

National Group: The Danish AIPPI 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? **Answer:** YES.

If yes, please quote the corresponding text from the law or regulations and reply to the following questions, if applicable:

Answer: *The Implementing Regulations for the Danish Patent Law comprises in § 3, subsection 4: If an invention relates to or uses a biological material originating from plants or animals the patent application must comprise information about the geographical origin of the material if the patent applicant has knowledge thereof. If the applicant does not have such knowledge of the geographical origin of the material this must be disclosed in the patent application. Lack of information concerning the geographical origin or the lack of*

knowledge about this does not have any effect on the prosecution of the application or the validity of any of the rights attached to the issued patent.

- a) Are these regulations found in patent law, general IP laws or in legislation implementing the Convention on Biological Diversity? **Answer:** *They are found in the Implementing Regulations of the Danish Patent Law.*
- 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? **Answer:** *This is not absolutely clear to us.*
- 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? **Answer:** *No; the language is "geographical origin". The regulation does not state that the name of a country must be indicated, but the general feeling is that this is the meaning. Furthermore, it is not clear if it should be the country of origin as defined in the CBD or the source country, i.e. the country where the material was obtained.*
- 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? **Answer:** *It is not limited to resources of our country.*
- e) Are there ways to complement, correct or amend the corresponding text in the patent application after filing? **Answer:** *YES, no problem!*
- f) Is disclosure of "prior informed consent" and/or agreements on "fair and equitable benefit-sharing" required? **Answer:** *NO, only if it relates to biological material of human origin.*
- g) Are human genetic resources treated differently or the same way as animal or plant genetic resources falling under the CBD? **Answer:** *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 about 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.*
- 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? **Answer:** *NO. The Danish legislation does not*

comprise any issues of traditional knowledge. There is no requirement for the provision of information concerning 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.)? **Answer:** *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 a 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.*
- 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?

Answer: *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:** *As far as the Danish group is aware, there are no problems. Furthermore, most Danish companies in the field of biotechnology subscribe to the principles on bioprospecting that BIO and EuropaBio have established. Also, the larger, innovation-driven, Danish companies have in addition their own policies which shall secure that the rules are complied with.*

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:** *Probably, very few. Furthermore, most, if not all, Danish patents for which it would be relevant originate from EP patents and for EP patents, there are no requirements for mentioning source and/or country of origin of genetic resources and/or traditional knowledge.*

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:** *We don't have knowledge of such decisions.*

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:** *There is no scheduled project for revising the existing regulation*

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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