

ADDRESSING THE DISCLOSURE REQUIREMENT AT THE INTERNATIONAL LEVEL - THE ROLE OF THE TRIPS AGREEMENT

Need for international recognition of disclosure requirements

An overview of the patent system may help to understand why the international recognition of disclosure requirements is necessary.

The patent system's objective is to encourage research and innovation. Is this happening? Some patents are good examples of how research and innovation are being encouraged and of how important it is to encourage this kind of research and innovation. Unfortunately, other patents are good examples of what should not be encouraged.

The patent system works only if exclusive rights are granted to inventions that comply with certain requirements. There is no valid reason to grant exclusive rights to someone who has made no contribution at all (lack of novelty) or whose contribution doesn't deserve such a reward (lack of inventive step). In other words, the patent system does not work if patents are granted to inventions that are not new, do not involve an inventive step or do not comply with other requirements.

Moreover, the patent system works only if there is a balance and if the rights of all those who have made an invention possible are recognized. The patent system doesn't work (at least not as it should) if it only recognizes the rights of those who have reached an invention by using the inputs provided by others and infringing their rights. In other words, the patent system does not work if it is used to validate misappropriation and to encourage no matter what kind of research or innovation.

It is urgent to rethink the patent system and how to rebalance it. Including disclosure requirements in an international instrument such as the Treaty on Trade related aspects of Intellectual Property Rights (TRIPS) Agreement would certainly help to solve these problems and to make the patent system healthier.

The current intellectual property (IP) system does little to ensure fair and equitable sharing of benefits derived from the use of genetic resources. Two examples of patents granted in the US to inventions related to Maca (*Lepidium meyenii*) and uña de gato (*Uncaria tomentosa*) show why international disclosure requirements are necessary in order to prevent use of the IP system to validate misappropriation of biological resources and traditional knowledge (TK).

Example 1: Patents related to Maca (*lepidium meyenii*)

US patents 6,267,995 (extract of *lepidium meyenii* roots for pharmaceutical applications) and 6,428,824 (treatment of sexual dysfunction with an extract of *lepidium meyenii* roots)¹, exploit the

¹ Patent applications for related inventions were also filed through the patent cooperation treaty (PCT) system. For additional information, see:

biochemical characteristics of Maca, a plant that has been grown for centuries in the mountains of Peru. It has been traditionally used by ancient Peruvians for fertility purposes, as an aphrodisiac, and to treat frigidity in women and impotence in men.

Using a purified extract of Maca roots, the inventors confirmed the traditional use of Maca as an aphrodisiac and filed patent applications in the US for:

- An isolated composition obtained by extracting *lepidium meyenii* roots;
 - A method of treating sexual dysfunction in an animal through the use of an isolated composition derived from an aqueous solvent extract of *lepidium meyenii* root.
- ... among other inventions.

Prior art found by a working group created in Peru to examine these patents shows that these *inventions* are not new or do not involve an inventive step.

Moreover, the Maca roots that were used for these *inventions* were taken from Peru² and there is no evidence that such material was obtained legally or that some kind of benefit sharing would have been contemplated by the holders of these patents. The granting of these patents therefore runs counter to one of the three main objectives of the convention on biological diversity (CBD), which is the “fair and equitable sharing of the benefits arising out of the utilization of genetic resources”³.

Example 2: Patents related to Uña de Gato (*uncaria tomentosa*)

US patent 4,844,901 (oxindole alkaloids having properties stimulating the immunologic system)⁴ relates to a preparation containing an extract from root parts of the *uncaria tomentosa* (willd.) Dc.

This patent claims:

- “1. A method for stimulating the immunological system comprising:
Providing oxindole alkaloids from the extract of the root of *uncaria tomentosa* (willd.),
administering the extract to a subject, and measuring the rate of increase in the
phagocytosis activation in the subject.
2. The method according to claim 1 wherein the rate of increase in the phagocytosis
activation in the subject is between 30-40% as a result of administering the extract.”

Native Peruvians have been using this plant against tumors and inflammations for years. Klaus Keplinger, one of the inventors mentioned in the patent and the assignee of the patent, was probably

Document WIPO/GRTKF/IC/5/13 “Patents referring to *Lepidium meyenii* (Maca): Responses of Peru”, submitted by the Delegation of Peru to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore on its 5th session and

Venero Aguirre, Begoña. Les connaissances traditionnelles et les brevets relatifs au *Lepidium meyenii*: un exemple à ne pas suivre; 2003. In Le Courrier ACP-UE, N° 201, November-December 2003.

² See:

Zheng, b., He, k., Kim, c., Rogers, l., Shao, y., Huang, z., Lu, y., Yan, s., Gien, l. Y Zheng, q. Effect of a lipidic extract from *lepidium meyenii* on sexual behavior in mice and rats. In Urology 55 (4).

