



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: India

Independent Members: S. Majumdar and Amrita Majumdar

Date: 17/10/2016

Questions

Questions:

- 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).

Ans. Yes, it is mandatory under Patents Act, 1970 to disclose source and/or country of origin to the Patent Office in case biological material is used for the invention. It is also mandatory for the patentee / applicant that is required to make a deposit under Budapest Treaty to declare the origin / source of biological material.

The Patents Act, 1970 prohibits patenting where “*traditional knowledge*” or “*plants and animals in whole or any part thereof*” is to be the subject-matter of the patent and thus, the issue of disclosure does not arise. However, Micro-organisms can be subject-matter of patent if other requirements are satisfied. Such applications must be accompanied by disclosure of source / origin of such micro-organisms along with their deposit as required under Budapest Treaty.

(i) All these requirements have been in place by virtue of Patents (Amendment) Act, 2002 and Patents (Amendment) Act, 2005. Both of these amendments were enacted much prior to the year 2010.

(ii) The law provides for opposition and revocation of patent on the grounds of non-disclosure or false disclosure of source or origin of the biological material.

“ **25. Opposition to the patent.**-(1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground-

.....

(j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

.....

(2) At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner on any of the following grounds, namely:-

.....

(j) that the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention;

.....”

“ **64. Revocation of patents.**-(1) Subject to the provisions contained in the Act, a patent, whether granted before or after the commencement of this Act, may, be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in the a suit for infringement of the patent by the High Court on any of the following grounds that is to say –

.....

(p) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

.....”

Further, in those cases where the deposit is required under Budapest Treaty, the disclosure requirement also mandates that the party also “*disclose the source and geographical origin of the biological material in the specification, when used in an invention*” (clause (ii)(D) to proviso to Section 10(4) of the Patents Act, 1970)

Also, there is specific prohibition when the subject-matter of the patent is *traditional knowledge*.

“ **3. What are not inventions.**- The following are not inventions within the meaning of this Act,-

.....

(p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.”

Thus, under the scheme of Patents Act, 1970, it is not possible to patent any invention that is traditional knowledge. Further, non-disclosure of geographical source / origin of biological material is sufficient ground for opposition / revocation of the patent.

Also, National Biodiversity Authority has been set-up under Biological Diversity Act, 2002 to look into biological resources and their commercial utilization. The law sets up a scheme which requires prior approval from this Authority before any application for patent is preferred. The scheme lays down the procedure for securing such approval with special emphasis on mandatory benefit sharing and penal provisions for contravention of the law.

The law defines biological resources and commercial utilization very broadly. It defines “biological resources to mean “*plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material*” (Section 2(c)).

The term “commercial utilization” has been defined to mean “*end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping*” (Section 2(f)).

This Act also prohibits application for any intellectual property right, which would include patents within its ambit, that is “*based on any research or information on biological resource obtained from India*” without prior permission from this authority (Section 6(1)). The authority is further mandated to “*impose benefit sharing fee or royalty or both or imposes conditions including sharing of financial benefits arising out of commercial utilization of such rights*” at the time of considering the grant of approval (Section 6(2)).

The law also mandates that the authority considers the “*equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications*” between “*the person applying for such approval, local bodies concerned and the benefit claimers*” (Section 21(1)). The purpose being that the approval process prior to filing of a patent application, ensures that the communities dependent upon such biological resources are adequately compensated.

Contravention of above requirements is “*punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees*” and “*where the damage caused exceeds ten lakh rupees such fine may commensurate with the damage caused*” under the law (Section 55(1), Biological Diversity Act, 2002).

- 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?

Ans. The disclosure requirements are explicitly provided in patent law and would cover all such applications whose subject-matter concerns “biological material”. The law also requires such a disclosure that fully and particularly describes the biological material that is sought to be made subject-matter of the patent. Further in accordance with India’s obligations as a signatory to the Budapest treaty, the law as amended in the year 2002 also requires deposition of biological material at one of the recognized depositories if such material cannot be sufficiently described in the specification or is not available to the public, i.e. fails to satisfy the disclosure requirement of Section 10 (4) (a) and (b) of the Patents Act.

