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

SUMMARY REPORT

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.

196 countries have ratified the CBD. The USA has not ratified the CBD, and so is not bound by it. As of April 2017[1], 95 parties have ratified or accessed the Nagoya Protocol.

Previous work of AIPPI

[1] As of January 2018, that number is 105.

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

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:

The present questionnaire was sent out in September 2016 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. This study also provides some indication of the impact of the Nagoya Protocol on patent applications.

Outcomes of the 2016 Questionnaire[2]

The questionnaire is attached as Annex 1.

Responses to the questionnaire were received from 23 National Groups (Argentina, Australia, Brazil, China, Denmark, Ecuador, France, India, Japan, Korea, Malaysia, Mexico, the Netherlands, New Zealand, Norway, Paraguay, Philippines, Sri Lanka, Sweden, Ukraine, United Kingdom, USA, and Vietnam).

Questions and Answers

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*)?

(a) to (j) refer to the corresponding sub-questions, see the Questionnaire.

Brazil: (a) Such a disclosure requirement exists since the Provisional Measure of 2001. A new law 13.123 based on the CBD with impact on patent applications and replacing the Provisional Measure was enacted in 2015. The law aims to simplify the procedure. (b) If an invention relates to a finished product or reproductive material obtained as a result of the access to GR or to associated TK, the disclosure requirement is triggered. (c) Source (*in situ, ex situ*) and country of origin are defined, but it is not (yet) clear what kind of information must be included in a patent application. (d) The disclosure requirement is restricted to Brazilian resources. (e) PIC for TK is required. (f) Human GR is not included. (g) TK is to be indicated only if connected to genetic/biological resource. (h) Requesting IP rights resulting from access to GRTK in Brazil or abroad without prior registration incurs a fine. It is the understanding of the authors of the report that also patent invalidation or revocation is supported by the law. (i) Proof of registration of GRTK has to be presented within 30 days. (j) Access to GRTK made prior to 30 June 2000 is not subject to the law.

China: (a) The disclosure requirement is found in the Patent Law, Art. 26.5. (b) The requirement is triggered when an invention is developed relying on GR. (c) Definitions are available in the Guidelines for Patent Examination. The direct and original source has to be indicated. (d) The disclosure requirement is applicable to GRTK from all geographical regions. (e) Disclosure of

[2] This Summary Report was compiled in March 2017.

PIC and/or ABS is not required. (f) The same rules are applicable to human GR. (g) TK is not involved. (h) If the applicant fails to disclose the source, the patent application will be rejected. However, the lack of disclosure is not a ground for patent invalidation. (i) Amendment of the submitted registration form for indicating the source is possible. (j) There is no cut-off date.

Denmark: (a) The disclosure requirement was introduced in 2000. The current version is found in Section 3 in the Order of Patents and Supplementary Protection Certificates No. 25. (b) The requirement is triggered if the invention relates to or makes use of GRTK. (c) The Order uses the expression "geographical origin". It contains no definition. If the applicant is not aware of the geographical origin, the applicant has to state in the application that the geographical origin is unknown. (d) The requirement is applicable to GRTK of all geographical origins. (e) Disclosure of PIC and/or ABS is not required. (f) Similar rules are applicable to human GR, further requiring consent. (g) TK is not separately defined. (h) Lack of information regarding the origin of GR is of no consequence. However, false or misleading information may trigger criminal sanctions. (i) Amendments are not needed. (j) There is no cut-off date.

Ecuador is a member of the Andean Community. (a) Andean Decisions 391 (1966) and 486 (2000) apply, and the National Regulation (2011) based on Andean Decision 391. These laws require disclosure. A draft IP law is very close to approval. (b) If products or processes have been obtained or developed from GR and/or TK, the requirement is triggered. (c) Source and Country of origin are defined. (d) The requirements apply to GRTK from Ecuador and the Andean Community countries. The IP draft law necessitates stating the source and/or country of origin of GRTK. (e) Disclosure of PIC and ABS is required. (f) Human GR are excluded from patentability. (g) TK is separately defined. PIC for TK from Andean Community states is required. (h) Sanctions are: Patent invalidation for lack of disclosure of PIC / ABS, fines and other sanctions for unauthorized access to GRTK. (i) Amendments of patent applications are possible. (j) There is no cut-off date.

France: There is no legal requirement that the source and/or country of origin of GRTK must be indicated in patent applications. However, (a) the Environmental Code 2016 implementing the Nagoya Protocol provides that the information provided for in Article 4 of Regulation (EU) No 511/2014 should be sent by the applicant on his own initiative to the French National Institute for Industrial Property (INPI). (b) Use of GRTK leading to the subject of the invention triggers the requirement. (c) Definitions are provided. Indication of source is required. (d) The disclosure requirement is (probably) restricted to GRTK from France. (e) A certificate of compliance or, if not available, disclosure of PIC and ABS is required. (f) Human GR are treated differently. (g) TK is to some extent the subject of Regulation (EU) No. 511/2014, defining TK as "traditional knowledge associated with GR". (h) Sanctions: Fine and imprisonment. (i) Not applicable (j) The requirement applies to resources to which access occurred as from the date of entry into force of the CBD (29 Dec 1993).

