



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:

Independent Member:

Date:

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***)?

(Answer)

There is not a requirement of indicating the source and/or country of origin of GRTK (Disclosure Requirement) in Japan.

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.

(Answer)

Since there is not a Disclosure Requirement in Japan, we do not have any experience with the application of such a requirement.

- 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.

(Answer)

Such statistical data are not available. Since there is not a Disclosure Requirement in Japan, the number of patents / patent applications mentioning source and/or country of origin of GRTK is estimated to be close to zero.

There is not a specific section of the patent register listing patents and patent applications comprising information on source 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.

(Answer)

Since there is not a Disclosure Requirement in Japan, there is not a legal provision for administrative or judicial decisions.

- 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.

(Answer)

Since there is not a Disclosure Requirement in Japan, the applicant does not need such additional time or 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.

(Answer)

We cannot provide an estimate because we do not know specific cases of compliance with any foreign Disclosure Requirement at Japanese companies.

Generally speaking, however, if the applicant already knows the source and/or country of origin of GRTK, it is estimated that he/she will need little time. If the applicant buys GRTK from a raw material supplier, he/she will need to get information on its source and/or country of origin and it will probably take a considerable amount of time to do so.

It is difficult to estimate the additional cost (legal fees) because the types of public certification documents required may differ from country to country.

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

(Answer)

Since there is not a Disclosure Requirement in Japan, such a requirement does not have an impact on patent valuation.

- 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")?

(Answer)

There is not a Disclosure Requirement in Japan. Nor have we heard that a Disclosure Requirement has any effect on R&D activities in Japan.

- 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?

(Answer)

Since there is not a Disclosure Requirement in Japan, such benefits or disadvantages do not exist.

- 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.

(Answer)

Japan does not have such a legal system, administrative authorities or agency.

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

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

(Answer)

Japan has not yet 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?

(Answer)

Since Japan has not yet implemented the Nagoya Protocol, there is not such an 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?

(Answer)

Since Japan has not yet implemented the Nagoya Protocol, there is not such an impact.

- 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?

(Answer)

Since Japan has not yet implemented the Nagoya Protocol, there is not such an impact.

- 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?

(Answer)

Since Japan has not yet implemented the Nagoya Protocol, there are not such special regulations or measures, to our 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.

(Answer)

In Japan, patent protection is available to traditional medicine so long as a relevant invention satisfies the patentability requirements. However, Japan does not have any specific legislation or examination practice for the protection of traditional medicine.

- 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.

(Answer)

To our knowledge, there have not been any authoritative studies in Japan on the impact of the Nagoya Protocol.

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**.