Therefore, the Patent law strictly mandates full disclosure of the origin or geographical source of the biological material if the same is the subject-matter of the patent application.

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

Ans. As indicated earlier, the Patents Act prohibits patenting in all those cases where the subject-matter of the application is “traditional knowledge” and thus, foreclosing the issue of disclosure of origin or source with respect to traditional knowledge.

The appropriate trigger, therefore, is whether the subject-matter of the application involves a “biological material”. In other words, when some biological material has been employed to perform or carry out the subject matter of the application, it triggers the requirement. This is because of disclosure requirement under Section 10(4) where the applicant is required to disclose the source and geographical origin of the said biological material.

- 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?

Ans. The Patents Act, 1970 does not provide for any definition for “country of origin” or “country providing the resource” and “based on genetic resource/traditional knowledge”

or “derived from biological resource and associated traditional knowledge”. However, the Biological Diversity Act, 2002 has provided an expansive definition for “biological resource” to mean “*plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material*”.

The National Green Tribunal in the case of *Bio Diversity Management Committee v. Western Coalfields Ltd. and Ors.* (MANU/GT/0169/2015) has also clarified that the Biological Diversity Act, 2002 is in respect of “*sustainable use of genetic resources and living organisms of plant, animal and micro-organism*”.

Though, the scope of the term “biological material/resource” under Patents Act, 1970 are yet to be addressed directly by Higher Courts (Supreme Court or High Court) but the present understanding seems to be expansive in nature covering all such resources that are from genetics of any living organism, including a micro-organism.

- 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?

Ans. The Patents Act, 1970 requires disclosure of source and geographical origin in case the subject-matter of the application concerns biological material from India. This requirement is not circumscribed under the Act to any particular country or region and thus, is applicable across the board for all applications. To put it simply – any application for patent concerning biological material would require the applicant to disclose the geographical origin, irrespective of the nationality of the applicant or country of origin of the biological material. The patent application form (Form 1) under paragraph 9 part (iii) requires to the applicant to make a declaration if the subject matter uses biological material from India and necessary permission from the competent authority to be submitted by the applicant before the grant of patent. In these cases, the approval of the National Biodiversity Authority is required prior to the grant of the patent. The requirement under Patents Act, 1970 is also complimented by the mandate of Biological Diversity Act, 2002 if the biological material originates from India.

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

Ans. The Patents Act, 1970 does not require the applicants to disclose either prior informed consent or agreements on fair and equitable benefit-sharing in relation to the subject-matter of the patent application. This is neither required for Indian applicants nor for foreign applicants.

However, the National Biodiversity Authority is empowered and mandated to ensure that every biological resource, **originating in India**, that is sought to be patented, either in India or outside in India, has an appropriate benefit sharing agreement laid out. The Act empowers the Authority to lay down such terms and conditions between the “person applying for the approval” and the “local bodies concerned and the benefit claimers” that provide for equitable benefit sharing and may include, besides fixation of royalty rates, the “*grant of joint ownership*”, “*transfer of technology*”, “*location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers*”, etc (Section 21 of Biological Diversity Act, 2002).

The National Biodiversity Authority has also informed under Right To Information Request, that, all the applications that were approved for purpose of securing intellectual property rights (Form III applications) had a “benefit sharing component”.

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

Ans.

Under Patents Act, 1970, however, naturally occurring genes are not patentable on account of prohibition laid down under Sections 3(c) and 3(j) of the Patents Act, 1970. Section 3(c) of the Patents Act, 1970 declares "*the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature*" as not being an invention and thus, not falling within the purview of the Patents Act, 1970. Section 3(j) of the Patents Act, 1970 declares "*plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.*"

However, modified gene sequences are capable of being patented and the Applicant is required to disclose "*relevant numbers of sequence listing ... at appropriate place in the specification*" along with the fees (05.03.08 of the Manual of Patent Office Practice and Procedure).