India: (a) A disclosure requirement has existed for quite some time, based on the Patents (Amendment) Acts 2002 and 2005. The source and geographical origin of biological material has to be disclosed. Under the Biological Diversity Act (2002), prior approval from the National Biodiversity Authority is required before filing a patent application. This law also mandates benefit sharing. (b) Whenever biological material is used, the requirement is triggered. (c) Source/country of origin is not defined. Patent applications for TK are prohibited. (d) The geographical origin of any GR has to be disclosed, but further requirements (permission from the competent authority) are limited to GR from India. (e) Disclosure of PIC and ABS is not required in the patent application. (f) Human GR are not covered by the Biological Diversity Act. (g) If subject matter of a patent application relates to TK, the application will be rejected. However, TK is not defined in the laws. (h) Non-compliance leads to patent invalidation. Criminal sanctions and fines are also foreseen. (i) Information may be added within three months. Changes to address non-compliance may be allowed also later (discretionary power of the Controller). (j) There is no cut-off date.

Mexico: No disclosure requirement exists for patent applications. However, under the general law of Sustainable Forest Development (GLSFD) a patent related to forest genetic resources should be cancelled if it does not recognize the rights of the indigenous communities to the GR/TK. An agreement between the patent applicant and the indigenous communities should be executed and submitted confirming ABS, PIC, and MAT. Corresponding further provisions requiring recognition of TK of indigenous communities are found in the Law of Ecological Balance and Environmental Protection, Law of Wild Life, and Law of Sustainable Fisheries and Aquaculture.

Norway: (a) The disclosure requirement is found in Section 8 b of the Norwegian Patents Act (2004). (b) The invention must either directly concern or use biological material or TK. The requirement still applies if the structure of the biological material has been altered. (c) Source and country of origin are clearly defined. It is noted that the guidelines for information specifically mention that if the place of origin is not known, the patent applicant should indicate this. (d) The provision applies to all GRTK, irrespective of origin. (e) Disclosure of PIC is required if this is mandatory under the law of the country of origin. (f) Human GR are treated the same, albeit with an additional requirement for consent to use. (g) TK is defined in line with the TK definition by WIPO. The source of TK is to be indicated also when it is not connected to GR. (h) Sanctions for non-compliance are a fine or imprisonment. The validity or legal status of the patent is not affected. (i) Amendments are possible. (j) There is no cut-off date.

Philippines: (a) disclosure requirements in patent applications are based on “Guidelines for Bioprospecting Activities” of 2005. These guidelines likewise require disclosure of country of origin in *foreign* patent applications if they are based on “Bioprospecting Undertakings” in the Philippines. Moreover, based on the Technology Transfer Act (2010), patent applications based on research in the Philippines have to disclose the primary (or secondary) source of GRTK. The Indigenous Peoples’ Rights Act requires PIC for use of GR for profit-making purposes. (b) The disclosure requirement is triggered whenever GR/TK is used for developing an invention. (c) Source and country of origin are clearly defined. (d) It appears that the disclosure requirement is restricted to national resources. (e) PIC and ABS are not required to be disclosed in a patent application. (f) Human GR are treated the same. (g) TK is properly defined. (h) Misrepresentation is sanctioned by fine or imprisonment. Violation of a Bioprospecting Undertaking leads to cancellation and confiscation of collected materials. (i) The applicant may amend the patent application. (j) There is no cut-off date.

Sweden: (a) The disclosure requirement is found in Section 5a of the Swedish Patent Decree, introduced in 2004 based on the EU Directive 98/44/EC on the legal protection of biotechnological inventions. (b) It is assumed that the invention must be directly based on the GR. (c) The Decree uses the expression “geographical origin”. (d) The disclosure requirement is applicable to GRTK from all geographical origins. (e) Disclosure of PIC and/or ABS is not required. (f) Human GR is not included. (g) TK is to some extent the subject of Regulation (EU) No. 511/2014 implementing the Nagoya Protocol, defining TK as “traditional knowledge associated with GR”. (h) Lack of information regarding the origin of GR is of no consequence. However, criminal sanctions are foreseen in the Environmental Code based on EU Regulation 511/2014 for wrongful use of GR and TK. (i) Information on the geographic origin of GRTK can be added to the patent application at any time. (j) There is no cut-off date.

