Disclosure of the Source of Genetic Resources and Traditional Knowledge in Patent Applications

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Introduction

The Terms of Reference for the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing (ABS-Working Group) adopted by the seventh Conference of the Parties (COP-7) of the Convention on Biological Diversity (CBD) list, as one element to be considered by this working group for inclusion in the international regime, the "disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights".[1] Besides the CBD, other international fora are currently considering such disclosure requirements, namely the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO). Disclosure measures are seen as increasing transparency in the context of access to genetic resources and traditional knowledge and the sharing of the benefits arising out of their utilization, in particular with regard to the obligations of the users of such resources and knowledge.[2]

When introducing a disclosure requirement in patent law, a number of issues arise, including the following: What terminology should be used? Should one speak about "genetic resources," "biological resources" or "biological material," and about "traditional knowledge" or "knowledge, innovations and practices of indigenous and local communities"? What information needs to be disclosed in the patent application? Is it the "source," the "country of origin" or the "geographic origin"? When does a disclosure have to be made, that is, what mechanism triggers the requirement? Are there any exceptions to the requirement? In what international instrument should the requirement be introduced? Is the requirement of a formal or of a substantive nature? Should it be optional or mandatory for States to implement the requirement at the national level? Should the wrongful disclosure or failure to disclose carry any sanctions and, if so, what kind? And finally, what existing international law[3] needs to be taken into account?

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1 See Decision VII/19, *Access and benefit-sharing as related to genetic resources (Article 15)*, Section D, Annex, subpara. (d)(xiv).

2 With this policy objective, disclosure requirements can be seen as measures which (at least indirectly):

- "promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources" (*id*., subpara. [d][v]);
- "ensure compliance with national legislations on access and benefit-sharing, prior informed consent and mutually agreed terms, consistent with the Convention on Biological Diversity" (*id*., subpara. [d][ix]); and
- "ensure compliance with prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with Article 8(j)" (*id*., subpara. [d][x]).

According to the Terms of Reference, these measures shall be considered by the ABS-Working Group for inclusion in the international regime.

3 This concerns namely the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT) of WIPO, the TRIPS Agreement, the CBD, and the International Treaty on Plant Genetic Resources for Food and Agriculture of FAO (FAO-IT).

This paper briefly analyses these issues and contains the author's proposals for the way forward with regard to the declaration of the source of genetic resources and traditional knowledge in patent applications.[4]

Genetic Resources and Traditional Knowledge

The disclosure requirement should mirror the terminology used in the international fora and agreements relevant to access and benefit-sharing:

- *Genetic resources*: The CBD and the Bonn Guidelines refer to "genetic resources," while the International Treaty on Plant Genetic Resources for Food and Agriculture (FAO-IT) refers to "plant genetic resources for food and agriculture" (PGRFA).[5] The respective definitions of these terms are largely synonymous.[6]
- *Traditional knowledge*: The use of terms in the relevant international fora is not uniform;[7] nevertheless, all terms used are presumably synonymous with the term "traditional knowledge".[8] Being a measure to be taken under patent law, the disclosure requirement focuses on traditional knowledge that can give rise to a technical invention. Furthermore, the traditional knowledge in question must be related to or associated with genetic resources. It thus seems best to use either the term "traditional knowledge related to genetic resources" or "traditional knowledge associated with genetic resources."

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4 For a more detailed analysis of these issues see: Girsberger, M.A. , 2004. *Transparency Measures Under Patent Law Regarding Genetic Resources and Traditional Knowledge: Disclosure of Source and Evidence of Prior Informed Consent and Benefit Sharing*, Journal of World Intellectual Property, Vol. 7 No. 4, July 2004, pp. 451-489.

5 See Art. 15 of the CBD, paras. 22 to 50 of the Bonn Guidelines, and Arts. 10 to 13 of the FAO-IT.

6 See Art. 2 the CBD and Art. 2 of the FAO-IT.

7 The FAO-IT, the WTO and WIPO uniformly use the term "traditional knowledge." In contrast, the CBD, the various CBD-fora and the Bonn Guidelines use different terms interchangeably. These include "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity"; "traditional knowledge"; "associated traditional knowledge, innovations and practices"; "knowledge, innovations and practices of indigenous and local communities"; and "traditional knowledge, innovations and practices associated with genetic resources."

8 The Secretariat of WIPO defines "traditional knowledge" as "knowledge which is:

- generated, preserved and transmitted in a traditional context;
- distinctively associated with the traditional or indigenous culture or community which preserves and transmits it between generations;
- linked to a local or indigenous community or other group of persons identifying with a traditional culture through a sense of custodianship, guardianship or cultural responsibility, such as a sense of obligation to preserve the knowledge, or a sense that to permit misappropriation or demeaning usage would be harmful or offensive, a relationship that may be expressed formally or informally by customary law;
- knowledge in the sense that it originates from intellectual activity in a wide range of social, cultural, environmental and technological contexts; and
- identified by the community or other group as being traditional knowledge."

