

Question Q94/Q166

National Group: Norway

Title: Q94 / Q166 - Requirement of indicating the source and/or country of origin of genetic resources and traditional knowledge in patent applications

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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?

Yes

If yes, please quote the corresponding text from the law or regulations.

The Norwegian Patents Act

Chapter 2 The Patent Application and Its Processing, Etc.

Section 8 b. If an invention concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.

If the providing country is not the same as the country of origin of the biological material or the traditional knowledge, the application shall also state the country of origin. For biological material, the country of origin means the country from which the material was collected from its natural environment and, for traditional knowledge, the country in which the knowledge was developed. If the national law in the country of origin requires that access to biological material or the use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that.

For biological material, the duty to disclose information under the first and second paragraphs applies even where the inventor has altered the structure of the received material. The duty to disclose information does not apply to biological material derived from the human body. If access to biological material has been provided in pursuance of Article 12.2 and Article 12.3 of the International Treaty of 3 November 2001 on Plant Genetic Resources for Food and Agriculture, a copy of the standard material transfer agreement (MTA) stipulated in Article 12.4 of the Treaty shall be enclosed with the patent application instead of the information stipulated in the first and second paragraphs.

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.

Section 8 c. 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, in accordance with the law of 21st February 2003 no 12 about bio banks.

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.

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?
 - Yes in the Norwegian Patents Act

- 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?
 - Inventions which directly concerns or uses 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.

- 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?
 - The concepts seem reasonably clear, especially when the Guidelines for the examiners at the Norwegian Industrial Property Office (The Norwegian Patent Office) and the preparatory works for the amendments of the Patents Act are taken into consideration.
 - The information to be included is specified in the Norwegian Patents Act and the Guidelines for the examiners at the Norwegian Industrial Property Office

- 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?

- The disclosure requirement is applicable for any country of origin.
- However, PCT national filings in Norway are exempted from the requirement and EPO validations in Norway are presumed exempted.

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

- Lack of disclosure in a patent application will cause the issue of an invitation to correct the matter from the Patent Office in the first Office Action.

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

- If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.
- No requirements regarding “fair and equitable benefit-sharing”.

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

- The requirement for disclosure applies for both animal or plant genetic resources. For non-human biological materials, providing country and country of origin must be disclosed . 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.

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?

- Traditional knowledge is defined according to WIPOs definitions:

WIPO currently uses the term "traditional knowledge" to refer to tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields. "Tradition-based" refers to knowledge systems, creations, innovations and cultural expressions which: have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and are constantly evolving in response to a changing environment. It should be emphasized, however, that a precise definition of traditional knowledge is not a crucial requisite for establishing a system for its protection. Actually, most patent laws do not define inventions. Likewise, most trademark laws do not define signs. The crucial element for the protection of any subject-matter is the identification of some characteristics that it must meet as a condition for protection - such as novelty, inventiveness and susceptibility of industrial application, for inventions, and distinctiveness, for trademarks. The same criterion could be applied to traditional knowledge as well.

- The source of traditional knowledge is to be indicated also when it is not connected to genetic/biological resources.

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.)?

- 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.

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?

- No, there are no time limits regarding when the genetic/biological material was obtained.

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.

Our experience is that in order to avoid the disclosure requirement and the work involved with it, applicants choose to file a PCT application claiming priority from the Norwegian application, and then refiling a Norwegian national PCT application which is exempted from the requirement.

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.

(Data: Norwegian Patent Office, period 29 June 2007 – 26 February 2010):

Applications falling under CBD:

1 application mentioning source and/or country of origin under CBD has been filed.

1 application granted wherein the applicant informed of source upon receiving information about duty to disclose from the Patent Office.

1 unpublished application under prosecution, not known whether source is given.

13 applications withdrawn, not known whether source was given.

1 application withdrawn, no source information was given.

Applications concerning biological material exempted from CBD (via PCT):

80 granted patents

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.

No decisions available to our knowledge.

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.

Not applicable