Vietnam: (a) The disclosure requirement is found in the IP Law (Rule 23.11 of Circular 01/2007/TT-BKHCN). (b) The disclosure requirement is triggered if an invention is directly based on GRTK. (c) The law gives no details as to source or country of origin, and with respect to what kind of information must be included in the patent application. (d) There is no clear indication in the law, but it is assumed that the requirement applies to GRTK from any geographical region. (e) The IP law is silent whether PIC and ABS must be disclosed or not. (f) Human GR are probably treated the same way. (g) TK not separately defined. It is assumed that the same principles as for GR also apply for all kind of TK. (h) In principle, if the Disclosure

Requirement is not complied with at the time of filing, the patent application may be refused and no patent granted. (i) Amendment may be not allowable. (j) The disclosure requirement applies to patent applications filed 2007 or later.

All other reporting National Groups (Argentina, Australia, Japan, Korea, Malaysia, the Netherlands, New Zealand, Paraguay, Sri Lanka, Ukraine, United Kingdom, and USA) indicated that there is no disclosure requirement in patent applications based on their national law. Further it may be noted that there is no disclosure requirement for European Patent applications and for patent applications filed under the Patent Cooperation Treaty (PCT).

The report from Sri Lanka indicated that a draft law on protection of TK is under consideration.

The US Report discusses invention based on GR under the general requirement of written description and enablement, 35 U.S.C. §112. The US patent law does not require a disclosure of "origin" of a GR.

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

Answers to this question did not reveal any great volume of experience. The answers given for many countries are "no experience" or "no experience yet", or "straightforward" for others.

In member states of the European Patent Convention there are comparatively few national applications, to which these (national) disclosure requirements would apply (see, e.g., the report from Norway).

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.

India reported that in the period of 2003 to 2016, there were 820 patent filings and 147 grants. For more details (figures by year) one should consult the document from India, which relies on data from the National Biodiversity Authority.

Norway indicated that there were only 11 cases between 2004 and 2016. The low number is the result of the fact that the disclosure requirement applies only to Norwegian national applications. It is also suggested for Norwegian PCT filings, but is not required. European applications do not require disclosure.

All other reports indicated that no particular information in compiled form is available.

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.

A decision is available from India, reporting that in an application from 2008 the Controller found that the biological material involved in the subject matter did not require the National Biodiversity Authority's permission as the applicant was using a waste material which did not have any effect on the sustainable use of biological resources of the country.

Otherwise, there is a lack of reports of administrative and judicial decisions concerning the disclosure requirement and the requirement of indicating PIC and MAT.

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.

Brazil indicated that applications where disclosure of origin of GRTK is provided only post filing are delayed by about six months. No extra cost is involved.

China: An estimate of extra time is 1.5 h, and extra cost is around 800 USD.

India: the cost for the permission from the National Biodiversity Authority is INR 500 (approx. 8 USD), and there is a substantial delay (6 months to a couple of years). The permission is a requirement for filing a patent application using GR from India.

Norway: The estimated extra cost is 2000 to 3500 NOK (250 to 400 USD).

Philippines: The report estimates extra cost to be 150-300 USD.

Sweden indicated that extra time and cost is marginal.

All other reports did not provide an estimate.

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

China: An estimate of extra time is 2 h, and extra cost is around 800 USD.

Practitioners in Korea, which does not have a disclosure requirement, estimated that the extra time is 1 to 3 hours and additional cost is 100 to 500 USD for foreign filings.

The reports for Norway and the Philippines estimate the same time and cost as for national applications.

Sweden indicated that extra time is spent when filing a (PCT) international application due to various foreign national disclosure requirements. 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.

All other reports did not provide an estimate.

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

The report from China indicated that the value of an application may be slightly decreased because of uncertainty about grant.

The report from Norway indicated that there is no significant difference.

No other report gave a substantial answer to this question.

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")?

For Brazil it is reported that the old regulation from 2001 requiring *a priori* authorization had a dissuasive effect on R&D. The hope is that under the newer law of 2005, the situation will improve.

For China, the extra burden is not considered to be too harsh.

In India, an increase of patent applications in the field is noted. This could be interpreted that there is no negative effect on R&D.

The report from Norway indicated that there is little awareness of the link between patenting and the duty to disclose information. A researcher has questioned whether material cultivated for many years in a laboratory is still the same as the original one collected many years ago.

The report from France indicated that it is too early to see any effect, since the law entered into force in 2016, and the corresponding Decree on GRTK is still in the drafting process.

Other reports from countries with a disclosure requirement and PIC/MAT did not express a view as to impact, or did not observe an impact.

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 report from Brazil indicated that benefit sharing was ill defined in the old regulation. There is hope that the new law will facilitate benefit sharing.

The report from China does not see any impact, since the disclosure requirement is only an additional formality.

India: In the “Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014” there is a minimum royalty stated, which should result in benefits for the local community.