(WIPO-IGC, 2003: *Overview of the Activities and Outcomes of the Intergovernmental Committee*, WIPO-document WIPO/GRTKF/IC/5/12 [3 April 2003], para. 45. See: http://www.wipo.int/documents/en/meetings/2003/igc/pdf/grtkf_ic_5_12.pdf).

The Concept of the "Source"

According to both the CBD (see Arts. 15.4 and 15.7) and the Bonn Guidelines (see paras. 17, 18, 28, 31, 32 and 48), a multitude of entities may be involved in access and benefit sharing with regard to genetic resources. The same applies with regard to PGRFA under the FAO-IT (see Arts. 9.2(b), 12.2, 12.3(e)-(h), 13.2(d)(ii) and 13.3). Parallel to genetic resources, the CBD (see Art. 8(j)) and the Bonn Guidelines (see paras. 31 and 48) allow for a multitude of entities to be involved in access and benefit sharing with regard to traditional knowledge, including primarily indigenous and local communities.

The disclosure requirement should reflect the multitude of entities that may be involved in access and benefit sharing. General terms, namely "source" and "origin," thus serve best the purposes of this requirement. "Origin," however, is contained in other terms of relevance with regard to genetic resources, in particular in "country of origin" and "geographic origin" and may be confused with these terms. Furthermore, the term "geographic origin" lacks an international definition. Additionally, both "country of origin" and "geographic origin" may be difficult or impossible to determine in practice. And finally, both concepts are much too restrictive to fully take into account the multitude of entities that may according to the CBD, the Bonn Guidelines and the FAO-IT be involved in access and benefit sharing. As a result, "source" seems to be clearly in the foreground to be used in the context of the disclosure requirement.

The term "source" should be understood in a broad sense to cover all potential "sources" of genetic resources and traditional knowledge allowed for in the CBD, the Bonn Guidelines and the FAO-IT. Based on these international instruments, the entity competent (1) to grant access to genetic resources and traditional knowledge, and/or (2) to participate in the sharing of the benefits arising out of their utilization, is in the foreground to be declared as the source. Depending on the genetic resource or traditional knowledge in question, one can distinguish between "primary" and "secondary" such sources: Primary sources are the Contracting Party providing genetic resources (see Arts. 15, 16 and 19 of the CBD), indigenous and local communities (see Art. 8(j) of the CBD), and the Multilateral System established by the FAO-IT (see Arts. 10-13); secondary sources are *ex situ* collections such as gene banks and botanical gardens, databases on genetic resources and traditional knowledge, and scientific literature.

Accordingly, there is what can be termed a "cascade" of possible primary and secondary sources: Patent applicants must disclose the primary source to fulfill the disclosure requirement, if they have information about this primary source at hand. A secondary source may only be disclosed if patent applicants have no information at hand about the primary source. Only if the patent applicant (or the inventor) has no information at hand about the primary or the secondary source, may he disclose that such source is unknown.

Considering the broad understanding of the term "source," cases where no primary or secondary source is known are likely to be rare. Nevertheless, cases are possible where patent applicants, for reasons beyond their control, do not have the necessary information to fulfill the disclosure requirement. An example at hand is a plant stored in a gene bank, which was collected decades ago, and for which no information about its source exists. For reasons of legal certainty and of fairness, patent applicants should in such cases be able to declare

that they do not have the necessary information (i.e., the source is unknown to the inventor or the patent applicant) and fulfill the disclosure requirement accordingly. Otherwise, they would be forced to either wrongfully disclose the source or to forego patent protection.

Mechanism "Triggering" Disclosure Requirement

With regard to genetic resources, an invention should be directly based on a genetic resource to which the inventor has had access in order for the disclosure requirement to apply. Accordingly, the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource, and the inventor must have had physical access to this resource, that is, at least sufficient enough contact to identify the properties of the genetic resource relevant for the invention. With regard to traditional knowledge, the inventor should know that the invention is directly based on such knowledge, that is, the inventor must consciously derive the invention from this knowledge.

Legal Basis of Disclosure Requirement

Generally, the requirements with regard to patent applications can be categorized as follows:

- *formal requirements* which are examined for the purposes of determining if a complete application has been filed;
- *formal requirements strongly linked to substance* concerning the various parts of the patent application for the purposes of search, examination and grant, that is, requirements which could affect the scope of a search or result in the rejection of the claims during the substantive examination of the patent application; and
- *substantive requirements*, under which the claims are evaluated for patentability, namely, definition of prior art, disclosure of the claimed invention, patentable subject matter, novelty, inventive step and industrial utility.

