

FRIENDS WORLD COMMITTEE FOR CONSULTATION (QUAKERS)
www.geneva.quno.info



Quaker United Nations Office

13 Avenue du Mervelet
CH-1209 Geneva, Switzerland

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

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The Politics and Practicalities of a Disclosure of Origin Obligation

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*

I. The Politics And Practicalities Of A Disclosure Of Origin Obligation¹

Carlos M. Correa

Developing countries are actively pursuing, in different fora, the recognition of an obligation to disclose the origin of biological resources and the associated traditional knowledge (TK) claimed in patent applications. While some countries (e.g. Andean Community members, Brazil, Costa Rica and India) impose such an obligation at the national level, its effectiveness will be limited in the absence of an *international* rule that sets the terms of the obligation and the consequences of failure to comply with it.

This paper examines some issues that may influence the establishment of an internationally binding disclosure of origin obligation, and suggests possible strategies to achieve the developing countries' objective. To this end, it addresses a number of political and practical questions that seem relevant.

1. Is the objective of developing countries clear enough?

In various submissions to the Council for TRIPS² and other declarations³, developing countries have stated their objectives in seeking a disclosure of origin obligation, namely

-- to prevent misappropriation of genetic resources and TK; and

-- to ensure compliance with prior informed consent and benefit sharing obligations, where applicable.

Although some developed countries (notably the USA) are opposed to the recognition of any disclosure of origin obligation (see below), others (notably the European Communities and their member States) are sympathetic to the concept, while they disagree about the consequences of non-compliance on the validity/enforceability of the relevant patent.

Developing countries seek a mandatory international requirement for the disclosure of origin of biological resources and/ or traditional knowledge claimed in a patent application, as one

¹ This paper is based on the presentation made by the author and subsequent discussions at the Seminar "A development agenda in a world of TRIPS-plus pressures", QUNO-QIAP-ICTSD Jongny-sur-vevey, Switzerland 3-5 September, 2004

² See Communication from India. IP/C/W/195, 12 July 2000; "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; "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; "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; "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; "Elements of the obligation to disclose the source and country of origin of biological resources and/or traditional knowledge used in an invention", submission from Brazil, India, Pakistan, Peru, Thailand, and Venezuela, IP/C/W/429 of September 21, 2004.

³ See, e.g., Declaration of like-minded Megadiverse countries (Cancun, 18 February 2002), para. h), www.megadiverse.com/armado_ingles/PDF/three/three1.pdf

of the mechanisms that may help to attain the objectives mentioned above. They are fully conscious that, given the territoriality of the intellectual property system, the establishment of a disclosure obligation at the national level only will not cover foreign applications, particularly in developed countries, where the rich markets are located.

Is the justification clear?

The need to introduce a disclosure of origin obligation has been justified in several submissions made by developing countries and in the literature on the matter⁴ both:

(1) within the patent system

- to improve examination; and,
- to determine inventorship;

(2) outside the patent system

- to ensure compliance with prior informed consent (PIC) requirements; and,
- to promote effective benefit sharing (BS) arrangements.

In September 2004, a group of developing countries explained the arguments justifying the disclosure of origin obligation within the patent system as follows:

“...a legally binding obligation to disclose the source and country of origin of biological resources and/or traditional knowledge used in inventions will guide the patent examiners in ensuring that all relevant prior art information is available to the patent examiners. Disclosure will also be relevant in helping patent examiners determine whether the claimed invention constitutes an invention that is excluded from patentability under Article 27 paragraphs 2 and 3 of the TRIPS Agreement. Further, disclosure would serve as part of a process to systematise available information of biological resources and traditional knowledge that will continuously build the prior art information available to patent examiners and the general public.

In addition to matters relating prior art, patentability and exclusions to patentability, the disclosure requirements will also be useful in cases relating to challenges to patent grants or disputes on inventorship or entitlement to a claimed invention as well as infringement cases. It has already been shown in the TRIPS Council that patent challenges involve a great cost in terms of time and resources, and are not a suitable option for developing countries. Patent grant challenges, cases on inventorship or entitlement as well as infringement cases form an important component of processes that ensure patent quality. In this regard, it is noteworthy that disclosure requirements of various types are already an accepted norm in international patent law practice.”⁵

In addition, the proposed obligation may contribute to make the Convention on Biological Diversity (CBD) principles effective, particularly in relation to the PIC and BS, where applicable. The role that this obligation may play in the context of the CBD has been widely recognized by the Conference of the Parties (COP) (see below).

