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: FRANCE

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Independent Member:

Date: October 17, 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***)?

   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 legal requirement in France that the source and/or country of origin of GRTK must be indicated **in patent applications** for inventions based on GRTK. It should be noted that some French Territories (e.g. Polynésie Française, Nouvelle-Calédonie) have specific provisions.

However, since 2016 and the implementation of the Nagoya protocol under French law (No. 2016-1087of August 4th, 2016), the Environmental Code 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).

The information provided for in Article 4 of Regulation (EU) No 511/2014 is :

(a) the internationally-recognised certificate of compliance, as well as information on the content of the mutually agreed terms relevant for subsequent users; or

(b) where no internationally-recognised certificate of compliance is available, information and relevant documents on:

   (i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;

   (ii) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised;

   (iii) the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;

   (iv) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation;

(v) access permits, where applicable;
(vi) mutually agreed terms, including benefit-sharing arrangements, where applicable.

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 not found in patent law but in the legislation implementing the Nagoya Protocol, which can be found in the Environmental Code.

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

The fact that the use of GRTK led to a patent application, irrespective of the fact that GRTK is claimed or not.

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?

Definitions are given in the French legislation implementing the Nagoya Protocol and in the EU Regulation No 511/2014. The information that should be sent to INPI are provided in Article 4 of Regulation (EU) No 511/2014.

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?

By application of French Law No. 2016-1087, the Disclosure Requirement is limited to GRTK of France. However, France is also submitted to the provisions of Regulation (EU) No. 511/2014

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

Yes, see Article 4 of Regulation (EU) No 511/2014.

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

Human genetic resources are treated differently from animal or plant genetic resources. French legislation implementing the Nagoya Protocol does not apply 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?

For the application of French Law No. 2016-1087 and Regulation (EU) No 511/2014, Traditional knowledge is only 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.

There are no specific sanctions in case of non-compliance of the Disclosure Requirement *per se* ; however, there are fine and criminal sanctions (150 000 € fine and one year imprisonment) for non-compliance of the provisions of Article 4 of Regulation (EU) No 511/2014.

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

Not applicable.

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 Requirement applies to resources to which access occurred as from 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.

It is too early to present any experience with the application of the Disclosure Requirement when filing and prosecuting patent applications in France.

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.

It is too early to give any data on the number of patent applications mentioning source and/or country of origin of GRTK in France.

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.

The French law on Biodiversity, n° 2016-1087, implementing the Disclosure Requirement in France, was adopted on August 8th, 2016. So far, the implementation decrees have not been issued and no administrative or judicial decisions could be found. The French Constitutional Court was questioned regarding the conformity of the law to the Constitution (2016-737 DC - August 4th, 2016 - www.conseil-constitutionnel.fr/decision/2016/2016737dc.htm), but none of the questions involved the Disclosure Requirement.

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.

It is too early to give an appropriate answer to that question.

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

It is too early to give an appropriate answer to that question.

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

See answer to question 8) below.

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 France, the measures on disclosure of genetic resources and traditional knowledge are regulated by the European Union Regulation n°511/2014 (entry into force on October 12th, 2014) and the new French law on Biodiversity, n° 2016-1087 (adopted on August

8th, 2016).

The French law has been debated in Parliament for over a year. In order to implement it, 35 Decrees are currently discussed, one of them specifically dealing with genetic resources and traditional knowledge. If the drafting process goes undisturbed, the Decree dealing with GRTK should be published before 2017.

Some cosmetic companies, such as LVMH (see the FRB 2013 report below, question 14), have already started to follow good practice and conduct on the matter. The reception of the Disclosure Requirement in other industrial sectors is hard to evaluate yet.

It is too early to observe any concrete impact of the Disclosure Requirement in France, whether on patent practice and valuation, or R&D activities. Implementation of new administrative procedures and controls will require a period of adaptation for both private actors and authorities.

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?

We are not aware of any benefits or disadvantages, including for third parties, of the Disclosure Requirement in France. It is too early to give an appropriate answer to the second question.

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.

