FRIENDS WORLD COMMITTEE FOR CONSULTATION (QUAKERS) www.quno.org

Quaker United Nations Office

Tel +41 (22) 748-4800
Fax +41 (22) 748-4819
Email quno@quno.ch

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Establishing a Disclosure of Origin Obligation in the TRIPS Agreement

Carlos M. Correa *
University of Buenos Aires

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* *Professor Correa is a member of a consultative group advising QUNO on its TRIPS programme of work. The views expressed in this paper do not necessarily reflect those of the Quaker United Nations Office.*

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Carlos M. Correa
University of Buenos Aires
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Several developing countries have advocated the introduction of an obligation to disclose the origin of biological materials (and the associated knowledge) claimed in patent applications. Such an obligation should include, according to some proposals, not only information about origin, but also about compliance with national access laws as well as effective fair and equitable benefit sharing under the relevant national regimes.[1]

This paper examines the purposes of such an obligation, its possible content and scope, and the consequences emerging from non-compliance, with a view to the possible incorporation of such an obligation into the TRIPS Agreement.

I. Purposes

The disclosure of origin obligation may contribute to address a major concern of developing countries: the "bio piracy" of biological resources and traditional knowledge (TK)[2]. Despite the complaints and pleas by developing countries affected by these practices, they continue unabated as no preventive measures have been taken by countries that most benefit from them, while the TRIPS Agreement has no rules to prevent such occurrences.

The adoption of such an obligation may constitute the first step in the development of a *misappropriation regime* aimed at avoiding the monopolization of biological materials and related TK. The disclosure of origin may fulfil three main functions relevant for the operation of the patent system:

(a) It would improve the substantive examination of patent applications involving such materials and knowledge. The provision of that information may, in effect, facilitate the determination of prior art[3] by providing useful information to the examiner. In some cases, it may simplify searching the databases on TK currently being established[4]. The information supplied would help to identify possible cases of misappropriation of biological materials and facilitate actions to challenge the validity of wrongly granted patents.

(b) It will also improve the determination of inventorship by the patent office or courts. Though a patent is granted (according to the "first to file" system) to the first person to apply for it, he/she should be entitled to the patent on the basis of an *act of invention*, or as a legitimate successor in right to the

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[1] See, e.g., *"The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge"*, Brazil on behalf of the delegations of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe, IP/C/W/356, 24 June 2002, para. 10.

[2] There has been extensive documentation of IPRs being sought over resources "as they are", without further improvement (e.g. US patent No. 5,304,718 on quinoa granted to researchers of the Colorado State University; US plant patent No. 5,751 on ayahuasca, a sacred and medicinal plant of the Amazonia) and on products based on plant materials and knowledge developed and used by local/indigenous communities, such as the cases of the neem tree, kava, barbasco, endod and turmeric, among others. See, e.g. Correa, Carlos (2001), *"Traditional Knowledge and Intellectual Property: Issues and options surrounding the protection of traditional knowledge. A discussion paper"*. QUNO, Geneva.

[3] In many countries, as well as in the case of PCT applications (Rule 5.1(a)(ii)), applicants are required to disclose known prior art.

[4] See *"Article 27.3(b), The Relationship Between The TRIPS Agreement And The Convention On Biological Diversity, And The Protection Of Traditional Knowledge*", communication from Switzerland, IP/C/W/400, 28 May 2003, para. 9.

inventor. Inventorship is a basic element in patent law and there are no limitations under the TRIPS Agreement with regard to means to determine it[5].

(c) The disclosure of origin may, in some cases, facilitate or permit the actual execution of the invention, such as where a biological material is endemic to a specific location.

In addition to these possible functions *within* the patent law, if the information to be provided encompassed (as proposed by some developing countries) a declaration or evidence about compliance with national access laws, such an obligation may have a significant role *outside* the patent system. It would, in effect, help countries supplying biological materials

(a) to promote compliance with access legislation, where applicable; and

(b) to keep track of the commercial exploitation of such materials for the purposes of benefit-sharing.

These two functions would be important to put into effect the principles and obligations of the Convention on Biological Diversity (CBD), as well as the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization" (Bonn Guidelines), in particular paragraph 16(d)[6].

II. National and regional precedents

Some national laws have already given some steps in relation to this matter (see examples in Box 1). There are also some proposals of legislation that address this issue.