Quite clearly, however, the disclosure obligation should only be seen as one of the elements of the system to prevent misappropriation that developing countries wish to build up. Even if complied with, such an obligation would not prevent misappropriation from taking place. For example, in the case of a US plant patent on *ayahuasca*, the applicant revealed that he had

⁴ See, e.g., Correa, Carlos ‘Establishing a Disclosure of Origin Obligation in the TRIPS Agreement’, *Occasional Paper No. 12*, QUNO, Geneva, 2003.

⁵ See, e.g., ‘Elements of the obligation to disclose the source and country of origin of biological resources and/or traditional knowledge used in an invention’, submission from Brazil, India, Pakistan, Peru, Thailand, and Venezuela, IP/C/W/429 of September 21, 2004, para. 4-5.

found the claimed variety in a private garden in Amazonia – so he had disclosed its source. The patent was challenged unsuccessfully but, under the plant patent regime of the USA, a patent on a material found in nature is deemed valid.

In yet another well-known case, the applicant for a US patent on yellow bean disclosed that the beans had been obtained from Mexico, so he did disclose the origin of the claimed material and the US Patent and Trademark Office granted it. In the case of the *hoodia* plant, the assumption was that scientists went to the Kalahari desert and obtained it from the San people. But there was published literature on the appetite-suppressing function of the plant.⁶ Similarly, in the case of the more than 100 patents relating to the *neem* tree, which grows in many countries that have done scientific research on its traditional uses, it is not clear if the information was acquired from any particular country.

Another issue is what capacity developing countries have to effectively monitor published applications/patents to determine whether materials under their jurisdiction have been misappropriated. Non-governmental organizations have helped in tracking patents over genetic resources, but it is uncertain the extent to which they may continue to do so. Most importantly, if a wrongly granted patent is found, who will be able to initiate invalidation procedures? They can be extremely costly, particularly in countries without pre-grant opposition procedures, where plaintiffs need to go to court or object to the patent in post-grant procedures with the patent office⁷.

These considerations do not deny the importance of establishing a binding disclosure obligation, but suggest that there are other elements that need to be taken into account in an effective misappropriation regime. One of them could be the clarification under the TRIPS Agreement that patents may not be granted on materials found in nature. Interestingly, in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which recently entered into force, there is a provision prohibiting claims of intellectual or other property rights over materials (or their parts or components) obtained from the Multilateral System established by the Treaty, “in the form received”.⁸

Another component of a misappropriation regime would be a novelty requirement that is truly universal, unlike the one applied in the USA and a few other countries, whereunder a non-written disclosure outside the USA does not destroy novelty.

Have practical issues been clarified?

The development of an international requirement for disclosure of origin, as discussed above, makes it necessary to address a number of practical issues, such as

⁶ See Wynberg, Rachel (2004), 'Rhetoric, Realism and Benefit-Sharing: Use of Traditional Knowledge of *Hoodia* Species in the Development of an Appetite-Suppressing Drug', *The Journal of World Intellectual Property*, vol. 7, No. 6, November.

⁷ The patent litigation costs in the USA normally run from \$1 million to \$3 million, while the cost of re-examination procedures before the U.S Patent and Trade Mark Office is between \$10,000 and \$100,000. Only in 10% of re-examination procedures patents are revoked in full. In Europe, litigation costs are between €50,000 and €500,000, and post-grant procedures before the European Patent Office cost between €15,000 and €25,000 per patent (around 35% of patents are revoked in these procedures). See Graham, S., Bronwyn, H., Harhoff, D., and Mowery, D. (2001), “Patent quality control: a comparison of U.S. patent re-examinations and European patent oppositions”, in National Research Council, Patents in the knowledge-based economy, The National Academy Press, Washington D.C..

⁸ Article 12.3 (d) stipulates that “Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System”.

- the concept of biological materials/genetic resources and associated traditional knowledge;
- the relationship between the claimed invention and the relevant biological material/s;
- the content of the obligation (e.g. to declare or prove the origin?);
- the role of patent offices (should they only file the information received or also check its veracity? Should they cooperate with other patent offices/institutions?);
- whether the requirement would apply to both pre- and post-CBD materials.

Although these issues can be reasonably solved, they are complex and may give rise to considerable debate, which, in turn, may delay the adoption of a solution in the context of the TRIPS Agreement and the treaties administered by WIPO. A checklist submitted by a number of developing countries to the Council for TRIPS identifies some of these issues,⁹ which were elaborated in a subsequent submission.¹⁰ A further clarification of the options available to deal with these (and other) technical issues may be required to speed up the negotiating process and ensure coherence in different fora .

