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: **SWEDEN**

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Note *that this is the second report on the same subject. The answers added and/or changed since 2010 are marked in underlined letters below.*

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***)?

   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).

Section 5a of the Swedish Patents Decree provides as follows (unofficial translation) concerning indication of the source of biological material. Traditional knowledge is not included.

> **"If an invention concerns biological material of plant or animal origin or if such material is used in an invention, the patent application shall contain information on the geographical origin of such material, if this is known. If the origin is not known, this shall be indicated.**
> **Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the application or the validity of the rights arising from a patent granted."**

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?

As noted, the quoted part comes from the Patents Decree. It was introduced in the context of implementation in Sweden as of May 1, 2004, of the EU Directive 98/44/EC on the legal protection of biotechnological inventions. It is stated in the Government Bill implementing EU Directive 98/44/EC that one objective of the provision is to facilitate for providers of genetic resources to monitor compliance with individual agreements, as well as compliance with the general access and benefit-sharing provisions under the CBD.

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

This is not explained in the preparatory comments on said Section 5a. The Swedish Group is not aware of any administrative or court cases in Sweden on this point. The EU proposal "Disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications" was submitted to WIPO in December 2004 and this proposal, including that for a disclosure requirement to be applicable, the invention must be "directly based on the specific genetic resources", is supported by Sweden. <u>As far as the Swedish AIPPI Group is aware, the proposal remains in the IGC.</u>

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?

The Patents Decree uses the expression "geographical origin" There is no explanation in the preparatory work as to what this means in practical terms, nor are there as far as the Swedish Group is aware any administrative or court cases on this point.

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?

The wording of the said Section 5a is not limited to material of any specific geographical origin. Again, however, the Swedish Group is not aware of any administrative or court cases on this point.

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

<u>No.</u>

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

Section 5a of the Patents Decree concerns only biological material of plant or animal origin. Thus, human genetic resources are not included. The Swedish word for "animal" excludes human beings.

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?

Not relevant for the disclosure requirement. see the introduction to Question 1 above. <u>Traditional knowledge is to some extent the subject of the Regulation</u>

(EU) No 511/2014 implementing the Nagoya protocol. There, traditional knowledge is defined in Article 3(7) as 'traditional knowledge associated with genetic resources', meaning traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources.

In implementing the Nagoya protocol, changes have been made to the Swedish Environmental Code in which reference to the EU Regulation is made, both regarding genetic resources and regarding traditional knowledge. The effect of the reference to traditional knowledge is a widening of the scope of the term. Additionally, criminal sanctions have been introduced regarding the wrongful use of genetic resources and traditional knowledge by breach of the EU Regulation. The legislator has deemed it unnecessary to change the Patent law when implementing the Nagoya protocol.

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.

Lack of information regarding the origin of biological material is of no consequence to the processing of patent applications or the validity of rights arising from granted patents. Section 5a of the Patents Decree contains in its second paragraph an explicit provision to this effect.

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

The application for a patent must not be amended so as to claim protection for subject matter which did not appear in the application at filing date or priority date (Section 13 of the Swedish Patents Act). If the application does not include information regarding geographical origin on the filing date, this information can be submitted later during the patenting process since such a complement or amendment would not be considered as altering the subject matter of the claimed invention. The information of geographic origin can therefore be submitted to the Patent Authority and added to the specification of the patent application as long as the application has not been decided upon.

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?

No.

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.

The Swedish Patent and Registration Office receives about 2500 national patent applications per year. Most patent filings by Swedish applicants, effecting the Swedish territory, are made to the European Patent Office, either directly or via PCT. Hence, at least partially due to the limited data, the application of the Disclosure Requirement in Sweden is very limited – in fact next to none.

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.

There are no statistical data available on the number of patent application disclosing the geographical origin of inventions concerning biological material. No specific section of the patent register is designated for information on geographical origin in patent application.

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.

As far as the Swedish AIPPI Group is aware, there are no administrative decisions in relation to the disclosure requirement (Swedish Patents Decree Section 5 a).

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.

The additional time spent on a patent application due to the national disclosure requirements is marginal, and so is the cost.

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

Swedish applicants usually use PCT to file international applications. This means that any additional time spent on foreign patent applications due to various foreign national disclosure requirements is first spent when preparing the PCT application, in order to safeguard that it complies with all relevant requirements. If the application is entered into national phase in a jurisdiction with strict and/or elaborate disclosure requirements, additional time and cost is typically spent on that national application. The cost in the PCT phase typically varies from 0 to 2500 EUR. The cost for a national phase application in a jurisdiction with burdensome requirements can exceed 5000 EUR.

7) Has the Disclosure Requirement had an impact on patent valuation (either

increasing or decreasing the perceived value of a patent) in your country?

To the knowledge of the Swedish AIPPI Group, the disclosure requirements have had no noticeable impact on patent valuation in Sweden.

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")?

The Swedish AIPPI Group understands the question as being limited to the Disclosure Requirement in patent applications.

Insofar as it applies to genetic resources, R&D in the biotechnology field in Sweden is primarily based on Swedish genetic resources. The Swedish AIPPI Group sees no change in patent activity that can be traced back to PIC or MAT requirements.

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?

The Swedish AIPPI Group is not aware of any such benefits or disadvantages.

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.

Sweden does not have a particular access regulation. In general, access is free as long as the access is made in compliance with relevant legislation such as that concerning national parks, residential areas or endangered species.

Link to CBD focal points in Sweden:

https://www.cbd.int/countries/nfp/default.shtml?country=se

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

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

Sweden has implemented the 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?

No.

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?

No.

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?

No.

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?

Sweden has adopted a decree on the utilisation of genetic resources and traditional knowledge associated with genetic resources, mainly comprising the practical implementations of Regulation (EU) No 511/2014 and the Commission Implementing Regulation (EU) 2015/1866. The Swedish Environmental Protection Agency has the responsibility of examining and controlling c.f. compliance with the requirement of due diligence declaration for research involving the utilisation of genetic resources and traditional knowledge associated with genetic resources, as well as any other requirements of academic research institutions regulated in Regulation (EU) No 511/2014 and Commission Implementing Regulation (EU) 2015/1866. The Commission is drafting and publishing guidelines on the Regulations, generally directed towards scope as well as directed towards different branches of industry. The Swedish Environmental Protection Agency plans on publishing these guidelines on their website and update guidance information as it develops and progresses.

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.

Patenting as well as all other forms of intellectual property protection is available in relation to traditional medicine, as long as the patentability requirements – or other relevant requirements regarding other intellectual property rights - are fulfilled. No specific legislation or examination practice applies.

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.

Before ratification of the Nagoya protocol, the Swedish Government, more specifically the Ministry of the Environment and Energy, carried out a legal investigation of the impact of such ratification in Sweden as well as putting forward legislative proposals. The investigation is published and available here:

https://data.riksdagen.se/fil/F1034C73-9B10-4E29-8C32-1AB0CF796933

The Ministry of the Environment and Energy referred the published investigation to a number of governmental agencies, institutions and other stakeholders, inviting them to comment on the proposals made. These consultations are available to the public and may be accessed here:

http://www.regeringen.se/remisser/2015/03/remiss-lagstiftning-for-genomforandet-av-nagoyaprotokollet/

After having received the consultations, the Ministry of the Environment and Energy submitted a legislative proposal to the Parliament. The proposal is available here:

http://www.regeringen.se/contentassets/78b7d4ddec384122a6243a867eb0abdb/nagoyaprotokollet-om-anvandning-av-genetiska.pdf