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?

Under the present legislation, the Patents Act 1953, there is no requirement to provide this information.

This legislation is being replaced by the Patents Bill, which is in progress through the House of Representatives. The Bill was introduced on 9 July 2008 and the public has had an opportunity to make submissions to the Select Committee. The report of the Select Committee is expected in late March 2010. The text of the Bill is available at http://www.legislation.govt.nz/bill/government/2008/0235/latest/versions.aspx

There is no disclosure requirement in the Bill. However, the explanatory note of the Bill states that the Bill aims to “update New Zealand’s patent regime to ensure that it continues to provide an appropriate
balance between providing adequate incentives for innovation and technology transfer while ensuring that the interests of the public and the interests of Māori in their traditional knowledge and indigenous plants and animals are protected.”

To assist in achieving this aim, the Bill will establish a Māori advisory committee to advise the Commissioner in relation to patent applications for inventions involving traditional knowledge or indigenous plants and animals. This committee will provide advice to the Commissioner on request to assist the Commissioner in determining whether such inventions are novel, or involve an inventive step, or whether the commercial exploitation of such an invention would be contrary to Māori values.

The relevant clauses of the Bill are:

Clause 275 Appointment and membership of Māori advisory committee
(1) The Commissioner must appoint a committee called the Māori advisory committee.
(2) The Commissioner may, at any time,—
   (a) appoint a person to the committee:
   (b) remove a member from the committee and, if the Commissioner thinks fit, appoint another member in that member’s place.
(3) A person must not be appointed as a member of the committee unless, in the opinion of the Commissioner, the person is qualified for appointment, having regard to that person’s knowledge of mātauranga Māori (Māori traditional knowledge) and tikanga Māori (Māori protocol and culture).
(4) A member of the committee may resign office by notice in writing to the Commissioner.

Clause 276 Functions of Māori advisory committee
The function of the Māori advisory committee is to advise the Commissioner (on request) on whether—
   (a) an invention claimed in a patent application is derived from Māori traditional knowledge or from indigenous plants or animals; and
   (b) if so, whether the commercial exploitation of that invention is likely to be contrary to Māori values.

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?

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.

This is not yet relevant. It is highly likely that the clauses establishing the Maori Advisory Committee will be retained in the final version of the Bill. The Bill is not expected to come into force until late 2010 or early 2011.

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.
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.

The Patents Bill is not yet in force, so there are no relevant 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?

As stated for Q1 above, the New Zealand Patents Act 1953 is being updated and replaced by the pending Patents Bill. The Patents Bill includes provisions that will establish a Māori advisory committee to advise the Commissioner in relation to patent applications for inventions involving traditional knowledge or indigenous plants and animals. This committee will only assess inventions/applications that utilise Māori traditional knowledge or plants and animals indigenous to New Zealand. There is no requirement in the Bill that the source and/or country of origin of genetic resources and/or traditional knowledge from other countries be indicated.

In addition, there is no requirement in the Bill to specifically identify within a patent application that the invention is based on Māori traditional knowledge or indigenous plants and animals.

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.

The progress of the Patents Bill can be monitored at http://www.parliament.nz/en-NZ/PB/Legislation/Bills/a/f/2/00DBHOH_BILL8651_1-Patents-Bill.htm

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

See clauses 275 and 276 of the Patents Bill (in Q1 above)

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?
There is no explicit disclosure requirement set out in the Patents Bill. Applications are likely to be assessed on a case-by-case basis to determine whether it is appropriate to refer it to the Māori advisory committee.

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?

There is no specific requirement in the Patents Bill to provide this information.

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?

There is no explicit disclosure requirement. However, the Māori advisory committee will only be used to assess applications in which the invention is based on Māori traditional knowledge or plants/animals indigenous to New Zealand.

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

Not applicable.

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

Not applicable.

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

The patentability of human genetic resources, whether from indigenous peoples or others, will be regulated by other clauses in the Patents Bill. For example, the Bill introduces specific exclusions to patentability in Clause 15. Clause 15(1) excludes human beings, and biological processes for their generation. The Bill also includes in Clause 14 general exclusions to patentability for inventions the
commercial exploitation of which are contrary to public order or morality. For the purposes of making a decision under Clause 14, the Commissioner may seek advice from the Māori advisory committee.

The text of these clauses is as follows:

**Clause 14 Inventions contrary to public order or morality not patentable inventions**

(1) An invention is not a patentable invention if the commercial exploitation of the invention, so far as claimed in a claim, is contrary to—

(a) public order (which in this section has the same meaning as the term order public as used in Article 27.2 of the TRIPS agreement); or

(b) morality.

(2) For the purposes of subsection (1), commercial exploitation must not be regarded as contrary to public order or morality only because it is prohibited by any law in force in New Zealand.

(3) The Commissioner may, for the purpose of making a decision under this section, seek advice from the Māori advisory committee or any person that the Commissioner considers appropriate.

(4) For the purposes of this section, TRIPS agreement means the World Trade Organization Agreement on the Trade Related Aspects of Intellectual Property Rights done at Marrakesh on 15 April 1994.

**Clause 15 Other exclusions**

(1) Human beings, and biological processes for their generation, are not patentable inventions.

(2) An invention of a method of treatment of human beings by surgery or therapy is not a patentable invention.

(3) An invention of a method of diagnosis practised on human beings is not a patentable invention.

(4) A plant variety is not a patentable invention.

(5) For the purposes of subsection (4), plant variety has the same meaning as that given to the term variety in section 2 of the Plant Variety Rights Act 1987.

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?

There is no requirement to indicate source.

There is no definition of traditional knowledge in the Patents Bill.
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.)?

There is no direct disclosure requirement and therefore no sanctions for failing to comply. In addition, it remains to be seen how the Māori advisory committee will function, it is unclear whether there is scope under the Bill for the Commissioner to refuse an application if it is contrary to Māori values, but an application can be refused for lacking novelty or inventive step (e.g. if the invention based on traditional knowledge is part of the prior art base.)

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?

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:

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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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