



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: Vietnam

Independent Member:

Date: 12 December 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**)?

Vietnam does have a legal requirement regarding the disclosure of source and/or country of origin of GRTK involved in the making of the invention when filing a patent application.

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).

The requirement is mostly provided for in Rule 23.11 of Circular No. 01/2007/TT-BKHCN dated 14 February 2007, effective as from 9 May 2007, detailing and guiding the implementation of a number of articles of the Vietnam IP Law.

(i) This legal requirement was introduced in 2007 (prior to 2010), and no substantial amendments have been made so far.

(ii) The legal requirement stipulated in Rule 23.11 of Circular No. 01/2007/TT-BKHCN is as follows:

23.11. Additional provisions applicable to patent applications for inventions concerning genetic resource or traditional knowledge

Apart from the general requirements for patent applications for inventions specified at Rules 23.1 thru 23.7 of this Circular, a patent application for invention concerning genetic resource or traditional knowledge must also contain documents explaining the origin of the genetic resource and/or traditional knowledge accessed by the inventor or the applicant, if the invention is directly based on that genetic resource and/or traditional knowledge. If the inventor or the applicant cannot identify the origin of the genetic resource and/or traditional knowledge, he/she shall so declare and bear responsibility for the truthfulness of his/her declaration.

- 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?

Yes. The Disclosure Requirement can be found in Rule 23.11 of Circular No. 01/2007/TT-BKHCN detailing and guiding the implementation of a number of articles of the Vietnam IP Law as said above.

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

According to Rule 23.11 of Circular No. 01/2007/TT-BKHCHN, if an invention is directly based on GRTK, then a patent application for that invention must also contain documents explaining the origin of the GRTK accessed by the inventor or the applicant.

- 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?

The Vietnam IP Law and its regulations are silent on what the concepts of "source" or "country of origin" or "country providing the resource", and "based on genetic resource/traditional knowledge" or "derived from biological resource and associated traditional knowledge" mean, and what information must be included in the patent application.

- d) Is the Disclosure Requirement limited to GRTK of your country or is it applicable also to GRTK obtainable from other countries or geographical regions?

The Vietnam IP Law and its regulations do not explicitly state that the Disclosure Requirement is limited to GRTK of Vietnam, so we are of the opinion that the requirement applies to any GRTK including those obtainable from other countries or geographical regions.

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

The Vietnam IP Law and its regulations are silent on the requirement regarding disclosure of PIC and/or agreements on "fair and equitable benefit-sharing" in patent applications for GRTK-related inventions.

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

The Vietnam IP Law and its regulations do not explicitly distinguish human genetic resources and animal or plant genetic resources, so we are of the opinion that these genetic resources are treated in the same way.

- 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 in the Vietnam IP Law and its regulations. However, the traditional knowledge of genetic resources is separately defined in the Law on Biodiversity as "*knowledge, experience and initiatives of native people on the conservation and use of genetic resources*" (Article 3.28, Law on Biodiversity).

The Vietnam IP Law and its regulations do not explicitly state that the source of traditional knowledge is to be indicated only if it is connected to

genetic/biological resources. Therefore we are of the opinion that for all types of traditional knowledge the source and/or origin thereof must be indicated in the patent applications for inventions which are directly based on such traditional knowledge.

- 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.

In principle, if the Disclosure Requirement is not complied at the time of filing, the patent application for invention may be refused to grant patent.

Other sanctions for non-compliance with the Disclosure Requirement are not explicitly stipulated in the Vietnam IP Law and its regulations.

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

According to Point 33.4.1 (2) of Guidelines for Patent Examination (enacted by the National Office of Intellectual Property of Vietnam in 2010, detailing and guiding the implementation of a number of articles of Circular No. 01/2007/TT-BKHCN), it is not allowed to amend a patent application by supplementing the information that cannot be directly and unambiguously derivable from the original description (including the drawings) and/or the original claims in order to clearly disclose the invention or sufficiently disclose the claims. Thus, we are of the opinion that if the disclosure of source or origin of GRTK or appropriate declaration of the applicant is not included in the original patent specification, then post-filing supplementation thereof may be unallowable.

- 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 Vietnam IP Law and its regulations are silent on this matter, so we are of the opinion that the Disclosure Requirement applies to patent applications filed after the effective date of Circular No. 01/2007/TT-BKHCN.

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 patent applications for inventions relating to GKTR are not popular in Vietnam, so we have little experience with the application of the Disclosure Requirement when filing and prosecuting such type of patent applications. However, it is worth again noting that in principle, if the Disclosure Requirement is not complied at the time of filing, the patent application may be refused to grant patent.

- 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.