Box 1

Disclosure Obligations under National Laws

Costa Rica

The National Seed Office and the Register of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission before granting intellectual or industrial property protection to innovations involving components of biodiversity. They must always provide the certificate of origin issued by the Technical Office of the Commission and the prior informed consent. Justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation. Failure to provide the necessary information in any of the cases referred to above could lead to the failure of the application or revocation of the patent (Biodiversity Law 7.788, Article 80).

India

The Patent Second Amendment Act (adopted in 2002) provides that the applicant must disclose in their patent applications the source of origin of the biological material used in the invention (section 10). It also allows for opposition to be filed on the ground that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention. The grounds for rejection of the patent application, as well as revocation of the patent, include non-disclosure or wrongful disclosure of the

[5] See the report of the WTO case *United States-Section 211 Omnibus Appropriations Act of 1998* (WT/DS176/AB/R) where the Appellate Body (supporting the panel's view) held that neither the TRIPS Agreement nor the Paris Convention addresses the question of how the ownership of a trademark is determined, and that this is an issue to be determined by national law (para. 188-189). The same doctrine is arguably valid for patents and other IPRs.
[6] See also paragraph 46 of Decision VI/10 and paragraph 1 of Section C of Decision VI/24 adopted by COP6.

source of origin of biological resource or knowledge in the patent application, and prior disclosure of knowledge, oral or otherwise.

According to section 6 of the Indian Biodiversity Bill, in addition, anybody seeking any kind of intellectual property rights on research based upon biological resources or knowledge obtained from India needs to obtain prior approval of the NBA. The NBA will impose benefit-sharing conditions. Section 18 (iv) stipulates that one of the functions of NBA is to take measures to oppose the grant of intellectual property rights (IPRs) in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource.

Andean Group

The Andean Group Decision 391 established that any IPRs or other claims to resources shall not be considered valid, if they were obtained or used in violation of the terms of a permit for access to biological resources residing in any of the Andean countries, as regulated under that Decision.

Andean Decision 486 provides in Article 26 (h) that applications for patents shall be filed with the competent national office and shall contain a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or by products originating in one of the Member Countries. If applicable, the applicant shall also submit a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations.

Brazil

The grant of industrial property rights by the competent bodies for a process or product obtained using samples of components of the genetic heritage is contingent on the observance of this Provisional Measure, the applicant being obliged to specify the origin of the generic material and the associated traditional knowledge, as the case may be (Article 31 Provisional Measure No. 2.186-16).

The European Directive on Biotechnological Inventions (No. 96/9/EC of March 11, 1996) includes, in Recital 27, an encouragement to provide information on geographical origin[7], but creates no incentive for the patent applicant to effectively do it. The draft regulation elaborated in Belgium for implementing the Directive stipulates (Article 4(3)) that the exploitation of an invention is contrary to *ordre public* and morality, especially when the invention can be shown to have been developed in circumstances which run counter to public order and morality, which is the case when an invention is developed on the basis of human tissue removal without the consent of the donor, or when an invention is developed on the basis of plant or animal material which was imported in violation of the law of the country of origin of these materials. As a consequence, an invention which is developed on the basis of human material without prior informed consent, or which uses plant or animal material which was imported in violation of the law of the country of origin, would run counter to Belgian *ordre public* and morality, and could be revoked on the basis of Art. 49(1)(1) of the Belgian Patent Act 1984[8].

[7] *"Recital 27: Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents;"*

[8] Van Overwalle, Geertrui (2000), *"The Legal Protection of Biological Material in Belgium"*, IIC, No. 3, p. 282.

III. Scope of the obligation

a. Country of origin and country providing biological materials

As the examples of national legislation and the proposals made in WTO indicate, the scope of the disclosure obligation may vary. It may refer to the *country of origin* of the biological material used, or to its *source*.

The "country of origin" of genetic resources is, according to the CBD, "the country which possesses those genetic resources in in-situ conditions". "In-situ conditions" means "conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties" (article 2 of the CBD).

Though in some cases biological materials are directly obtained from the countries of origin (for instance, where they are collected in the context of bio-prospecting programs), they are often supplied by sources that conserve such materials in "ex-situ" conditions, that is, "outside their natural habitats" (article 2 of the CBD), for instance in gene banks or botanical gardens. For this reason, the "country of origin" of a biological material may be, but is not necessarily, the "country providing genetic resources".

The determination of a single "country of origin" of a biological material is often complex or impossible. On the one hand, certain materials (including wild plants or animals) may be found in many countries, especially in neighbouring countries. On the other, the distinctive characteristics of cultivated species may be acquired in different countries, such as in the case of plant varieties that incorporate traits from different places.

