



**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**

## National Group: Norway

Date: 12 December 2016

Report by Mr Yngve Øyehaug Opsvik (Q 1 and Q 11- Q 14) and Ms Kari Simonsen (Q 2 – Q 10)

### Questions

- 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**)?

Yes – The provision was introduced in 2004 and there have been no substantial amendments to it since then. An unofficial translation of the relevant provision into English follows:

#### **The Norwegian Patents Act**

##### **Chapter 2 The Patent Application and Its Processing, Etc.**

*Section 8 b. If an invention concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.*

*If the providing country is not the same as the country of origin of the biological material or the traditional knowledge, the application shall also state the country of origin. For biological material, the country of origin means the country from which the material was collected from its natural environment and, for traditional knowledge, the country in which the knowledge was developed. If the national law in the country of origin requires that access to biological material or the use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that.*

*For biological material, the duty to disclose information under the first and second paragraphs applies even where the inventor has altered the structure of the received material. The duty to disclose information does not apply to biological material derived from the human body. If access to biological material has been provided in pursuance of Article 12.2 and Article 12.3 of the International Treaty of 3 November 2001 on Plant Genetic Resources for Food and Agriculture, a copy of the standard material transfer agreement (MTA) stipulated in Article 12.4 of the Treaty shall be enclosed with the patent application instead of the information stipulated in the first and second paragraphs.*

*Breach of the duty to disclose information is subject to penalty in accordance with the Penal Act § 221. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.*

*Section 8 c. If an invention concerns or uses biological material from the human body, the patent application shall include information on whether the person from whom the material has been derived has given his/her consent to the use of the biological material, in accordance with the law of 21st February 2003 no 12 about bio banks.*

*Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 221. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.*

*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?

In patent law (The Patents Act).

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

- The invention must either directly concern or use biological material or traditional knowledge.
- The provision applies even if the structure biological material has been altered.

- 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 concepts are clearly explained when the preparatory works and the Norwegian Industrial Property Office's guidelines are taken into account.

- 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 provision applies to all GRTK, irrespective of origin. The provision does not apply to PCT applications.

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

- Disclosure of PIC is required if this is mandatory under the law of the country of origin.
- No express requirements regarding fair and equitable benefit-sharing

- f) Are human genetic resources treated differently or the same way as animal or plant genetic resources?
- Human genetic resources are treated the same, albeit with an additional requirement for consent to use the biological material.
- 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?
- Traditional knowledge is defined according to WIPOs definitions:  
  
WIPO currently uses the term "traditional knowledge" to refer to "the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge that is embodied in the traditional lifestyle of a community or people, or is contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources"
  - The source of traditional knowledge is to be indicated also when it is not connected to genetic/biological resources.
- 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.
- The sanctions for non-compliance are set out in the Penal Act section 221. The penalty is fines or imprisonment for up to 2 years.
  - The validity or legal status of the patent is not affected by a breach of the provision.
- i) Is there any ability to amend the relevant text in the patent application after filing to address non-compliance?
- Yes, the text may be amended, cf. the Patents Act section 13.
- 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 duty to provide information of the country of origin of the genetic material/traditional knowledge is limited to applications that are not a national filing of PCT applications. Thus, in practice this is mostly only relevant for applications filed without claiming priority/filed directly in Norway – which for the most therefore are priority application from Norwegian R&D institutions and companies.

There are not that many academic or private R&D environments in Norway that perform bioprospecting activities, and there are therefore only a very few applications that have been filed, where the applicant will have to provide information of the origin of the biological/genetic material. This is mainly within the field of marine biology, i.e. where naturally occurring genetic material (often microorganisms) have been identified and found to have an industrial applicability.

- 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.

The Norwegian Intellectual property office (the "NIPO") registers and keeps statistics of the applications claiming or relating to naturally occurring genetic material and traditional knowledge. However, as the duty to provide information cannot be requested for national filings of PCT applications (Patents Act section 33, and Norwegian guidelines, C IV 2a.4.1), the list of application is very short (11 applications filed since 1/1-2004).