Is the requirement consistent with the TRIPS Agreement?

Some concerns have been raised about the extent to which an obligation to disclose the origin of biological materials would be consistent with the TRIPS Agreement, in particular with article 27.1.

One argument is that this obligation would introduce an *additional* requirement of patentability, in addition to novelty, inventive step (non-obviousness) and industrial applicability (utility), thereby violating the first part of this provision. Another argument is that it will discriminate with regard to the enjoyment of patent rights, in a manner contrary to the last part of article 27.1.

The obligation to disclose the origin of biological materials is *not* a patentability requirement. It is a component of the disclosure requirement that, in the case of the TRIPS Agreement, is established in article 29. The introduction of the proposed disclosure obligation via an amendment of this article will not be inconsistent with any other provision of the Agreement.

Establishing such obligation, on the other hand, will not discriminate in the enjoyment of patent rights in a manner inconsistent with article 27.1. As noted by the WTO panel in *Canada – Patent Protection for Pharmaceutical Products*, ‘discrimination’ is not the same as ‘differentiation’. Moreover, WTO members can adopt different rules for particular product areas, provided that the differences are adopted for *bona fide* purposes. The panel held that:

Article 27 prohibits only discrimination as the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit *bona fide* exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in

⁹ See IP/C/W/ 420 and IP/C/W/420 Add. 1.

¹⁰ “Elements of the obligation to disclose the source and country of origin of biological resources and/or traditional knowledge used in an invention”, submission from Brazil, India, Pakistan, Peru, Thailand, and Venezuela, IP/C/W/429 of September 21, 2004, para. 4-5.

dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than frustration of purpose.¹¹

Is there coherence in different fora?

The possible adoption of a disclosure of origin obligation has been addressed in different international fora.

WTO

Developing countries have insisted on the need to reconcile the TRIPS Agreement with the Convention on Biological Diversity (CBD), and to implement, at the international level, a disclosure of origin obligation as one important mechanism for that purpose. As mentioned, several submissions were made on this issue at the Council for TRIPS. The European Communities and their member States have shown sympathy for the idea, provided that non-compliance with the requirement does not affect the validity or enforceability of the granted patent.¹² Switzerland has proposed to incorporate a provision to the same effect as a non-mandatory requirement for patent applications in the Regulations of the Patent Cooperation Treaty (PCT).¹³

The recognition of the disclosure of origin obligation through an amendment to the TRIPS Agreement may be one of the outcomes of the current Millennium Round of trade negotiations. One important concern, however, is that developed countries are likely to require a price to be paid to accept that amendment, in terms of concessions in other fields, within the TRIPS arena or elsewhere. No clear assessment has been made so far about the 'trade value' of a disclosure of origin obligation. As mentioned before, however, it may be realistically not too high. Moreover, the establishment of such an obligation cannot be seen as an advantage conferred on some countries, but as a measure against abuses, grounded not only on economic but also on ethical considerations. No price should be paid for the adoption of a measure that is required to implement accepted principles of international law, as contained in the CBD, which aim at ensuring good faith, transparency and equity in transactions involving genetic resources and associated TK.

WIPO

The debate about a disclosure of origin obligation was one of the key determinants for the establishment, by WIPO's General Assembly in 2000, of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGCGRTKF). The Committee's mandate includes access to genetic resources and benefit sharing, protection of TK and protection of expressions of folklore. While some technical studies have addressed this issue, no progress has been made so far towards the effective implementation of the disclosure obligation.

Some developing countries suggested the inclusion of a provision implementing this obligation into the draft Substantive Patent Law Treaty.¹⁴ Switzerland, as noted, and the

¹¹ WT/DS 114/R, para. 7.92.

¹² See '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.

¹³ See WTO document IP/C/W/400, 28 May 2003.

¹⁴ See WIPO document SCP/9/8 Prov. para. 68-70 and 78.

