Standing Committee on TRIPS

Standing Committee on IP and Genetic Resources / Traditional Knowledge

Questionnaire on the requirement of indicating the source and/or country of origin of genetic resources and traditional knowledge in patent applications

Background

The discussion on what can be termed as "special disclosure requirements for patent applications involving genetic resources" has been ongoing for many years, not only in the World Trade Organization (WTO/TRIPS), but more so within the framework of the Convention on Biological Diversity (***CBD***) and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (***Nagoya Protocol***). Discussions also take place within the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of WIPO, which has begun to discuss the text of a possible international instrument.

Briefly summarised, many countries rich in biological/genetic resources and traditional knowledge (***GRTK***) demand that patents for inventions based on GRTK should only be granted if GRTK has been obtained in conformity with the requirements of the CBD and the Nagoya Protocol. As a means for checking whether the requirements of the CBD are met, these proponents ask for the inclusion of the source or country of origin of GRTK in patent applications, proof of prior informed consent (***PIC***), and proof, that in return for access, benefit sharing has been properly agreed (access and benefit sharing or ***ABS***) on mutually agreed terms (***MAT***). Their position is that these requirements contribute to transparency and stop biopiracy/misappropriation of GRTK.

Opponents of these disclosure requirements argue, inter alia, that patent law should not be used to enforce international conventions in fields other than patent law, and that new disclosure requirements would create uncertainty in relation to patent rights. Further, they point to the practical problems in providing and collecting such information, and including it in patent applications.

Other complications include:

(a) clarification of the circumstances in which an invention can be regarded as being based on or derived from genetic resources or traditional knowledge; and

(b) there is no generally accepted definition of "traditional knowledge".

196 countries have ratified the CBD. The USA has not ratified the CBD, and so is not bound by it. Currently, 78 countries have ratified the Nagoya Protocol.

For further background information see:

- WTO/TRIPS, http://www.wto.org/english/tratop_e/dda_e/meet08_brief05_e.htm and www.wto.org/english/news_e/news14_e/trip_ss_25feb14_e.htm, https://docs.wto.org
- CBD, http://www.cbd.int
- More particularly on the Nagoya Protocol, http://www.cbd.int/abs/
- WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, http://www.wipo.int/tk/en/igc/.

Previous work of AIPPI

As part of AIPPI's study on the disclosure requirements for patent applications involving GRTK, AIPPI collected information from its National and Regional Groups and Independent Members by a questionnaire distributed in 2006. A Resolution was passed at the Gothenburg Congress (2006) based on the results of this first questionnaire:

- Resolution, http://aippi.org/wp-content/uploads/committees/166/RS166English.pdf

AIPPI collected further information by a questionnaire distributed in 2010, in a joint effort of the Standing Committees on TRIPS and on IP and Genetic Resources / Traditional Knowledge:

- Summary Report, http://aippi.org/wp-content/uploads/committees/166/QS16601_summary_report_questionnaire.pdf
- Annex 1, http://aippi.org/wp-content/uploads/committees/166/QS166annex_1.pdf
- Annex 2, http://aippi.org/wp-content/uploads/committees/166/QS166annex_2_-_list_of_nrg_responses.pdf
- Annex 3, http://aippi.org/wp-content/uploads/committees/166/QS16602_summary_responses_questionnaire_q94-q166.pdf

The purpose of the present questionnaire is to update the information collected from the National and Regional Groups and Independent Members on provisions in existing laws and draft bills, and to collect information on practical experience with the application of such laws and regulations, including the cost to applicants of the disclosure requirement, as well as any benefit to third parties. This study should also provide an indication of the impact of the Nagoya Protocol on patent applications. This will result in a useful resource for negotiators in different international fora dealing with these topics.

National Group: New Zealand – submitted by Michael Brown and Helen Bellchambers, AJ Park

Independent Member:

Date: 7 December 2016

Questions

The Groups are invited to answer the following questions under their national laws:

1) Is there a legal requirement in your country that the source and/or country of origin of GRTK must be indicated in patent applications for inventions based on GRTK (***Disclosure Requirement***)?

   No

   If yes, please: (i) indicate whether this legal requirement was introduced after 2010 or, if introduced prior to 2010, whether there have been substantial amendments since 2010; (ii) provide concise quotes of the corresponding text from the laws or regulations or a concise summary; and (iii) reply to the following questions a) to j).

   a) Is the Disclosure Requirement found in patent law (including utility model law, plant variety protection law or design law), general IP laws, in legislation implementing the CBD or the Nagoya Protocol, or any other (and if so, what) sources of law?

   b) What "triggers" the Disclosure Requirement, i.e. what relationship between the invention and the GRTK is required?

   c) Is it clear what the concepts 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" mean, and what information must be included in the patent application?

   d) Is the Disclosure Requirement limited to GRTK of your country or is it applicable also to GRTK obtainable from other countries or geographical regions?

   e) Is disclosure of PIC ("prior informed consent") and/or agreements on "fair and equitable benefit-sharing" required?

   f) Are human genetic resources treated differently or the same way as animal or plant genetic resources?

   g) Is "traditional knowledge" separately defined, and is the source of traditional knowledge to be indicated only if it is connected to genetic/biological resources or in general?

   h) Are there sanctions for non-compliance (e.g. patent invalidation, revocation or lack of enforceability, patent transfer to the owner of the resource, fines, criminal sanctions etc.)? If yes, please briefly describe any applicable sanctions.

i) Is there any ability to amend the relevant text in the patent application after filing to address non-compliance?

j) Is any Disclosure Requirement limited by reference to whether access occurred prior to a particular date, e.g. prior to the date of entry into force of the CBD?