Other reports are silent on 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.

Brazil: Access to GRTK is managed by the Council of Management of the Genetic Patrimony (CGEN). The registry system is yet to be regulated.

China: Administrative Department of Animal Husbandry and Veterinary Medicine (for some GR)

Denmark: Danish Nature Agency

Ecuador: Environmental Ministry

France: not yet appointed

India: National Biodiversity Agency

Mexico: Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), and Ministry of Environment and Natural Resources (SEMARNAT).

Philippines: A registry for indigenous knowledge systems is planned.

Vietnam: Ministry of Natural Resources and Environment for species prioritized for protection, or the provincial level People's Committees for other cases.

All other reports indicate that there is no agency in their country, or did not answer this question (Argentina, Australia, Japan, Korea, Malaysia, the Netherlands, New Zealand, Norway, Paraguay, Sri Lanka, Sweden, Ukraine, United Kingdom, and USA).

Korea established a database of TK and provides a portal service for public access to it.

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

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

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?**

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?**

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?**

Argentina: Protocol not ratified. No ABS, PIC or MAT.

Australia: Protocol not yet implemented. No ABS, PIC or MAT.

Brazil: Protocol not yet implemented. ABS, PIC and MAT need not to be disclosed.

China: Protocol not yet implemented. No ABS, PIC or MAT.

Denmark: Reference given to Regulation (EU) 511/2014 implementing the Nagoya Protocol for the European Union, and the Commission Implementing Regulation (EU) 2015/1866. No ABS, PIC or MAT.

Ecuador: Protocol not yet implemented. ABS, PIC and MAT required.

France: Law implementing the Protocol in force, but waiting for Decree. No ABS, PIC or MAT.

India: Protocol implemented. ABS, PIC and MAT are checked by the National Biodiversity Agency.

Japan: Protocol not yet implemented. No ABS, PIC or MAT.

Korea: Protocol not yet implemented. No ABS, PIC or MAT.

Malaysia: Not a party to the Protocol. No ABS, PIC or MAT.

Mexico: Protocol not yet implemented. ABS, PIC and MAT required.

Netherlands: Protocol implemented. No impact (no ABS, PIC or MAT).

New Zealand: Protocol not ratified. No ABS, PIC or MAT.

Norway: Protocol implemented. No impact (no ABS, PIC or MAT).

Paraguay: Protocol not yet implemented. No ABS, PIC or MAT.

Philippines: Protocol implemented. There are no data yet concerning the impact.

Sri Lanka is not a party to the Protocol. No ABS, PIC or MAT.

Sweden: Reference given to Regulation (EU) 511/2014 implementing the Nagoya Protocol for the European Union, and the Commission Implementing Regulation (EU) 2015/1866. No ABS, PIC or MAT.

Ukraine: Protocol not yet implemented. No ABS, PIC or MAT.

United Kingdom: Reference given to Regulation (EU) 511/2014 implementing the Nagoya Protocol for the European Union, and the Commission Implementing Regulation (EU) 2015/1866. No ABS, PIC or MAT.

USA: Not a party to the Protocol. No ABS, PIC or MAT.

Vietnam: Protocol not yet implemented. ABS, PIC and MAT may be required.

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?

Brazil: registration is required for research on GRTK.

Ecuador: reports that research at universities is supported. The National Environmental Authority may enter into access contracts with such institutions.

India: The law prohibits transfer of research results relating to biological resources obtained from India to outside India without prior approval from the National Biodiversity Authority. This approval is not required for research papers or oral dissemination. Patenting research results requires that the normal rules are followed.

Mexico: University research has to be in line with the laws based on the Biodiversity Convention, see response to question 1.

For research involving Maori Traditional Knowledge, special rules have to be followed in New Zealand (and elsewhere).

In the Philippines, there are special rules for scientific research on GR for non-commercial purposes. An undertaking has to be executed, but there are no costs.

In Vietnam there is a special program on conversation and sustainable use of GR.

Apart from these special arrangements, universities have to follow general rules, without regulations and measures to promote the protection and development of GRTK.

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.

Most countries will analyse inventions in the field of “traditional medicine” according to the standard rules of patentability.

Australia: A public consultation on Indigenous Knowledge and IP was held. A summary of the submissions will be released in due course.

In Brazil, natural active substances are not patentable. Formulations may be protected if they fulfill the patentability requirements (which is probably not the case for traditional formulations)

In India, Traditional medicine is not patentable. There is a national register for TK including traditional medicine.

Sri Lanka reports special rules for Ayurveda medicine. These rules do not deal with IP protection.

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.

The following reports mention Nagoya Protocol impact studies and public consultations:

Australia, China (TK ABS study from 2012), Ecuador (review by Congress), France (several studies), India, Korea (2009), Sweden, USA.

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