Due to this difficulty, the prior informed consent and benefit sharing provisions of the CBD are established with respect to the "country providing genetic resources" and not the "country of origin". The CBD provides in this regard that

> "Access to genetic resources shall be subject to prior informed consent of the *Contracting Party providing such resources*, unless otherwise determined by that Party" (article 15.5) (emphasis added).
>
> "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, … with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the *Contracting Party providing such resources*. Such sharing shall be upon mutually agreed terms" (article 15.7) (emphasis added).

The distinction between "country of origin" and "country providing" the resources is significant for defining the scope of the disclosure obligation. If the obligation required information about the "country of origin", the applicant may be obliged to make a costly and time-consuming search to generate information not available to him and difficult to obtain. Alternatively, he may be required to submit, on a *bona fide* basis, whatever information he has about the source (e.g. gene bank, farming community) from which he obtained the biological resources at stake, without necessarily obliging him to enquire about the country of origin. Another option would be to require the information about the country of origin and, if not available to the applicant, about the source. In any case, it should be borne in mind that the obligations under the CBD relate to the country *providing* the material.

National laws differ as to the specific information required to fulfil the disclosure of origin obligation. The Indian patent law, for instance, requires the applicant to "disclose the source and geographical origin of the biological material in the specification, when used in an invention" (Section 10(4) (d), as amended). The EC Directive on Biotechnological Inventions refers to the "geographical origin". The submissions on the subject made to the Council for TRIPS allude to

-"country of origin"[9];
- "origin of genetic resources"[10];
-"source and country of origin"[11];
-"sources of any biological material"[12];
- "geographic origin"[13];
-"source of origin"[14];
-"source of a specific genetic resource"[15];

This terminology seems to indicate that the objective of most of the proponents of the disclosure obligation is to require information about the direct source of the biological material, rather than the "country of origin" in the sense of the CBD. In order to be consistent with this Convention it is important to establish which country is *providing* the material. It should be noted, however, that for the purposes of the CBD, "the genetic resources being provided by a Contracting Party …are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention" (article 15.3)[16].

In sum, in order to be consistent with the CBD, a provision on the subject may refer to the providing country as understood under the Convention. In the case of the EC and their member States, for instance, they suggest to require "the indication of the geographical origin of genetic resources, which they know, or have reason to know, or, when the country of origin is not known, the research centre, gene bank or entity from which they acquired the resource"[17].

b. Generation or transmission of available information

It has been argued that applicants may lack the information necessary to comply with such a disclosure of origin obligation, and that it would increase the transactions costs for filing patent applications and acquiring patent rights. This issue would arise if the applicant were required to obtain and submit information not available to him The applicant may just be required, however, to provide *bona fide*

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[9] Communication from India. IP/C/W/195, 12 July 2000, p. 16.
[10] Communication from Norway, IP/C/W/293 29 June 2001, para. 6.
[11] "*The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*", submission by Brazil on behalf of the delegations of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe, IP/C/W/356, 24 June 2002, para. 10.
[12] *"Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement"*, Joint Communication from the African Group, IP/X/W/404, June 26, 2003, para. II (c).
[13] *"Review Of Article 27.3(b) Of The TRIPS Agreement, And The Relationship Between The TRIPS Agreement And The Convention On Biological Diversity (CBD) And The Protection Of Traditional Knowledge And Folklore. A Concept Paper"*. Communication from the European Communities and their Member States, IP/C/W/383, 17 October 2002, para. 54.
[14] *"The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge"*. Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/403, June 24, 2003, para. 5, 10.
[15] "*Article 27.3(b), The Relationship Between The TRIPS Agreement And The Convention On Biological Diversity, And The Protection Of Traditional Knowledge"*. Communication from Switzerland, IP/C/W/400, 28 May 2003, fn. 5.
[16] It should be noted that the Convention only applies to materials acquired in conformity with its rules, after the entry into force of the Convention.
[17] Communication from the European Communities and their Member States. *"Review Of Article 27.3(b) Of The TRIPS Agreement, And The Relationship Between The TRIPS Agreement And The Convention On Biological Diversity (CBD) And The Protection Of Traditional Knowledge And Folklore. A Concept Paper"*, IP/C/W/383, 17 October 2002, para. 54.

information he knows or has reason to know. In this case, he would not need to generate information, but only to transmit fully whatever is available to him.

c. Object of the information

Another important issue relates to the object of the information to be supplied by the applicant. The proposals made at the Council for TRIPS refer to

-"biological resource and of the traditional knowledge used in the invention" [18];
-"biological resources and traditional knowledge used or involved in the invention"[19];
-"inventions based on biological resources and/or traditional knowledge" [20];
- an invention "directly based on such a resource" [21];
-"the genetic resources or TK used" [22].