Further, human genetic resources are considered outside the purview of the Biological Diversity Act, 2002 and thus, no requirement of prior approval from National Biodiversity Authority or mandatory benefit sharing is required. Whereas, both the requirements are to be fulfilled if the subject-matter of the patent application is animal or plant genetic resource derived from biological resource originating in India.

- 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?

Ans. As stated earlier, if subject-matter of the patent is found to be in relation of "traditional knowledge", then the said application would be rejected.

Though, no definition has been provided under the Patents Act as to what constitutes "traditional knowledge". However, once the subject-matter of the patent application is found to be in relation to traditional knowledge, then it would be rejected on this ground itself. Thus, the question of disclosure of the source would not arise.

Under the Biological Diversity Act, 2002, the party seeking a patent for any biological resource (which would include genetic resource) would require prior approval from the said authority. This approval would have to be filed with the Patent Office prior to the grant of the patent (03.04.01, Manual of Patent Office Practice and Procedure).

In 2001, the Indian Government initiated the process of digitization of Ancient Indian texts about medicinal plants and their formulations as well as their translation into foreign languages. The digital depository is a collaborative project under Council of Scientific & Industrial Research (CSIR), a government research organization and the Ministry of AYUSH (formerly, the Department of AYUSH).

The Head of the project can be reached at "Head, CSIR- Traditional Knowledge Digital Library Unit, A 93/94, CSIR NEERI Building, Naraina Industrial Area Phase I, Naraina, New Delhi 110 028". The official website of TKDL is <http://www.tkdil.res.in/>.

- 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.

Ans. The Patents Act, 1970 provides for invalidation of a patent application where the patentee does not disclose or wrongly discloses the source or geographical origin of the biological material. This remedy of invalidity is available at all stages, including, pre-grant as well as post-grant stage. This remedy of invalidity could be exercised independently in a revocation petition before the tribunal and could be set-up as a defense in infringement proceedings.

The Biological Diversity Act, 2002 also provides for criminal punishment in case any applicant proceeds to secure patent rights over biological resources from India. Section 55 of the Biological Diversity Act, 2002 provides for maximum of five years of imprisonment or fine extending to ten lakh rupees and also provides for computation of damages in case such damages exceed ten lakh rupees. Further, the penal provision empowers the Court to club the above penalties depending upon the gravity of the offence.

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

Ans. As per rule 13(8), the applicant is provided three months from the date of filing of application to complete the deposit with an International Depository Authority in those cases where the biological material cannot be described fully and particularly.

In case of National Phase PCT Application entering India which lacks this information, the applicants can include this information within three months from the date of filing of the application in India.

Further in practice the Controllers under their discretionary powers allow the applicants to make changes in the specification in order to address non-compliance pertaining to source and origin of such material.

- 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?

Ans. The requirement of disclosure is applicable to all patent applications because, under the rules affecting procedure are usually considered retrospective in nature (*Smt. Dayawati and Anr. v. Inderjit and Ors.* AIR 1966 SC 1423). Therefore, the applicant whose application concerns a biological material where the access has occurred prior to the requirement under the Patents Act would also be required to follow the requirements of disclosure and deposit because, such requirements are procedural in nature.

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. In practice, the Controller requires the applicants to obtain permission from the National Biodiversity Authority whenever biological material has been used in performing the invention. In other words, when the applicant makes the declaration on Form1 (administrative form accompanying the patent specification giving important details regarding the Patent) that the subject matter involves biological material, then the applicant is required to disclose the source / country of origin of that biological material. In case that biological materials is sourced from India, then the applicant is required to seek permission from the National Biodiversity Authority.

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.

The Biological Diversity Act, 2002 does require the National Biodiversity Authority to publish their decisions regarding approvals for patent rights over biological resources from India. However, no data as to enforcement action taken by the National Biodiversity Authority is available. And thus, to that extent, the data so available is limited.