³ CBD, Article 1.

⁴ For additional information, see:

Venero Aguirre, Begoña. Mitos y verdades sobre la biopiratería y la propiedad intelectual. In Anuario Andino de Derechos Intelectuales, Año I, N° 1, Lima, January 2005.

guided in his research by this TK. However, it seems clear that he discovered something new and inventive: that this plant could also be used for stimulating the immunological system.

Keplinger's contribution deserves some kind of acknowledgement or compensation, such as the one provided by the patent system. However, if we consider that Keplinger would not have been able to develop his invention if he had not been guided by the TK of native Peruvians, it is obvious that the contribution of the native Peruvians who developed and preserved that TK also deserves some kind of acknowledgement or compensation.

When faced with patent claims of this nature, the inadequacy of the current IP system becomes apparent. If we take the first example, it is clear that the patent system was not created to grant exclusive rights to inventions that are not new and do not involve an inventive step. If we take the second example, even though the patentability requirements are apparently fulfilled, there is still a problem: the contribution of the inventor is acknowledged and recognized but the contribution of the indigenous peoples that guided him in his research is not.

What should be done to prevent these patents from being granted? National measures may help to prevent misappropriation in some cases, but international measures are needed and cannot be replaced by national measures.

Misappropriation measures have been adopted by the Andean community countries through decision 391 and decision 486. However, they are useless when the misappropriation occurs in countries outside the Andean community which do not have misappropriation provisions in their legislation. Peru has gone even further: a working group was convened to examine the patents granted and applications filed for inventions related to Maca, and a national anti-biopiracy commission was recently created. However, so far their experience has shown that challenging patents such as those described above is not an easy task. Despite the efforts of the working group (since July 2002) and the national commission (since August 2004), no results have been obtained yet. Furthermore, challenging patents granted to invention that are new and involve an inventive step, such as Keplinger's on *uncaria tomentosa* root, would be even more difficult and perhaps impossible.

Developing a *sui generis* system to protect TK or adopting provisions to regulate access to genetic resources may and shall be done by countries that choose to do so at a national level⁵. However, the experience of Andean community countries shows that these national measures must be complemented by international measures such as disclosure requirements in order to be effective.

Role of different international fora

Several international fora conduct discussions and activities on disclosure requirements.

The CBD's ad hoc open-ended working group on access and benefit sharing, ad hoc open-ended working group on article 8 j), and conference of the parties have pushed WIPO and even the WTO to take into account issues such as protection of TK and access to genetic resources that were not originally linked to the IP system.

⁵ In doing so, they should establish clear and reasonable rules. They should take into account that those interested in their resources or in the traditional knowledge of their indigenous peoples have more than one choice, most of the time. They can go to another country that has laws not that hard to comply with.

In addition, WIPO's intergovernmental committee on intellectual property and genetic resources, traditional knowledge and folklore has contributed enormously to the understanding of TK protection and access to genetic resources from an IP perspective. It has produced very comprehensive documents that were necessary to move forward.

Moreover, progress that may be reached in other fora such as WIPO's working group on reform of the PCT should not be neglected. The PCT system applies to 126 countries and may have important practical implications.

However, the WTO remains the most relevant forum for discussion of disclosure requirements, and the inclusion of disclosure requirements in the TRIPS Agreement is vital. Although the progress achieved in different international fora such as WIPO and CBD should not be overlooked, and these organizations may continue to deal with these issues, such discussions should not be taken as an excuse not to move forward in the WTO context.

As a matter of fact, even if there was a negotiating mandate in WIPO, developed countries may choose not to be members of that particular instrument and the objective of making the disclosure requirements mandatory at an international level would not be achieved. This is a choice they wouldn't have in the WTO context. If the TRIPS Agreement was modified in order to include mandatory disclosure requirements, this would reach all its members.

Additionally, if we consider that the TRIPS Agreement needs to be rebalanced, it is clear that this *can only be done* through a modification of the TRIPS Agreement itself.

Nature, format, and elements of disclosure requirements in the TRIPS agreement

Much has been written about the disclosure requirements that should be included in the TRIPS Agreement⁶. However:

- No consensus has been reached about whether these requirements would take the form of simple formalities, an additional requirement of patentability, a component of the disclosure requirement or an additional substantive condition on entitlement to apply for patent rights;
- No consensus has been reached about whether these requirements should be mandatory or facultative, or about what the consequences of non-compliance with these requirements should be (for example, denial or rejection of the application, invalidation or revocation of the patent, unenforceability of the patent);
- No consensus has been reached either about how these requirements should be discharged (via a statement, submission of evidence, submission of a certificate of origin), about how far the

⁶ See:

Correa, Carlos. Establishing a Disclosure of Origin Obligation in the TRIPS Agreement. Occasional Paper No. 12, QUNO, Geneva, 2003.