European Communities are willing to accept such requirement (albeit in a different form) in the context of the Patent Cooperation Treaty.¹⁵

CBD

The need to establish a disclosure of origin obligation was addressed by the Panel of Experts on Access to Genetic Resources and Benefit Sharing¹⁶, by the Ad Hoc Open-ended Working Group on Access and Benefit-sharing¹⁷, and by the 6th Conference of the Parties, which invited Parties and Governments to encourage the disclosure of the country of origin of the genetic resources and traditional knowledge in applications for intellectual property rights, where the subject matter of the applications concerns or makes use of genetic resources or such knowledge in its development, as a possible contribution to tracking compliance with PIC and the mutually agreed terms on which access to those resources and knowledge was granted.¹⁸ The 7th Conference of the Parties invited WIPO to “examine and where appropriate address”, *inter alia*, options for model provisions for the establishment of that obligation. This request for model provisions seems to overlook that developing countries’ aim, as mentioned, goes beyond the development of optional models. It may not be “appropriate” for WIPO to consider such options, but rather concentrate in drafting general binding rules. The CBD invitation also requested WIPO to explore the possible role of certificates of origin, which would indicate whether the supplier of biological materials has complied with applicable access and benefit sharing provisions. Whatever the merits of the proposal to establish such certificates could be,¹⁹ the development of this concept is likely to take considerable time and it may divert attention and efforts away from that required to achieve concrete and more immediate results in relation to the disclosure of origin obligation.

UPOV

The disclosure of origin obligation is relevant not only to patents, but also in the field of plant varieties protection (PVP). The issue was addressed by UPOV’s Council on the following terms: "UPOV encourages information on the origin of the plant material, used in the breeding of the variety, to be provided where this facilitates the examination [for distinctness], but could not accept this as an additional condition of protection ... Indeed, in certain cases, for technical reasons, applicants may find it difficult, or impossible, to identify the exact geographic origin of the material used for breeding purposes". Equally "UPOV encourages the principles of transparency and ethical behaviour ..."²⁰

Article 5 of the UPOV 1991 Convention provides that “[T]he grant of the breeder's right shall not be subject to any further or different conditions, provided that the variety is designated by a denomination in accordance with the provisions of article 20, that the applicant complies

¹⁵ See WTO document IP/C/W/400, 28 May 2003.

¹⁶ See Report of the Panel of Experts on Access and Benefit-sharing, document UNEP/CBD/COP/5/8, paragraph 127, 2 November 1999.

¹⁷ See Recommendations adopted by the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, document UNEP/CBD/COP/6/6, Annex (31 October 2001).

I. ¹⁸ SEE REPORT OF THE SIXTH COP, DOCUMENT UNEP/CBD/COP/6/20, PAGE 274 (27 MAY 2002). SEE ALSO SOUTH CENTRE AND CIEL, CBD REQUEST TO WIPO ON THE INTERRELATION OF ACCESS TO GENETIC RESOURCES AND DISCLOSURE REQUIREMENTS. ESTABLISHING AN ADEQUATE FRAMEWORK FOR A WIPO RESPONSE, BACKGROUND NOTE, DECEMBER 2004.

¹⁹ A ‘certificate of origin’ might fulfill some of the functions to be performed by the disclosure of origin obligation. However, the content, effects and mechanics of such a certificate have not been clarified so far Their possible role was examined at a UNU/IAS Roundtable held in Yokohama, 22 July 2004.

²⁰ See UPOV C/37/21, ANNEX III.

with the formalities provided for by the law of the Contracting Party with whose authority the application has been filed and that he pays the required fees”.

As in the case of patents, however, the disclosure of origin obligation would not constitute an additional condition of protection, but a component of the obligation to provide information necessary to examine a PVP application that may be required by the law of a Contracting Party.

Free Trade Agreements (FTAs)

The FTAs entered into between the USA and several developing countries (e.g. Chile, Central American countries and Dominican Republic, Morocco) do not specifically refer to the disclosure of origin obligation. Moreover, provisions incorporated in such agreements that limit the grounds for revocation/forfeiture of patents would seem to exclude the possibility of revoking a patent in case of non-compliance with a disclosure obligation if it were imposed by the national law. Although not all FTAs include identical provisions on this matter, and some are more restrictive than others, they could undermine any action to obtain the recognition of a disclosure obligation internationally.

The language used in some FTAs allowing for revocation or cancellation of a patent in cases of “fraud, misrepresentation, or inequitable conduct” (e.g. CAFTA article 15.9.4) is not a substitute for an express disclosure of origin obligation, since to the extent that such disclosure is not established as a legal requirement, no fraud, misrepresentation, or inequitable conduct could be invoked, unless such conduct is also inconsistent with the general obligation to disclose imposed under patent law (for instance, when the applicant falsely claims inventorship with regard to knowledge that is found to have been acquired from an indigenous community).

Is there political support?

