?

a) Art. 5.2 of Italian Law No. 78 of 22.02.2006, enacting the EU directive 98/44/EC on legal protection of biotechnological inventions in Italy, provides that “ The source of the biological material either of animal or of vegetal derivation, on which an invention is based, is stated at the filing date of the patent application, with reference of the Country of origin, to enable

both the verification of the compliance with the legislation regarding import and export of such type of material, and the organism from which the biological material was isolated.”
Implementing Provisions of the Italian Industrial Property Code (C.P.I.) recently issued (Law Decree no. 33 13.01.2010) at art. 21.2, prescribe that the lack of such statement is annotated onto the Registry of Industrial Property.

- b) What "triggers" the disclosure requirement, i.e. how close must the relationship of the invention to the biological/genetic resource be to require disclosure?

b) The disclosure requirement under a) is compulsory in all cases where the claimed invention “is based on biological material of human or vegetal origin”. Although there is no specific definition of the above 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.

- c) Is it clear what the concept of “source” or “country of origin” or "country providing the resource", and “based on genetic resource/traditional knowledge” or "derived from biological resource and associated traditional knowledge” means and what information must be included in the patent application?

c) The above Italian provision refers solely to the protection of invention based on “biological material” and does not contain provisions concerning “traditional knowledge”. The provision refers to a statement, implying that the information should not be included mandatorily in the text of the patent application.

As to the information that must be included in the patent application, Art. 5.3 of Law No. 78 provides that, when the biological material, that is the object of the invention or is used to carry out the invention, is of human origin, then the patent application must enclose an express prior informed consent by the person from whom it was drawn.

Moreover, Art. 5.4 of Law No. 78 prescribes that a patent application on an invention having as the object or using a biological material that contains a genetically modified microorganism or organism must be accompanied by a declaration warranting that all obligations deriving from national and community provisions concerning such modifications (e.g. legislative Decree No. 244 of 08.07.2003, implementing Directive 2001/18/EC) have been respected.

- d) Is the disclosure requirement limited to biological/genetic resources or traditional knowledge of your country only or is it applicable also to biological/genetic

resources or traditional knowledge obtained or obtainable from other countries and geographical areas?

d) The provisions of Law No. 78 regarding disclosure requirements are not limited to biological/genetic resources of our country.

e) Are there ways to complement, correct or amend the corresponding text in the patent application after filing?

e) In general term, Art. 172.2 of the Industrial Property Code (C.P.I.) allows the applicant to amend before the grant its application and any relating documents in the aspects which are not substantial.

f) Is disclosure of “prior informed consent” and/or agreements on “fair and equitable benefit-sharing” required?

f) See under c) above.

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

g) 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 content to the drawing and the use of the biological material from the person it has been drawn is required.

h) Is traditional knowledge properly defined, and is the source of traditional knowledge to be indicated only if it is connected to genetic/biological resources (e.g. falling under the CBD) or in general?

h) Neither Law No. 78, nor the patent Law (C.P.I.) contains provisions regarding traditional knowledge.

i) 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.)?

i) 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 the biotechnological inventions.

- j) 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. prior to the date of entry into force of the CBD?

j) The law does not contain any indications exempting from the disclosure requirement concerning the source and the country of origin of biological material, in patent application claiming inventions based on genetic/biological resources.

2) Please indicate your *experience* with the application of the legal requirement as listed under 1) when filing and prosecuting patent applications in your country.

2) *No experience.*

3) Please give *statistical data* on the number of applications mentioning source and/or country of origin of genetic resources and/or traditional knowledge, following the legal requirement as listed under 1) in your country. If such data are not available, please give an estimate of the number of such applications.

3) *Not available*

4) Please indicate whether *administrative or judicial decisions* on the application of the legal requirement as listed under 1) are available. If yes, please provide the text of such decisions.

4) *Not known.*

5) If there is no legal requirement of indicating the source and/or country of origin of genetic resources and/or traditional knowledge in patent applications for inventions based on such genetic resources or traditional knowledge in your country: Do you know of any *project of law* in your country dealing with the topic? If yes please provide the corresponding text and review it for the questions a) to i) as under 1). Please include also links to websites which would allow us to follow the progress on these projects of law.

5) *Not aware at the moment.*

SUMMARY

Italian Law provides that the source of the biological material either of animal or of vegetal derivation, on which an invention is based, should be stated at the filing date of the patent application, with reference of the Country of origin, to enable both the verification of the compliance with the legislation regarding import and export of such type of material, and the organism from which the biological material was isolated. The lack of such statement is annotated onto the Registry of Industrial Property. The provision is not limited to biological/genetic resources of our country.

No provision is foreseen concerning “traditional knowledge”.

When the biological material, that is the object of the invention or is used to carry out the invention, is of human origin, then the patent application must enclose an express prior informed consent by the person from who it was drawn.

No relevant case law is available

No sanctions are presently provided for not filing the prescribed statements or declarations, but the government has been delegated by law to enact ad hoc legislation.