The requisite authority was also approached for statistics on grants and refusals of such applications and imposition of benefit sharing conditions in cases where the approvals were granted. The inputs forwarded by the National Biodiversity Authority is provided below.

The details from the website of National Biodiversity Authority are reproduced below from the links <http://nbaindia.org/text/24/TOTALAPPLICATIONSRECEIVED.html>, <http://nbaindia.org/content/683/61/1/approvals.html>:

Year	Total Applications made for obtaining IPR	Grant of Approval for obtaining IPR
2003-04	0	-data not provided-
2004-05	1	-data not provided-
2005-06	0	-data not provided-
2006-07	94	0
2007-08	174	11
2008-09	58	21
2009-10	97	9
2010-11	15	4
2011-12	35	6
2012-13	63	8
2013-14	62	14
2014-15	74	22
2015-16	148	51

2016-17	25	35
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The National Biodiversity Authority under the Right To Information Request, has also disclosed that till date no application for seeking IPR has been refused. The Request also discloses that a total of 606 applications remain “neither approved nor rejected” till 31st March 2016.

In the same request, the National Biodiversity Authority has also disclosed that they do not maintain any database, whether physical or electronic, that provides the correlation between the applications approved by them and the corresponding patent application number, name of inventors or status of such patent applications

- 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.

Ans. The Courts in India are yet to address the question of necessity of Disclosure Requirement in connection with biological material and / or traditional knowledge. As mentioned before a patent application will not be granted unless the necessary permission from NBA is received when the subject matter involves use of biological material sourced from India. Once such requirement is met the Patent Office allows the application subject to satisfying the other objections in the examination report. In the matter of application number 4228/KOLNP/2008 the controller found that the biological material involved in the subject matter did not require NBA’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.

- 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.

Ans. The prescribed fee for form III, i.e. for applying for the necessary permission from the NBA is INR500.

As regards time, even though the law requires disposal of such applications within 3 months, in practice it takes a longer time. Such time can range from 6 months to couple of years.

- 6) Please provide an estimate of the additional time and cost as described in question 5) associated with compliance with any foreign Disclosure Requirement. There is no requirement to comply with foreign disclosure requirements for obtaining an Indian patent.

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

Even though the BD Act has as well as the requirements pertaining to disclosure of biological material in the Indian Patents Act has been around for quite a while, there are ambiguities and lack of clarity when it comes to practicing such provisions.

So far we have not seen a significant impact of the disclosure requirement on patent valuation in India.

- 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”)?

Ans. As provided in the table above, it appears that the number of applications seeking the approval of NBA has steadily increased over the years along with number of annual approvals being granted by NBA.

- 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 Requirements improved patent examination, or led to sharing of financial or other benefits?

Ans. The Biological Diversity Act, 2002 makes it mandatory to enter into a benefit sharing agreement with the members of local community before the accessing party is able to secure a grant of patent (Section 6 and 21 of the Biological Diversity Act, 2002).

Also, the government has recently released “Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014” which were notified as statutory rules under the Biological Diversity Act, 2002 in November 2014. Rule 9 further provides that the monetary sharing should be in the “range of 0.2 to 1.0%” between the NBA and applicant in case applicant commercializes the patent so received or should be in the range of “3.0 to 5.0%” of the license fee and “2.0 to 5.0% of the royalty received annually”.

In a specific instance, the NBA fixed about 0.2% on annual gross ex-factory sale as the rate for monetary sharing should the Applicant commercialize the product on its own and placed a 3.0% rate of the fee received from license and 2.0% of annual royalty should the applicant license the invention involving the biological resource. (In re: *1280/MUM/2008*)

Among other requirements, it requires the applicant to get in to a prior benefit sharing agreement and lists out the minimum royalty sharing required to be paid to the local community. Further the National Biodiversity Authority is given a key role in ensuring that the benefits are adequately shared in case of successful commercialization of the invention resulting from the biological resource so sourced from that community (Rules 9,10 of the Regulations).