In Vietnam, the statistics on the number of patent applications mentioning source and/or country of origin of GRTK in Vietnam are not published, and there is no specific section of the patent register listing patents and patent applications comprising information on source or country of origin of GRTK.

We regret that we could not give an estimate of the number of such patents and patent applications in Vietnam since we could not find any indication for the estimation.

- 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.

To our knowledge, there have been no administrative or judicial decisions on the application of the Disclosure Requirements available in Vietnam.

- 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.

According to the Vietnam IP Law and its regulations, the disclosure of source and/or origin of GRTK or appropriate declaration of the applicant is required at filing. No provisions on the additional time and cost associated with compliance with the Disclosure Requirement are provided for in the Vietnam IP Law and its regulations. In practice, we are also not aware of any cases in relation to the matter. Thus, we are not able to provide the estimate in 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.

For the same reason as said above in question 5), we are not able to provide the estimate in 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?

As said above, the disclosure of source and/or origin of GRTK or otherwise declaration of the applicant is required for a patent application to be allowed. Without the disclosure, the patent may not be granted.

- 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")?

We are not aware of this matter since there are no official statistics and/or researches regarding the effect of the Disclosure Requirement on R&D activities in Vietnam.

- 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?

As said above, disclosure of source and/or country of origin of GRTK involved in the making of the invention or otherwise declaration of the applicant is mandatory when filing a patent application. Without the disclosure, the patent may not be granted.

There are no provisions stating that the Disclosure Requirement will lead to the sharing of financial or other benefits. Such benefit sharing is stipulated in MAT ("mutually agreed terms") and/or PIC ("prior informed consent").

- 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.

To our knowledge, Vietnam has no legal system and/or administrative authorities or agency to provide a certificate to provide proof of the source and/or country of origin of GRTK.

However, under Article 18.3 of Decree No. 65/2010/ND-CP detailing and guiding a number of articles of the Law on Biodiversity, in order to obtain PIC ("prior informed consent") which might be considered as proof of the source and/or country of origin of GRTK to some extent, the applicant should contact the Ministry of Natural Resources and Environment for species prioritized for protection, or the provincial-level People's Committees for other cases.

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

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

Vietnam did adopt the Nagoya Protocol in 2014, but until now there are not any decrees, circulars, and guidelines detailing the implementation of the Nagoya Protocol officially approved in Vietnam. At the moment the Vietnamese Government has been drafting a Decree on management of ABS as part of obligations to the Protocol, but the time of ratification of the Decree could not be predicted.

However, it is worth noting that the current Vietnamese provisions provided for in the Law on Biodiversity and Decree No. 65/2010/ND-CP detailing and guiding a number of articles of the Law on Biodiversity have substantially conformed to those of the Protocol.

Despite the above, from our recent preliminary study, we found that there is no legal guidance on detailed procedures for registration to provide access to GRTK, obtain Prior Informed Consent and negotiate Mutually Agreed Terms. Also, there is no legal guidance on how to determine the total benefit, the time of benefit arising from R&D, transfer and business benefits arising in the case of secondary use onwards. In addition, our preliminary study reveals that neither ABS permits have been issued nor ABS contracts have been approved

by the Vietnamese competent authorities so far. No public-private partnership has been developed following the provisions of the ABS regimen being in force in Vietnam.

- 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?

The Vietnamese Laws are silent on this matter. In practice, there have been no relevant events happened in Vietnam so far. Thus we have no idea about the 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?

The Vietnamese Laws are silent on this matter. In practice, there have been no relevant events happened in Vietnam so far. Thus we have no idea about the 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?

The Vietnamese Laws are silent on this matter. In practice, there have been no relevant events happened in Vietnam so far. Thus we have no idea about the 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?

Circular No. 17/2016/TT-BKHCHN dated 1 September 2016, effective as from 15 October 2016, of the Ministry of Science and Technology, stipulating the implementation of the program on conservation and sustainable use of genetic resources toward 2025, oriented toward 2030 may be considered special regulations and/or measures for academics and/or academic institutions to protect and promote the protection and development of genetic resources in Vietnam.

- 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.

In Vietnam, traditional medicine is eligible for patent protection. However, there is no specific legislation or examination practice for the protection of traditional medicine, except that source and/or origin of the traditional medicine or appropriate declaration of the applicant must be provided. In other words, in principle, traditional medicine

related applications are treated in the same way as other types of patent applications.

- 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.

To our knowledge, there have been no authoritative studies in Vietnam on the impact of the Nagoya Protocol.

Procedure

It would be most helpful if the National/Regional Groups / Independent Members would fill out the Questionnaire and send their answers to the General Secretariat of AIPPI (StandingCommittees@aippi.org) by **17 October 2016**.

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-querlain.com).