

National Group: Sweden

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Questionnaire February 2010

**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:

Section 5a of the Swedish Patents Decree (1967:838 as amended 2004:162) provides as follows (unofficial translation) concerning indication of the source of biological material. Traditional knowledge is not included.

“If an invention concerns biological material of plant or animal origin or if such material is used in an invention, the patent application shall contain information on the

geographical origin of such material, if this is known. If the origin is not known, this shall be indicated.

Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the application or the validity of the rights arising from a patent granted."

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

As noted, the quoted part comes from the Patents Decree. It was introduced in the context of implementation in Sweden as of May 1, 2004, of the EU Directive 98/44/EC on the legal protection of biotechnological inventions. It is stated in the Government Bill implementing EU Directive 98/44/EC that one objective of the provision is to facilitate for providers of genetic resources to monitor compliance with individual agreements, as well as compliance with the general access and benefit-sharing provisions under the CBD.

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?

This is not explained in the preparatory comments on said Section 5a. The Swedish Group is not aware of any administrative or court cases in Sweden on this point. On a general level, Sweden supports the EU proposal "Disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications" submitted to WIPO in December 2004. This proposal includes that for a disclosure requirement to be applicable, the invention must be "directly based on the specific genetic resources".

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 Patents Decree uses the expression "geographical origin". There is no explanation in the preparatory work as to what this means in practical terms, nor are there as far as the Swedish Group is aware any administrative or court cases on this point.

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 wording of the said Section 5a is not limited to material of any specific geographical origin. Again, however, the Swedish Group is not aware of any administrative or court cases on this point.

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

The application for a patent must not be amended so as to claim protection for subject matter which did not appear in the application at filing date or priority date (Section 13 of the Swedish Patents Act). If the application does not include information regarding geographical origin on the filing date, this information can be submitted later during the patenting process since such a complement or amendment would not be considered as altering the subject matter of the claimed invention. The information of geographic origin can therefore be submitted to the Patent Authority and added to the patent application as long as the application has not been decided upon.

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

No.

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

Section 5a of the Patents Decree concerns only biological material of plant or animal origin. Thus, human genetic resources are not included. The Swedish word for “animal” excludes human beings.

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?

Not relevant, see the introduction to Question 1 above.

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.)?

Lack of information regarding the origin of biological material is of no consequence to the processing of patent applications or the validity of rights arising from granted patents. Section 5a of the Patents Decree contains in its second paragraph an explicit provision to this effect.

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.

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.

There is no particular procedure, e.g. a form that shall be filled in by the applicant or a notification to be sent to a provider of a resource, regarding disclosure under Section 5a of the Patents Decree. The Patents Decree Section 5a has as far as the Swedish Group is aware not led to any special difficulties in the filing and prosecution of patent applications.

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.

As a consequence of the procedure under 2, no figures regarding the exact number of applications can be presented. It is difficult to provide an estimate of the number of relevant patent applications.

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.

As repeatedly noted above, the Swedish Group is not aware of any administrative or judicial decisions in regard to Section 5a of the Patents Decree. The absence of such decisions may not be surprising, given that information, or absence of information, under the Patents Decree Section 5a does not bring any sanctions.

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 relevant.

Procedure

It would be most helpful if the National Groups would fill out the Questionnaire and send in their answers to the General Secretariat of AIPPI by **12 March 2010** to:

f.martin@aippi.org

Please use a separate sheet for indicating your answers or include the answer in the present text at the end of each question.

For inquiries, please contact any of the chairs of Q94 and Q166:

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