Correa, Carlos. The Politics & Practicalities of a Disclosure of Origin Obligation. In South Bulletin 97/98, February 2005.

Sarnoff, Joshua. Compatibility with existing international intellectual property agreements of requirements for patent applicants to disclose origins of genetic resources and traditional knowledge and evidence of legal access and benefit sharing, available in PIIPA's website (www.piipa.org).

Commission on Intellectual Property Rights. Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, February 2003.

applicant of a patent should go in order to comply with these requirements, or about how far the patent office should go in order to verify the compliance of these requirements;

- Last but not least, no consensus has been reached about what is meant by disclosure requirements, about the terms that should be used to define these disclosure requirements, or in which cases these requirements should apply (inventions directly based on biological resources or TK, inventions developed using biological resources or TK).

Some kind of consensus needs to be reached in order to move forward. The following ideas may contribute to efforts to reach such a consensus:

- These requirements may be considered formal or substantive, but they should be mandatory⁷ and there should be a sanction for non-compliance of these requirements before and after the grant of a patent.
- It would be wise to allow agreements to be reached between the patent applicant or patent holder and the holders of rights on the genetic resources or TK before applying the sanction. This could contribute to a win-win situation.
- Simplicity should be sought when defining how these requirements should be discharged.
- Remaining realistic about what a patent office may really be capable of doing in order to verify the compliance of these requirements would be advisable.
- Clear rules about when these requirements apply (the relationship between the invention and the resource or knowledge) and about what is required (disclosure of the country of origin or of the source or both? and so on) is of the utmost importance.
- A careful analysis of how far to go when establishing the disclosure requirements is needed. It will be necessary to draw a line at some point if we want to reach a consensus.

Next steps towards introducing disclosure requirements and a misappropriation regime in the TRIPS agreement

First, the checklist of issues submitted to the WTO by Brazil, Cuba, India and Peru, among others, and the submissions that followed⁸ are a good example of the kind of documents that are needed to move forward in discussions about disclosure.

A new submission with concrete proposals that take into account reactions of developed countries to the checklist and the submissions that followed would be extremely useful, especially if it was endorsed by the highest number of developing countries as possible.

Second, more practical examples of misappropriation would be useful to understand why the disclosure requirements should be introduced in the TRIPS Agreement and how. For example, the delegation of Peru intends to submit a new document about the problems the national anti-biopiracy commission continues to face in its attempt to fight biopiracy.

Third, many arguments have been provided to justify the inclusion of disclosure requirements in the TRIPS Agreement. However, one argument that should be stressed is that it would benefit the IP system itself. It is clear that the IP system was not created with the aim of regulating access to genetic resources or protecting TK. However, the IP system can collaborate with the access to

⁷ Facultative requirements would probably be as useful as not having any disclosure requirements at all at an international level.

⁸ See: Documents IP/C/W/420, IP/C/W/429, IP/C/W/438 and IP/C/W/442.

genetic resources and TK protection regimes. By doing so, it would legitimize itself and leave without arguments those who attack the IP system because of patents such as the ones mentioned above.

This may help to overcome the endless discussion about whether TRIPS and the CBD are compatible or not. No matter what each delegation thinks about this specific issue, all the delegations may be more open to reach some kind of consensus about how to make the IP system fairer and therefore stronger.

Fourth, considering that in the framework of the mandate contained in paragraph 19 of the Doha declaration the relationship between the TRIPS Agreement and the CBD has been examined, it is time to move on and go to the next level. This should be the aim of obtaining, in the Hong Kong ministerial meeting, a specific and clear negotiating mandate to modify the TRIPS Agreement in order to include mandatory disclosure requirements.

Fifth, careful consideration should be given as to where will be the best place to introduce these requirements. One of the options that could be contemplated would be to include a new paragraph in article 27 (27.4) and a third paragraph in article 29 (29.3). The disclosure of evidence of prior informed consent and benefit sharing requirements could be included in article 27, bearing in mind that exclusions from patentability are related to inventions that may be new, involve an inventive step and be capable of industrial application but shouldn't be granted patents because of reasons that go beyond the patent system logic itself. On the other hand, article 29 could be the best place to include the disclosure of origin requirement as 29.3

These steps are essential if the international patent regime is to be reformed in a sustainable and fair manner. The current system recognizes only the contribution made by those developing inventions on the basis of biological materials or traditional know-how. However, it is also necessary to recognize the contribution made by countries that supply the biological materials and by the indigenous peoples who supply their traditional knowledge. To fail to recognize the latter contribution makes the recognition of the former unfair and inequitable⁹.

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⁹ Venero Aguirre, Begoña. Les connaissances traditionnelles et les brevets relatifs au *Lepidium meyenii*: un exemple à ne pas suivre; 2003. In *Le Courrier ACP-UE*, N° 201, November-December 2003.