Procedures of deliverance by a competent administrative authority of permit of access and utilization of GRTK have been created by Article 37 of French law No 2016-1087 dated 8 August 2016 (which introduced Articles L.412-3 to L.412-20 in the French Environmental Code).

Such permit will serve as an internationally recognized certificate of compliance, as defined by paragraph 2 of article 17 of the Nagoya Protocol.

This certificate serves as evidence that the GRTK have been accessed in accordance with prior informed consent (PIC) and that mutually agreed terms (MAT) have been established. It notably contains information regarding the source and country of origin of the GRTK, namely the issuing authority, the date of issuance and the provider of the GRTK.

The French administrative authority responsible for the deliverance of this permit has not been appointed yet and will be designated by Decree.

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

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

Article 37 of French law n°2016-1087 entitled “Law for the recapture of biodiversity, nature and landscapes” dated 8 August 2016, has implemented the Convention on Biological Diversity (CBD) and the Nagoya Protocol. The Decrees implementing its provisions have not been adopted yet.

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.

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?

There are no specific regulations for academics and/or academic institutions

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.

The French Code on Intellectual Property in its Article L. 611-16 excludes among others from the patentability the methods of therapeutic treatments of the human body; although not explicitly mentioned, this covers traditional medicine which is, therefore, not patentable. There is no other Intellectual Property right able to protect 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.

Before France passed Law No. 2016-1087 on Biodiversity enforcing the Disclosure Requirement, there has been a series of institutional studies exploring the situation and giving expectations regarding the information on genetic resources and traditional knowledge first included in the Nagoya Protocol.

Regarding the French law on Biodiversity itself, various bodies of the French Government and Parliament have issued documentation on the matter, which can be found on the website of the Parliament:

http://www.assemblee-nationale.fr/14/dossiers/biodiversite.asp

In particular:

- A 2014 Study of Impact regarding the law:

http://www.assemblee-nationale.fr/14/pdf/projets/pl1847-ei.pdf

- An information report on the implementation of the Nagoya Protocol from 2012:

http://www.assemblee-nationale.fr/14/europe/rap-info/i0396.asp

One of the main bodies issuing documentation on this matter is the FRB (*Fondation pour la Recherche sur la Biodiversité*), most often in partnership with the French Ministry on Ecology & Sustainable Development (*Ministère de l'écologie, du développement durable, des transports et du logement, Commissariat Général au Développement durable, Sous-direction de l'économie des ressources naturelles et des risques*) or the French Ministry of Higher Education and Research. Many of their works are available on their website:

http://www.fondationbiodiversite.fr/en/documents/frb-presentation-and-programmes.html
In particular:
- A 2011 study on the pertinence and feasibility of access and benefit-sharing in the French Overseas Departments, on genetic resources and associated traditional knowledge:
http://www.fondationbiodiversite.fr/images/stories/telechargement/ed_48_apa_outre_mer.pdf
- A 2013 FRB study, in partnership with LVMH, on using natural substances in the cosmetics industry and implications for access and benefit-sharing:

http://www.fondationbiodiversite.fr/images/documents/APA/APA_2014_EN.pdf

Other bodies have published Guides, for instance, on an European Level the CETAF (Consortium of European Taxonomic Facilities) published in 2015 a Code of Conduct and best Practices on Access and Benefit-Sharing:

http://cetaf.org/sites/default/files/final_cetaf_abs_coc021015_0.pdf

On the national Level, a 2011 joined study giving directory lines on Access and Transfer of genetic resources was released by CIRAD (French Agricultural Research Centre for International Development), INRA (French National Institute for Agricultural Research) and IRD (French Research Institute for Development), available here:

http://www.cirad.fr/en/publications-resources/publishing/studies-and-documents/lignes-directrices-pour-l-acces-aux-ressources-genetiques-et-leur-transfert

Of interest also, a Report dated November 2015 which was prepared by the Foundation on the Research on Biodiversity, CIRAD, CNRS, IFREMER, Institut Pasteur, IRD, INRA and MNHN upon request of the French Ministry of Higher Education and Research; that Report is entitled “Entry into force of European regulations on the activities of research and development on genetic resources and traditional knowledge.

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).