



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: United States of America

Independent Member:

Date: 2016 October 24 (draft)

• *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. In the United States, there is no requirement to disclose the source or origin of genetic resources or associated traditional knowledge (GR/TK), whether in relation to the access and benefit sharing goals of the Convention on Biological Diversity (CBD), or otherwise.

To the extent that there is any requirement to disclose information regarding a genetic resource, it arises only as a consequence of application of the generally-defined requirements of patentability, e.g., novelty, non-obviousness, written description, and enablement.

For example, information regarding a genetic resource may be necessary to meet the requirement for adequate disclosure under 35 U.S.C. §112, first paragraph if access to samples of the genetic resource is necessary to practice the claimed invention without undue experimentation, to demonstrate possession of the claimed invention, or to disclose the best mode known of practicing the invention at the time the application was filed. However, even in this case, there is no requirement to disclose the country of origin. There is only a requirement to provide access to the resource.

If the claimed invention does not require any information related to the genetic resource (including a genetic resource that may have been used somehow in the course of developing the invention) in order to meet the disclosure requirements of §112, no additional disclosure is needed. Thus, whether there is a need to disclose information regarding a genetic resource will depend on the particular facts and circumstances of each application.

An applicant may provide an adequate description of a genetic resource by a number of means. One would be to describe the physical characteristics of genetic resource by reference to objective, physical properties of the resource (e.g., structure, characteristics, etc). A second would be to provide a deposit of the genetic resource in a public depository, or refer to a prior deposit of the material. Finally, one could identify a location from which samples of the biological resource may be reliably obtained.

Thus, to the extent that any obligation exists under U.S. patent law standards to identify a location from which samples of the biological material can be obtained, that obligation can be satisfied by providing a description of any location from which samples of the genetic resource can be obtained. In most instances where access to samples of a disclosed biological material is necessary, that obligation can be most efficiently discharged by providing a deposit of the material in a recognized depository institution, such as the American Type Culture Collection (ATCC).

The U.S. patent law does not require a disclosure of the genetic or evolutionary “origin” of a genetic resource in any circumstance, as such information is not necessary to identify where one of skill could go to obtain a sample of the genetic resource. In other words, to the extent that there is any “disclosure” obligation under the general U.S. patent law with regard to a genetic resource in a particular application, that obligation can be met by simply identifying any location from which a sample of the material can be obtained.

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).

No. There is no independent requirement for disclosure of source/origin of genetic resources or traditional knowledge. As such, there is no context in the U.S. system for this question.

- 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?

No, not relevant for the reasons previously stated.

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

No, not relevant for the reasons previously stated.

- 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?

No. We are not aware of a consistent or coherent definition of “source,” “country of origin,” or “based on genetic resource/traditional knowledge.” None of these terms is explicitly defined in the Convention on Biological Diversity (CBD), especially with regard to informing patent applicants as to the type of information that must be supplied, when or how extensive such information must be set forth in a patent application. As noted

above, these concepts of source/origin are not requirements of the U.S. law, so there are no corresponding definitions of the terms.

Under 35 U.S.C. §112, as explained above, an invention must be sufficiently described and enabled in the patent application. Section 112, however, is not concerned with or defined in reference to concepts of “source” or “origin.” These terms are not used in U.S. patent law.

The issue of whether personal property rights may exist in biological material under state law has been treated by some courts. *Washington Univ. v. Catalona*, 490 F.3d 667 (8th Cir. 2007) (cert. denied *Catalona v. Washington Univ.*, 128 S.Ct. 1122 (2008) (holding that individuals who provided biospecimens (such as blood or tissue) for genetic cancer research did so as *inter vivos* gifts (*i.e.*, gifts made during one’s life, as opposed to testamentary gifts made after death) and, accordingly, retained no property rights that would allow them to request the return of the biospecimens or the transfer of the biospecimens to a third party); *Moore v. Regents of the Univ. of California*, 793 P.2d 479 (Cal. 1990) (holding that no action based on a theory of conversion may be prosecuted where the subject matter of the allegation are excised cells taken from Plaintiff in the course of a medical treatment; however, that an action may be based on theories of breach of fiduciary duty or lack of informed consent).

- 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?

No, not relevant for the reasons previously stated.

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

No. Disclosure of the existence of prior informed consent and/or agreements regarding benefit sharing are entirely irrelevant to the question of compliance with the disclosure requirements of §112, or other patentability criteria in the US system.

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

As indicated above, disclosure concepts are not relevant to, nor are they found in, U.S. standards relating to adequacy of disclosures or other substantive patentability criteria.

- 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?

As noted above, there are no requirements in the U.S. patent system pertaining to genetic resources or traditional knowledge. Accordingly, there is no definition in the U.S. patent law

concerning “traditional knowledge.” Information that may embody traditional knowledge, if publicly known in the US or published anywhere in the world prior to the effective filing date of the patent application, would be part of the prior art.

- 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.

No, not relevant for the reasons previously stated.

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

Although there is no requirement of identifying the source and/or country of origin of GRTK for the reasons previously stated, referring to the general requirement of disclosure under 35 U.S.C. 112, it is possible to make a deposit of biological or genetic material and amend the text of an application to refer to such a deposit after the filing date of an application with respect to a biological material specifically identified in the original specification. *In re Lundak*, 773 F.2d 1216 (Fed. Cir. 1985); and MPEP §§ 2406.01-2406.02 (9th ed. 2015).

- 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, not relevant for the reasons previously stated.

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 United States is not a signatory to the Nagoya Protocol. Therefore, the disclosure effects of the Disclosure Requirement have no effect to applicants for United States patents.

- 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.

No, not relevant for the reasons previously stated.

- 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.

No, not relevant for the reasons previously stated.

- 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.

No, not relevant for the reasons previously stated.

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

No, not relevant for the reasons previously stated.

- 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, not relevant for the reasons previously stated.

- 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")?

No, not relevant for the reasons previously stated.

- 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?

No, not relevant for the reasons previously stated.

- 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.

The United States of America is not a signatory to the Nagoya Protocol and has not 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, not relevant for the reasons previously stated.

- 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, not relevant for the reasons previously stated.

- 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, not relevant for the reasons previously stated.

- 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.

- 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.

U.S. patent law permits patents on methods of practicing medicine and surgical procedures, but enforcement is restricted.

- 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.

We are currently unaware of any authoritative studies in our country on the impact of the Nagoya Protocol. We did locate, however, articles published in our country that do discuss aspects of the Nagoya Protocol. Links to three exemplary articles are as follows:

The Nagoya Protocol and Synthetic Biology Research: A Look at the Potential Impacts
http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=5916&context=faculty_scholarship

Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, and Synthetic Biology
<http://poseidon01.ssrn.com/delivery.php?ID=789116067090118101117103109080011010100085029034061049102012105014085118066127080110057122057000109057009020085124095077085124033036011060059107100126071075066119005039042064016012126084122003122011102075007104126005095093090073084104086106124098092122&EXT=pdf>

Potential effects of the Nagoya Protocol on the exchange of non-plant genetic resources for scientific research: Actors, paths, and

consequences

<http://www.sciencedirect.com/science/article/pii/S0921800912004600>

- 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).