The policy objective of the disclosure of the source is to increase transparency in the context of access and benefit sharing. Accordingly, this requirement is examined for the purposes of determining if a complete patent application has been filed; it is thus linked neither to the search, examination or grant of patents, nor to the evaluation of the claims for patentability. As a result, it has to be considered as a formal requirement, not a formal requirement strongly linked to substance or a substantive requirement.

Being of a formal nature, Article 27(1) of the PCT and Rule 4.1 of the PCT-Regulations as well as Article 6(1) of the PLT apply. At present, neither Rule 4 nor Rule 51*bis*.1 of the PCT-Regulations contain provisions on the disclosure requirement. Accordingly, in order to clarify the legal situation at the international level, it appears necessary to amend the PCT-Regulations and thereby explicitly enable the national legislator to introduce such a measure. Moreover, it is necessary to take into account Article 62.1 of the TRIPS Agreement, which states that Members of the WTO may only require "reasonable" procedures and formalities as a condition of the acquisition or maintenance of patents.

Optional vs. Mandatory Introduction at National Level

Considering the state of play at the international level and the opinions expressed by the various stakeholders, it seems advisable to go for an optional solution (an "enabling clause" in the relevant international agreement) at this point in time, granting those States willing to act at the national level the possibility to do so, without, however, preempting the results of future international discussions on the issue. Furthermore, an optional solution would most likely be found more easily than a mandatory one, and could thus be realized in less time. Additionally, it would allow governments and the international community to gain experience with the disclosure requirement, without prejudice to further international efforts.

Opting for a mandatory solution would indeed ensure that all States, which are a Contracting Party to the chosen international instrument, are obliged to implement this requirement at the national level. This may be seen as bringing increased legal certainty and as a clear political sign for the willingness of the international community to achieve the policy objectives of the disclosure requirement. Such a solution, however, is at this stage of the international discussions unlikely to be found any time soon, and will thus take considerable more time to be introduced than an optional solution.

Sanctions for Failure to Disclose or Wrongful Disclosure

In order for the disclosure requirement to achieve its policy objectives, failure to disclose or wrongful disclosure should be subject to legal sanctions. These sanctions should be the same as are imposed with regard to other formal requirements in patent law; accordingly, the sanctions currently foreseen in the PCT and the PLT would apply. In addition, national law could foresee that criminal sanctions such as fines may be imposed, or that judges may order the publication of their rulings.

Conclusions

Based on the preceding analysis, the following conclusions can be drawn:

- Patent applicants should be required to disclose the "source" of "genetic resources" and "traditional knowledge related to genetic resources" in patent applications. This requirement should only apply if patent applicants (or the inventors) do have available information on the source; otherwise, they should be required to declare that the source is unknown to them;
- Due to its policy objective – increasing transparency in the context of access and benefit sharing – the disclosure requirement has to be considered as a formal requirement. Accordingly, the provisions of the PCT and the PLT apply. Furthermore, considering that the international discussions on disclosure requirements in patent law have only just begun, it seems at this point in time preferable to make it optional for States to implement this requirement in their national laws. This way, there is no risk of preempting further international discussions on this issue, without preventing States from taking action at the national level;
- Failure to disclose or wrongful disclosure should be sanctioned according to the current provisions of the PCT and PLT. Additionally, criminal and other sanctions may apply; and
- It has to be considered that patents are generally applied for after several years of research and development activities, and thus considerable time after the initial access to

genetic resources and traditional knowledge. Hence, the disclosure requirement does not provide for a remedy with "immediate" effects. Furthermore, the disclosure requirement will only be able to fulfill its policy objectives if in fact patents are applied for. Accordingly, the measure could be circumvented by foregoing patent protection. It is thus self-evident that the introduction of a disclosure requirement in patent law will not solve all the issues arising in the context of access and benefit sharing regarding genetic resources and traditional knowledge. As such, the disclosure requirement needs to be complemented by further measures taken within other legal domains – the majority of them obviously not related to IPRs – in order to fully solve these issues. This notwithstanding, the disclosure requirement presents a viable measure to be taken under patent law which contributes to the resolution of the issues arising.

Proposals by Switzerland to Amend the PCT

At the fourth session of the Working Group on Reform of the PCT of WIPO held in May 2003, Switzerland submitted proposals regarding transparency measures under patent law in the area of genetic resources and traditional knowledge. These proposals contain precise wordings for amendments to the relevant PCT-Regulations. More specifically, Switzerland proposed for the national patent legislation to explicitly require the declaration of the source of genetic resources and traditional knowledge in patent applications, if an invention is directly based on such resources or knowledge. In May and October 2004, Switzerland submitted to WIPO additional comments and further observations, respectively, on these proposals. These proposals are largely congruent with the opinions expressed in this paper.

References

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