



## 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](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](http://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](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](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](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](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: ABPI – Brazilian Intellectual Property Association**

**Independent Member:**

**Date: 17.10.2016**

## 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**)? **Yes.**

*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;*

The legal requirement was introduced in 2001 by the Provisional Measure 2.186-16 of 23 August 2001. A new law was enacted in 2015 (Law 13.123, of 20 May 2015, regulated by the by-laws 8772, of 11 May 2016), replacing the previous Provisional Measure 2.186 of 23 August 2001.

- (ii) provide concise quotes of the corresponding text from the laws or regulations or a concise summary; and*

The new law aims to simplify the procedure of determining the origin of GRTKs. The main change of the law is the fact that it redesigned the GRTK legal framework, from a *a priori* authorization requirement granted by the government (as required in the 2001 Provisional Measure) to a declarative obligation in which the party accessing the GRTK registers such access in a relevant database.

- (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?

The Disclosure Requirement is found in legislation implementing the CBD, Law 13.123, of 20 May 2015.

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

If an invention relates to a finished product or reproductive material obtained as a result of the access to genetic patrimony or to associated traditional knowledge, the granting of the intellectual property right (e.g. patent) by the competent organization (e.g. INPI - Brazilian Patent and Trademark Office) is conditioned to the registration or authorization in conformity with Law 13.123, of 20 May 2015 (see articles 12 and 47).

- 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?

Law 13.123 defines the "source" or the genetic patrimony of the country as that found in *in situ* conditions, including domesticated species, spontaneous populations or maintained *ex situ*, provided that they are found in situ in national territory, in the continental platform, in the territorial sea, or in the exclusive economic zone.

The law does not distinguish between "country of origin" or "country providing the resource".

The law also defines "based on genetic resource/traditional knowledge" and "derived from biological resource and associated traditional knowledge".

The law does not define what information must be included in the patent application as this has yet to be regulated by the INPI (Brazilian Patent and Trademark Office) at this time (early October 2016).

(see article 1 of Law 13.123/15)

- 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 Disclosure Requirement is limited to Brazilian GRTKs (see article 1 of Law 13.123).

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

The access to associated traditional knowledge of identifiable origin is conditioned to the obtainment of PIC.

Evidence of prior informed consent may occur at the discretion of the indigenous population, the traditional community or traditional farmer, by the following instruments, in the form of the regulation:

I - signature of a prior informed consent;

II - audiovisual recording of the prior informed consent;

III - opinion of the competent official body; or

IV - access as provided for in a Community protocol.

Access to associated traditional knowledge of unidentifiable origin does not require prior informed consent.

(see article 9 of Law 13.123).

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

Law 13.123 does not apply to human genetic patrimony (Article 4, Law 13.123). No specific Law has been enacted to contemplate access to human 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?

Traditional knowledge is not separately defined. Traditional knowledge is to be indicated only if connected to genetic/biological resources.

The Law defines associated traditional knowledge as information or practice of an indigenous population, traditional community or traditional farmer regarding the properties or direct or indirect uses associated with the genetic patrimony.

It further defines associated traditional knowledge of unidentifiable origin as associated traditional knowledge wherein it is not possible to link its origin to at least one indigenous population, traditional community or traditional farmer (Article 4, Law 13.123).

- 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.

Article 80 of the by-laws 8772 of 11 May 2016 determines that requesting intellectual property rights resulting from access to genetic resources or associated traditional knowledge, in Brazil or abroad (*ex situ*), without prior registration incurs in several fines that vary according to type of entity that has performed the access.

Although it has not been regulated yet by the INPI, it is our understanding that the current law and by-laws could support patent invalidation or revocation of a patent obtained in non-conformity with the Law.

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

Furthermore, Art. 109 of the by-laws 8772 of 11 May 2016 states that in order to meet the provisions of § 2 of art. 12 of the Law No. 13,123/2015, the user, in the act of applying for intellectual property rights, should indicate whether there was access to genetic resources or associated traditional knowledge, to ascertain if said access was properly registered according to Law 13.123/2015.

Art. 110 further states that in the absence of registration, the entity responsible for the IPR (e.g, INPI) has to notify the applicant of the intellectual property right to present proof of registration within thirty days, under penalty of permanent shelving of the IPR application.

- 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?

Access to genetic patrimony made prior to 30 June 2000 is not subjected to the requirements of Law 13.123 of 2015 (see Article 3 of the by-laws 8772, of 11 May 2016 ).

*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.

When Provisional Measure 2.186 of 2001 was in force, the Disclosure Requirement when filing and prosecuting patent applications was relatively straightforward. The Disclosure Requirement under the new Law has yet to be regulated by the INPI.

- 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.

These data, while publicly available on a case by case basis on the patent register, are not compiled in a specific section of the patent register listing patents and patent applications comprising information on source or country of origin of GRTK.

~~We estimate that approximately 10-15% of Brazilian patents and patent applications mention source and/or origin of a Brazilian 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.

N/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.

If the Disclosure Requirement is provided upon filing there is no additional time/fees incurred. ~~If an Office Action is issued and the Disclosure Requirement is provided post filing, there is a delay of about an additional 6 months in the prosecution are lost but no official fees are charged by the BPTO and approximately 500 USD in attorney fees.—???~~

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

Not applicable since there is no foreign Disclosure Requirement.

- 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.

- 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 *a priori* authorization requirement system established by Provisional Measure 2.186 of 23 August 2001 has dissuaded R&D activities in the country involving biological materials due to the difficulties in obtaining the access authorization, PIC and MAT terms.

There is hope that the new Law 13.123 enacted in 2015, that redesigned the GRTK legal framework, from *a priori* authorization requirement to a declarative obligation, will help foster R&D in the country in this field.

- 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?

Benefit sharing was ill defined by Provisional Measure 2.186 of 23 August 2001. There is hope that the new Law 13.123 of 2015 and the by-laws that regulate it, with its new provisions, will facilitate benefit sharing.

- 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.

Access to GRTK is regulated by CGEN - the Council of Management of the Genetic Patrimony - that is responsible for managing and maintaining the access registry and grant access authorizations where applicable. CGEN is managed by the Ministry of the Environment.

The registry system - Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado – SisGen – as defined in Article 20 of the 8.772 by-laws, is yet to be regulated.

Further information may be obtained at <http://www.mma.gov.br/patrimonio-genetico/conselho-de-gestao-do-patrimonio-genetico>

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

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

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?

[Access to Brazilian GRTKs for the purposes of academic research must be informed and adequate registration of such access made in the appropriate registry \(articles 11 and 12 o Law 13.123/15\).](#)

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.

[Natural active substances present in traditional medicines are not patentable as naturally occurring compounds are not patentable in Brazil.](#)

[Traditional medicine formulations may be patented in Brazil provided the formulation itself meets the patentability requirements of any other pharmaceutical formulation. However, the majority of traditional formulations would probably not meet such criteria and they would be obvious compositions comprising natural compounds.](#)

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.

N/A

## 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-guerlain.com](mailto:c.mateu@armengaud-guerlain.com)).