Accordingly, the obligation would apply with regard to two components:

(a) biological "materials" or "resources". The CBD defines the latter as including "genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity" (article 2).

(b) traditional knowledge. In some cases, only the knowledge "associated" with a biological material is referred to, while in others the obligation would seem to apply in all cases where TK is used, even if not associated to such materials. If the obligation sought would be aimed at effectively implementing the CBD, the relationship between the TK and biological resources would be essential to determine what TK should be disclosed.

d. Use of the biological material in the invention

The submissions to the Council for TRIPS (with one exception) are rather vague on the issue of the relationship between the biological material used and the invention. The question to be addressed is how direct or indirect the use of a biological material in an invention should be so as to trigger the information requirement. The Swiss proposal is the only one to specifically refer, as noted above, to an invention "*directly* based on such a resource" . The African Group suggestion is clearly much broader: "biological resources and traditional knowledge *used or involved* in the invention" (emphasis added) [23].

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[18] *"The Relationship Between The TRIPS Agreement And The Convention On Biological Diversity And The Protection Of Traditional Knowledge"*, Brazil on behalf of the delegations of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe, IP/C/W/356, 24 June 2002, para. 10.

[19] *"Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement"*. Joint communication from the African Group, IP/C/W/404, June 26, 2003, para. III (D).

[20] *"The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge"*. Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/403, June 24, 2003, para. 6.

[21] *"Article 27.3(b), The Relationship Between The TRIPS Agreement And The Convention On Biological Diversity, And The Protection Of Traditional Knowledge"*. Communication from Switzerland, IP/C/W/400, 28 May 2003, fn. 5.

[22] *"Review Of Article 27.3(b) Of The TRIPS Agreement, And The Relationship Between The TRIPS Agreement And The Convention On Biological Diversity (CBD) And The Protection Of Traditional Knowledge And Folklore. A Concept Paper"*. Communication from the European Communities and their Member States, IP/C/W/383, 17 October 2002, para. 54.

[23] *"Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement"*. Joint communication from the African Group, IP/C/W/404, June 26, 2003, para. III (D).

The CBD applies to cases of access to and subsequent commercial exploitation of genetic resources, "with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources" (article 15.7). Though it is unclear the extent to which the exploitation of derived or modified material triggers the benefit sharing obligation under the Convention, this obligation does apply in cases of commercial exploitation of derived materials to the extent that the accessed genetic resources are incorporated into the commercialized product.

For the disclosure obligation to be justified, in sum, a key point is the relationship between the biological material and the claimed[24] invention. Though this issue cannot be addressed in depth here, it should be considered in preparing possible negotiating texts.

e. Compliance with the CBD

Some of the submissions to the Council for TRIPS suggest that the obligation to disclose the origin should not only comprise of information about the source, but also in relation to acts that demonstrate compliance with obligations provided under the CBD in relation to prior informed consent and benefit sharing. Thus, a group of developing countries has suggested to

> "require that an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition to acquiring patent rights: ... (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes"; (iii) evidence of fair and equitable benefit sharing under the relevant national regimes".[25].

Similarly, the African Group proposes to require confirmation about "compliance with all access regulations in the country of origin" [26].

It seems clear that the information required concerns compliance with the applicable *domestic* legislation in the Member where the genetic resources and traditional knowledge where obtained. So far, however, a relatively small number of countries have implemented the CBD and adopted access legislation.

The special status of plant genetic materials for food and agriculture (PGRFA) should be duly acquainted in a provision aimed at implementing the disclosure of origin obligation. As noted, the distinctive characteristics of plant varieties have generally been acquired in different countries. There is a strong interdependency among countries with regard to PGRFA. The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)[27] recognizes these specific features of PGRFA. The Treaty, which was developed in harmony with the CBD (article 1), provides a specific access regime (the "Multilateral System") for crops listed in Annex I. Such materials will be subject to facilitated access with no need to apply prior informed consent procedures case-by-case. Parties will only be bound to enter into a standard material transfer agreement (article 12.4). The Treaty also stipulates that recipients of PGRFA from the Multilateral System shall not seek intellectual property rights over the material, and its parts and components, "in the form received" (article 12.3(d)).

