

National Group: Switzerland

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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?

Yes, there is a legal requirement introduced into the Swiss Patent Law (Bundesgesetz über Erfindungspatente) as amended on 22 June 2007, which entered into force on July 1, 2008. Copies of the relevant articles:

<p>II. Angaben über die Quelle genetischer Ressourcen und traditionellen Wissens</p>	<p><i>Art. 49a</i></p> <p>¹ Das Patentgesuch muss Angaben enthalten über die Quelle:</p> <ul style="list-style-type: none"> a. der genetischen Ressource, zu welcher der Erfinder oder der Patentbewerber Zugang hatte, sofern die Erfindung direkt auf dieser Ressource beruht; b. von traditionellem Wissen indigener oder lokaler Gemeinschaften über genetische Ressourcen, zu dem der Erfinder oder der Patentbewerber Zugang hatte, sofern die Erfindung direkt auf solchem Wissen beruht. <p>² Ist die Quelle weder dem Erfinder noch dem Patentbewerber bekannt, so muss der Patentbewerber dies schriftlich bestätigen.</p>
<p>II. Falsche Angaben über die Quelle</p>	<p><i>Art. 81a</i></p> <p>¹ Wer vorsätzlich falsche Angaben nach Artikel 49a macht, wird mit Busse bis zu 100 000 Franken bestraft.</p> <p>² Der Richter kann die Veröffentlichung des Urteils anordnen.</p>
<p>C. Formerfordernisse</p>	<p><i>Art. 138</i></p> <p>Der Anmelder hat dem Institut innerhalb von 30 Monaten nach dem Anmelde- oder dem Prioritätsdatum:</p> <ul style="list-style-type: none"> a. [...] b. Angaben über die Quelle zu machen (Art. 49a);

The amended Patent Ordinance (Patentverordnung) deals with the subject in the newly added 6th chapter, Art. 45a:

Sechstes Kapitel:

Angaben über die Quelle genetischer Ressourcen und traditionellen Wissens

Art. 45a

¹ Die Quelle genetischer Ressourcen oder traditionellen Wissens im Sinne von Artikel 49a des Gesetzes ist in der Beschreibung der Erfindung zu nennen.

² Als Quelle nach Absatz 1 gelten insbesondere:

- a. das genetische Ressourcen zur Verfügung stellende Land im Sinne der Artikel 2 und 15 des Übereinkommens vom 5. Juni 1992 über die Biologische Vielfalt;
- b. das multilaterale System im Sinne von Artikel 10 Absatz 2 des Internationalen Vertrags vom 3. November 2001 über pflanzengenetische Ressourcen für Ernährung und Landwirtschaft;
- c. eingeborene und ortsansässige Gemeinschaften im Sinne von Artikel 8 Buchstabe j des Übereinkommens vom 5. Juni 1992 über die Biologische Vielfalt;
- d. das Ursprungsland der genetischen Ressourcen im Sinne von Artikel 2 des Übereinkommens vom 5. Juni 1992 über die Biologische Vielfalt;
- e. *Ex-situ*-Quellen wie beispielsweise botanische Gärten oder Genbanken;
- f. wissenschaftliche Literatur.

Answer to the sub-questions a) to j)

- a) Regulations in the Patent Law Art. 49a, Art. 81a and Art. 138 lit. b, and in the Patent Ordinance Art. 45a.
- b) If the invention is "directly based" on the genetic resource or the traditional knowledge.
- c) Only the source has to be indicated. The inventor/applicant can also indicate that he does not know the source. "Source" is defined in the patent ordinance Art. 45a, and is in particular
 - a. Country providing the genetic resource in the sense of Art. 2 and 15 CBD
 - b. The multilateral system in the sense of Art. 10 para. 2 of the International Treaty on the Plant Genetic Resources for Food and Agriculture
 - c. Indigenous and local communities in the sense of Art. 8j of the CBD
 - d. Country of origin of the genetic resource in the sense of Art. 2 CBD
 - e. *Ex situ* sources, such as botanical gardens or gene banks
 - f. Scientific literature.
- d) The disclosure requirement applies independently of the country or geographical area of origin.
- e) The source has to be indicated within 30 months from the application (priority) date. If the requirements of Art. 49a are not fulfilled, the office will set a date until which the requirements have to be fulfilled (PatV Art. 67 para. 2). If the applicant fails to do so, the application will be rejected. It is not apparent that the information can be complemented, corrected or amended at a later date.
- f) No disclosure of prior informed consent or of benefit sharing agreements is required.
- g) Human genetic resources are perhaps also subject to the new Art. 49a. There is no formal limitation to genetic resources according to the CBD, although the

legislative message mentions the definition of genetic resources in the CBD (which does not cover human genetic resources).

- h) **Traditional knowledge: Indications only required in connection with genetic resources, and only if the invention is directly based on such traditional knowledge.**
- i) **Sanction: fine up to SFR 100'000 for wrongful provision of false information (Art. 81a para. 1), but no patent invalidation, it being specified that the fact that the applicant confirms in writing that he does not know the source (as provided under Art. 49a para. 2) could potentially trigger his criminal liability to the extent that this could be deemed as a wrongful provision of false information. In addition, the court can order the publication of its decision (Art. 81a para. 2).**
- j) **The disclosure requirement is not dependent on the date on which the inventor/applicant had access to the resource or the traditional knowledge.**

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 experience yet to report. At least the legal requirements seem to be clear, so an applicant knows what information to provide in the application on filing.

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.

There are no statistical data available, since the requirement has been introduced quite recently. At least one patent has been filed and source indications made by the applicant concerning genetic resources.

Inventions from Switzerland in the field of biotechnology are usually filed and prosecuted in the European Patent Office, which does not have a requirement for indicating the source or country of origin of a genetic resource or traditional knowledge connected to it. The Swiss Patent Office does not examine substantial patentability requirements (novelty, inventive step), but only formal aspects. Some biotechnological applications are filed in Switzerland to create a priority date, but will then not be followed up in Switzerland after the 12 month priority period.

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.

We are not aware of any administrative or judicial 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.

Not applicable.

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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