The following questions 2) to 14) deal with the effects of the Disclosure Requirement and aspects of the Nagoya Protocol, and the experiences of applicants (and representative of applicants) with those requirements. These questions should be answered by all National and Regional Groups and Independent Members to the extent applicable.

2) Please indicate your experience with the application of the Disclosure Requirement when filing and prosecuting patent applications in your country.

Not applicable – Nagoya Protocol not ratified in New Zealand and no domestic equivalent

3) Please give statistical data on the number of patent applications mentioning source and/or country of origin of GRTK in your country. Is there a specific section of the patent register listing patents and patent applications comprising information on source or country of origin of GRTK? If such data are not available, please give an estimate of the number of such patents and patent applications and indicate the basis of the estimate.

Not applicable - No specific register, and no requirement to mention source and/or country of origin of GRTK

4) Please indicate whether administrative or judicial decisions on the application of the Disclosure Requirements is available. If yes, please provide a concise summary (or a link to an on-line version) of such decisions.

Not applicable

5) Please provide an estimate per patent application of the additional (a) time and (b) cost in legal fees associated with compliance with the Disclosure Requirement in your country.

Not applicable

6) Please provide an estimate of the additional time and cost as described in question 5) associated with compliance with any foreign Disclosure Requirement.

Unknown

7) Has the Disclosure Requirement had an impact on patent valuation (either increasing or decreasing the perceived value of a patent) in your country?

Not applicable - No disclosure requirement

8) Has the Disclosure Requirement had any effect on R&D activities in your country, e.g., a change in the number of patent applications for inventions in biological technology fields, or an increase or decrease of such activities using biological materials such as plants, animals and microorganisms, etc. from either your country or other countries due to the ease or difficulty of obtaining PIC or MAT ("mutually

agreed terms")?

Not applicable - No disclosure requirement

9) Are you aware of any benefits or disadvantages, including for third parties, of the Disclosure Requirement in your country? For example, has the Disclosure Requirement improved patent examination, or led to the sharing of financial or other benefits?

Not applicable - No disclosure requirement

10) As a source country or country of origin, does your country have any legal system and/or administrative authorities or agency to provide any type of certificate to provide proof of the source and/or country of origin of GRTK? If yes, which ministry or authority is responsible? Please include also links to websites which would allow accessing information and contacting the responsible local authorities.

No

11) The following questions relate specifically to the Nagoya Protocol.

a) If your country has not (yet) implemented the Nagoya Protocol, please indicate this.

New Zealand has not implemented Nagoya Protocol

b) The Nagoya protocol stipulates ABS ("access and benefit sharing"). In your country, is there any impact on intellectual property protection and/or enforcement if ABS is not satisfied?

Not applicable - not implemented Nagoya Protocol

c) The Nagoya Protocol also stipulates PIC ("prior informed consent"). In your country, is there any impact on intellectual property protection and/or enforcement if there is any failure or defect in PIC?

Not applicable - not implemented Nagoya Protocol

d) The Nagoya Protocol also stipulates MAT ("mutually agreed terms"). In your country, is there any impact on intellectual property protection and/or enforcement if there is any failure or defect in MAT?

Not applicable - not implemented Nagoya Protocol

12) Academic research often involves GRTK. Are there any special regulations and/or measures for academics and/or academic institutions such as universities to protect and promote the protection and development of GRTK?

Not specifically, but New Zealand universities would usually take the principles of the Treaty of Waitangi into account for research relating to Māori traditional knowledge.

13) "Traditional medicine" may fall within GRTK. Information relating to traditional medicine is generally not found in the literature or in other written form in the public domain. Does your country permit patent or any other form of intellectual property protection in relation to traditional medicine? If yes, does your country have any specific legislation or examination practice for the protection of traditional medicine? Please include links to websites dealing with these practices or legislation, if appropriate.

Traditional medicine is patentable so long as it meets the patentability criteria set out in the Patents Act 2013. Of particular relevance to GRTK is section 15, which states that 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 ordre public as used in Article 27.2 of the TRIPS agreement); or

(b) morality.

The Commissioner of Patents may, for the purpose of making a decision under section 15, seek advice from the Māori advisory committee or any person that the Commissioner considers appropriate.

https://www.iponz.govt.nz/about-ip/maori-ip/maori-advisory-committees/

14) Have there been any authoritative studies in your country on the impact of the Nagoya Protocol? If yes, please provide author(s), title, and information where such studies can be found.

No

Procedure

It would be most helpful if the National/Regional Groups / Independent Members would fill out the Questionnaire and send their answers to the General Secretariat of AIPPI (**StandingCommittees@aippi.org**) by **17 October 2016.**

For inquiries please contact: Konrad Becker, Chair of the Standing Committee on IP and Genetic Resources / Traditional Knowledge (konrad.becker@bluewin.ch), Maria Carmen de Souza Brito, the next Chair of the Standing Committee on IP and Genetic Resources / Traditional Knowledge (mcarmen@dannemann.com.br), and Catherine Mateu, Chair of the Standing Committee on TRIPS (c.mateu@armengaud-guerlain.com).