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[24] In principle, for the disclosure obligation to apply, the biological resource should be part of the patent *claims*, and not merely of the description. A claim is one or more statements in a patent or application that precisely define the specific features of the invention for which patent protection is granted or sought.

[25] Communication by Brazil on behalf of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe, IP/C/W/356, para 10. See also Paragraph 1 of Section C of Decision VI/24 adopted by COP6 of the CBD, which states that the information about the source of genetic resources in applications for intellectual property rights is "*a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted*".

[26] *"Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement"*. Joint communication from the African Group, IP/C/W/404, June 26, 2003, para. III (D).

[27] Available at www.fao.org

IV. Discharging the obligation

Various suggestions on how to discharge a disclosure of origin obligation have been made. They include:

(a) a simple statement or declaration[28] by the applicant;

(b) a statement accompanied by the submission of evidence, for instance, a copy of the access contract or government authorization, where applicable;

(c) submission of a certificate of origin attesting to the fact that the applicant has complied with the relevant access regulations[29].

All three alternatives would permit interested parties to monitor the use of biological resources and eventually make benefit sharing claims. Of course, alternatives (b) and (c) create a heavier burden than alternative (a). Those stricter requirements would seem to be justified if the patent offices were mandated to assess the evidence submitted as part of the examination process. It is questionable, however, whether patent offices should be expected to undertake such an assessment, which implies the application of a foreign law (the access legislation in the providing country) and an evaluation for which the offices are not technically prepared.

V. Mandatory or facultative

The obligation to disclose the origin may be established as a mandatory obligation - non-compliance with which would entail certain legal consequences - or as a voluntary formality, simply encouraged, not imposed on applicants. Switzerland, for instance, sees merits in establishing a disclosure of origin requirement, but it suggests including it with regard to PCT applications only and as a facultative requirement that domestic law may impose upon applicants[30]. Nevertheless, the approach followed in the majority of submissions made to the Council for TRIPS[31] is unambiguously based on a mandatory requirement.

VI. Consequences: formal or substantive requirement

The issue has been raised whether an obligation to disclose the origin would be a simple formality or a substantive requirement. This distinction, however, may not be crucial in terms of the consequences of failure to comply, since existing general disclosure requirements in patent law have both formality and substantive aspects [32], and there are non-substantive conditions under patent law that may lead to the refusal of an application or the revocation of the patent (such as failure to pay registration or renewal fees). The obligation to disclose the origin of biological materials would not impose a new substantive condition: it would help with the determination of patentability and inventorship according to existing applicable rules.

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[28] See, e.g., the wording of the Swiss proposal for a PCT rule incorporating the obligation to disclose origin, in *"Article 27.3(b), The Relationship Between The TRIPS Agreement And The Convention On Biological Diversity, And The Protection Of Traditional Knowledge"*, Communication from Switzerland, IP/C/W/400, 28 May 2003, fn. 5.

[29] Dutfield, Graham (2002), *"Sharing The Benefits Of Biodiversity: Is There A Role The Patent System?"*. Journal of World Intellectual Property, November, p. 21.

[30] *"Article 27.3(b), The Relationship Between The TRIPS Agreement And The Convention On Biological Diversity, And The Protection Of Traditional Knowledge*". Communication from Switzerland", IP/C/W/400, 28 May 2003, fn. 5.

[31] See references above.

[32] See WIPO, *"Draft Technical Study On Disclosure Requirements Related To Genetic Resources And Traditional Knowledge"*, Document prepared by the Secretariat, WIPO/GRTKF/IC/5/10, May 2, 2003, para. 134.

The consequences that may be associated with the failure to comply (including the intentional submission of false information) with a disclosure of origin obligation are controversial. Some proposals suggest that rejection of the application or invalidation of the patent should be the solution. Thus, according to the Swiss submission,

> "based on Article 10 of the PLT, the national patent law may foresee that the validity of a granted patent is affected by a lacking or incorrect declaration of the source, if this is due to "*fraudulent intention*". This could, for example, be the case if the patent applicant submits an intentional wrongful declaration that the source is unknown[33].

For some developing countries, failure to comply should result in the revocation of the patent or in its non-enforceability as determined, for instance, under the doctrine of "inequitable conduct" in the USA[34].