In effect, the Patent Office requires disclosure of origin of the “biological material” that forms part of the patent specification. They further mandate that in case such “biological material” is sourced from India, then, the party must gain the requisite approval from the National Biodiversity Authority. Thus, the purpose of Nagoya Protocol that is to ensure fair and equitable benefit sharing for the biological resources is completed by the requirements posed by the two agencies – Patent Office by insisting on approval from National Biodiversity Authority and National Biodiversity Authority in turn ensuring access and benefit sharing (involving fixing of royalty rates, etc.) prior to the grant of the approval needed by the Patent Office.

In the case of *Re: 4228/KOLNP/2008*, the Patent Office specifically required disclosure of origin of all the biological material and further stipulated, that, in case any of them originate from India, then the requisite approval from National Biodiversity Authority is

required to meet the “disclosure requirements under section 10(4) of the [Patents] Act”. Also, in the case of *Re; 1280/MUM/2008*, the Patent Office inquired into the origin of the biological material that formed the subject-matter of the patent and reiterated the need for the approval by the National Biodiversity Authority (Order dt. 05/09/2013) even though, the rest of the patent specification was found to be in order. The application only proceeded to grant on 11th July 2016 (Order dt. 11/07/2016) after the necessary approval from the National Biodiversity Authority was brought to the knowledge of the Patent Office.

- 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 the websites which would allow accessing information and contacting the responsible local authorities.

Ans. Yes, the Biological Diversity Act, 2002 has set up National Biodiversity Authority to monitor and implement the requirement of Disclosure and Benefit Sharing in case any biological resource is sourced from India.

The website of National Biodiversity Authority is <http://nbaindia.org/> .

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

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

Ans. India is a party to Nagoya Protocol since the year 2014.

- 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”).

Ans. Yes. The approval from National Biodiversity Authority is required prior to the grant of the patent by Patent Office.

The National Biodiversity Authority, in turn, ensures that the applicant enters into a prior access and benefit sharing agreement as well as mutually agreed terms with the local communities at the time of grant of approval (Section 21 of the Biological Diversity Act, 2002).

Thus, under the scheme of laws in India, the applicant seeking to use a biological resource originating in India must necessarily get into a mutually agreed terms and conditions with local communities and benefit claimers and subsequently have the same approved by the National Biodiversity Authority. The absence of the approval from the National Biodiversity Authority would not lead to the grant of the patent even if the application is found in order on

other counts.

- 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?

Ans. Biological Diversity Act, 2002 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 dissemination of knowledge in any seminar or workshop.

However, even the universities and / or their staff is under specific obligation to seek approval from National Biodiversity Authority prior to filing a patent application if such application pertains to biological resource originating in India. This requirements applies across the board irrespective of the nationality of the university or their staff.

- 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.

Ans. "Traditional Medicine" is not patentable under Indian Patents Act. The law explicitly prohibits patenting of "traditional knowledge" or "the effects" of traditional knowledge. This would include within its ambit "traditional medicine".

The Government of India has set-up "Traditional Knowledge Digital Library" which is a database of traditional medicinal systems practiced in India. It was specifically set-up to prevent acts of bio-piracy, that is, attempts to patent what was already known / part of the practitioner knowledge in India. This initiative provides for translated version of the treatises of traditional medicine system.

The website link is <http://www.tkdل.res.in/tkdل/langdefault/common/Home.asp?GL=Eng>
As per the official website, the TKDL database contains "more than 2.97 lakh formulations from the texts of traditional medicine systems of India which are Ayurveda, Unani and Siddha" and that the "task of digitizing the medicinal information available is being done in a phased manner".

- 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.

An indicative list of some studies on the implementation of Nagoya Protocol by India is provided below:

Kabir Sanjay Bavikatte and Morten Walløe Tvedt, 'Beyond the Thumbrule Approach: Regulatory Innovations for Bioprospecting in India', 11/1 Law, Environment and Development Journal (2015), p. 1, available at <http://www.lead->

journal.org/content/15001.pdf

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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).