The developments described above indicate that developing countries have succeeded in introducing this issue in international fora and that the concept of establishing a disclosure obligation (though not necessarily its implementation) is gaining growing acceptance. The statement by the UPOV Council and the terms of the CBD invitation to WIPO (which omits a reference to the possible establishment of an international obligation) suggest, however, that coherence in actions undertaken in different fora should be improved.

Developing countries seem considerably united in their quest for a disclosure of origin obligation or, at least, there are no open divergences among them. As mentioned above, they have been successful in convincing some developed countries (notably the European Communities and Switzerland) about the justification of a disclosure obligation, though outstanding differences remain about the possible ways of implementing it.

The USA, however, objects to the disclosure obligation on a number of grounds. It argues that²¹:

- disclosure will not prevent misappropriation, but create uncertainty about patent rights;

²¹ Based on a presentation by Karen Hauda from the U.S. Patent and TradeMark Office at the “Global Biotechnology Forum”, UNIDO, Concepcion (Chile), March 2-5, 2004. See also the U.S. submission to the Council for TRIPS “Article 27.3(b), relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore” (IP/C/W/434, November 26, 2004), where essentially the same arguments are elaborated.

- it is unclear how much disclosure will be required, who determines if it is proper, and how derivative material is treated.

The USA further sustains that a solution to the problem raised by developing countries can be found under national law, by means such as :

- collection permits;
- contractual arrangements;
- unfair competition rules;
- civil/criminal penalties;
- databases;
- post-grant examination;
- harmonization of patent law.

Other developed countries are skeptical about the merits of a disclosure obligation as a means to achieve its intended objectives, as it would not ensure compliance with CBD principles and may find opposition from some industries. However, in practice, patent applicants normally disclose the source of biological materials on which the patent claims are based upon.²²

While developing countries have a strong case for promoting a disclosure of origin obligation, an apparent limitation is that only a few of them (namely Brazil, Costa Rica, India, Andean Communities countries) have established an obligation of that kind at the national level. One reason for this, however, is that the provisions in national laws would be largely ineffective in the absence of an internationally binding obligation

An important issue to explore is who is in fact interested and can actively lobby for the incorporation of a disclosure obligation at the national level. Is it indigenous communities, is it NGOs, or is it something the governments will have to push for on their own? Unlike other areas of intellectual property law, where business actors are influential, there are no clear constituencies at the national level acting with the same level of organization, resources and perseverance to obtain the recognition of a disclosure obligation.

Towards a comprehensive strategy

In developing a political strategy towards the establishment of an international mandatory disclosure of origin obligation, consideration should be given to different aspects that may influence the outcome, such as:

- Should negotiations be held sequentially or in parallel in different fora?
As mentioned above, the obligation may be incorporated not only in the TRIPS Agreement, but also in WIPO-administered treaties, as appropriate.
- How should work be conducted within WIPO?
Priority should be given to work in the framework of the PCT and in the Standing Committee on Patents. A pending task for developing countries seems to be the preparation of a proposal for the PCT.

²² See, e.g., CBD Secretariat, 'La Convention sur la Biodiversité Biologique et l'Accord sur les droits de propriété intellectuelle liés au commerce (TRIPS) : relations et synergies', UNEP/CBD/COP/3/23, 5 Octobre 1996.

- What other actions will be necessary?

As mentioned above, the implementation of a disclosure of origin obligation should be seen as one component of a broader misappropriation regime. Other elements of such a regime should be elaborated and discussions thereon pursued. It should be clear that if developing countries were successful in obtaining the recognition of the disclosure obligation, they would have won an important battle, but in no way established mechanisms that will effectively prevent misappropriation and ensure benefit sharing.

Main conclusions

Developing countries should continue to simultaneously pursue the recognition of an international disclosure of origin obligation in different fora. In the case of WIPO, the issue should be consistently raised in all relevant discussions and negotiations, such as at the IGCGRTKF, the Standing Committee on Patents and in the context of the PCT reform. In view of the Swiss proposal for amending the PCT regulations, developing countries should eventually submit their own proposal for a PCT reform that reflects their interests and objectives.

WTO should remain the main forum for negotiation on this matter. An amendment to Article 29 of the TRIPS Agreement, if reached, would ensure that an almost universal, mandatory minimum standard become applicable. But developing countries should be careful about demands of ‘payment’ for a concession in this field.

An international disclosure of origin obligation is *one* component of a broader misappropriation regime that need to be put in place in order to reconcile the TRIPS Agreement with the CBD. The recognition of such an obligation should be seen as a first step, but not as a definitive solution to the problems arising from misappropriation of genetic resources and TK.