In contrast, the EC and their Member States have held that

> "such a disclosure requirement should not act, *de facto* or *de jure*, as an additional formal or substantial patentability criterion.[35] Failure to disclose, or the submission of false information should not stand in the way of the grant of the patent and should have no effect on the validity of the patent, once it is granted. Legal consequences to the non-respect of the requirement should lie outside the ambit of patent law, such as for example in civil law (claim for compensation) or in administrative law (fee for refusal to submit information to the authorities or for submitting wrong information). Patent law should not be used to sanction non-respect of domestic access and benefit-sharing requirements through the rejection of the patent application or the invalidation of the patent"[36].

Failure to provide information about the origin of biological materials and TK may, like other requirements under patent law, be deemed sufficient ground for refusal of a patent application. In addition, the revocation of a grant would be justified, if it were proven that the invention failed to meet the patentability requirements or the applicant was not the true inventor.

VII. Modification of the TRIPS Agreement

The incorporation of a disclosure of origin obligation would require a modification of the TRIPS Agreement. Article 27.1 lays down the three requirements of patentability (novelty, inventive step, industrial applicability). The obligation to disclose may affect how such requirements are applied in a particular case, but would not create a new patentability requirement. A possible modification may be considered in the context of article 29 of the Agreement. According to the African Group,

> "compared to other alternatives, Article 29 of the TRIPS Agreement seems to be the most suitable for an appropriate modification to contain these rights and obligations, by including the requirements for equity, disclosure of the community of origin of the genetic resources

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[33] *"Article 27.3(b), The Relationship Between The TRIPS Agreement And The Convention On Biological Diversity, And The Protection Of Traditional Knowledge"*, communication from Switzerland, IP/C/W/400, 28 May 2003, para.8.

[34] *"The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge"*, submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/403, June 24, 2003, para. 14.

[35] Except in those cases where the disclosure of the geographical origin of the genetic resource is already required under Article 29 TRIPS.

[36] *"Review Of Article 27.3(b) Of The TRIPS Agreement, And The Relationship Between The TRIPS Agreement And The Convention On Biological Diversity (CBD) And The Protection Of Traditional Knowledge And Folklore. A Concept Paper"*, Communication from the European Communities and their Member States, IP/C/W/383, 17 October 2002, para. 55.

> and traditional knowledge, and a demonstration of compliance with applicable domestic procedures"[37].

VIII. Information

It would be worthwhile to explore how the information about origin of biological resources included in patent applications may be fully and promptly communicated to countries interested in monitoring possible appropriation and commercial use of their resources.

The Swiss submission has noted, in this regard, that the obligation to disclose the origin, conceived as a transparency measure,

> "could be further strengthened by establishing a list of government agencies competent to obtain information about patent applications containing a declaration of the source of genetic resources and/or traditional knowledge. For easy reference, this list could be made accessible on the Internet. Patent offices receiving patent applications containing such declaration could inform the competent government agency that the respective State is declared as the source. This information could be provided in a standardized letter sent to the competent government agency[38].

IX. Consistency with article 62.1

According to Article 62.1 of the TRIPS Agreement,

> "Members may require, as a condition of the acquisition or maintenance of intellectual property rights ... compliance with reasonable procedures and formalities".

The establishment of a mandatory obligation to disclose the information known to the applicant, or that he/she has reason to know, about the country providing the biological material and associated TK, would seem to be a "reasonable" requirement under article 62.1[39], given the legitimate objectives pursued and the fact that it would not impose a cumbersome or intolerable burden on applicants.

X. Conclusion

As a matter of principle, a patent should not be granted to a person who has not made an "inventive contribution" to the available pool of knowledge. The disclosure of origin obligation would permit to obtain information necessary to better apply the existing requirements relating to patentability and entitlement.

The incorporation of such an obligation may also constitute an important step for the implementation of the principles and obligations under the CBD, having in view the special status of PGRFA as provided for under the ITPGRFA. It may, in particular, help to curb the misappropriation of genetic resources and associated TK and facilitate the equitable sharing of benefits arising from their commercial exploitation.

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[37] *"Taking Forward The Review Of Article 27.3(b) Of The TRIPS Agreement"*. Joint communication from the African Group, IP/C/W/404, June 26, 2003, para. III (D).

[38] *"Article 27.3(b), The Relationship Between The TRIPS Agreement And The Convention On Biological Diversity, And The Protection Of Traditional Knowledge"*, communication from Switzerland, IP/C/W/400, 28 May 2003, para 11.

[39] "Reasonable" means "in accordance with reason, not absurd; within the limits of reason; tolerable, fair". *The Concise Oxford Dictionary*, 1988, p. 863.