

National Group: German National Group

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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:

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

- 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?
- e) Are there ways to complement, correct or amend the corresponding text in the patent application after filing?
- f) Is disclosure of “prior informed consent” and/or agreements on “fair and equitable benefit-sharing” required?
- g) Are human genetic resources treated differently or the same way as animal or plant genetic resources falling under the CBD?
- 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?
- 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.)?
- 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?

Answers:

There is a legal requirement in Germany that the place of origin of biological material relating to plants or animals that is the subject matter of a patent application should be indicated. Such legal requirement is stated in § 34a Patentgesetz (German statute on patents) which was introduced into the statute by an act revising the patent statute in order to implement the EU-Directive 98/44/EC of 6. July 1998 on the Legal Protection of Biotechnological Inventions into German law. § 34a Patentgesetz reads

in German:

Hat eine Erfindung biologisches Material pflanzlichen oder tierischen Ursprungs zum Gegenstand oder wird dabei derartiges Material verwendet, so soll die Anmeldung Angaben zum geographischen Herkunftsort dieses Materials umfassen, soweit dieser bekannt ist. Die

Prüfung der Anmeldungen und die Gültigkeit der Rechte aufgrund der erteilten Patente bleiben hiervon unberührt.

and in English:

If an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known. This is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

The wording of § 34a Patentgesetz is practically identical with the recital no. 27 of the EU-Directive 98/44/EC of 6. July 1998 on the Legal Protection of Biotechnological Inventions.

- a) As mentioned above, the provision is as § 34a part of the German patent statute.
- b) 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.
- c) The provision as cited above uses the term "geographical origin" which seems to be fairly clear. The other expressions as indicated in the question are not used by the cited provision.
- d) The disclosure requirement is not limited to biological material originating from Germany but applies to biological material originating from any place.
- e) It would be admissible under German patent law to complement an application with a piece of formal information as the indication of a geographic origin as requested by § 34a Patentgesetz.
- f) No, that is not a requirement under the above referenced provision.
- g) Human genetic resources are not addressed in the above 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.
- h) There is no requirement to indicate a country/place of origin with respect to traditional knowledge as such.
- i) There are no sanctions for non-compliance. Sentence 2 of the above referenced provision states that the processing of the application and the validity of the patent are not affected by non-compliance.
- j) 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.

Answer:

To my knowledge, the requirement under § 34a Patentgesetz does not play a big role in German practice.

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.

Answer:

I could not get statistical data yet. If I shall succeed to get statistical data, I will update our report.

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.

Answer:

To my knowledge, there are no administrative or judicial decisions yet on the application of § 34a Patentgesetz.

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.

Answer:

Does not apply since there is a legal requirement as explained above. To my knowledge, there is no legislative project to change or amend or expand the cited provision.

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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