There is no specific section of the patent register that shows that a patent or patent application comprises information of source of origin or GRTK, but the statistics are available upon request with the NIPO.

- 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.

To our knowledge, there are no administrative or judicial decisions. The decisions would however be available in the file history of an application.

- 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.

There are no legal fees associated with compliance with the disclosure requirement. Thus, the only costs would be those incurred to gather information, prepare documents and file. The costs involved are normally a minor part of the total cost of preparing and prosecuting a patent application. As there is only a few cases to base the estimate upon, a very cautious estimate would be that the additional cost is in the range of NOK 2000 (i.e. for time spent to inform the client of the duty, meetings, discussions, telecons, and correspondence in this respect, to NOK 3500 if it turns out that the information is not easily available, or if there are questions whether the material is indeed covered by the regulations and further work is therefore needed.

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

See question 5.

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

No, there is no significant difference in the number of patent application filed after the disclosure requirement entered into force. This is based upon my own experience, and has also been confirmed by NIPO as well as persons situated in the TTOs at the Universities in Norway.

- 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")?

In general, there is little awareness of the link between patenting and duty to disclose information in the Norwegian academic and R&D circles. However, when information is given about the duty to disclose information, this seems to have little effect on the IP strategy/patent filing etc. In most cases, applicants have had no problems in providing the relevant information.

In a limited number of cases, it has been questioned whether the genetic material was in fact naturally occurring. In one case the material had been cultivated for many years in the laboratory and one questioned whether said material was then the same as the material being collected many years earlier, regardless of the fact that it may have changed, e.g. by mutation. No information about the place of origin was therefore filed. This had no consequences for the patenting of the invention, nor for the applicant.

- 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?

I am not aware of any benefits or disadvantages, including for third parties. The duty to disclose information of place of origin/GRTK has not had any effect on the patent examination. The only difference is that if the examiner finds that information is lacking, he/she will request information but also at the same time inform the applicant that this is of no relevance to the patentability of the invention, at the same time informing that if information is not provided, it may lead to prosecution. This is outlined in the guidelines for examination.

We have experienced that one examiner incorrectly has requested information of place of origin in a national filing of PCT an application, although this is contrary to the regulations/guidelines. In this case, the applicant did not have reliable information of the place of origin (the samples were received/collected many years ago, and without properly recording place of origin). As the applicant firstly did not have the requested information, and secondly, since it was a PCT application, the applicant chose to ignore the examiner's request for it.

I know of one case where information was not provided (due to the fact that the institution/applicant did not know the origin of the material (the applicant had received a lot of various samples taken various places).

It is noted that the guidelines for information specifically mention that if the place of origin is not known, the applicant should simply reply by confirming that this is the case.

- 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.

To my knowledge, there are no legal system/administrative authorities providing a type of certificate that provides proof of the source of origin. According to the guidelines for examination, no documentation is required in order to prove that the applicant is given the right to isolate/use the genetic material/GRTK. Nor is the examiner required to check if the information is correct. The examiner is obliged to report if there is reasons to believe that the criminal law provisions are violated. In case the supervisor of the examiners shares the opinion of the examiner, and it may result in that the director of NIPO reports further to the trade ministry, which may decide upon whether a review should be submitted (cf. guidelines C IV 2a.4.3).

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

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

- The protocol is implemented.

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 impact.

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?

- No special regulations for academics and/or academic institutions have been put in place. However it appears that several research institutions have internal regulations which oblige them to abide by the protocol.

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 cannot be patented or protected as such.

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.

- To our knowledge, no studies exist.

## 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](mailto: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](mailto: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](mailto:mcarmen@dannemann.com.br)), and Catherine Mateu, Chair of the Standing Committee on TRIPS ([c.mateu@armengaud-querlain.com](mailto:c.mateu@armengaud-querlain.com)).