

How to Address the Disclosure Requirement at the International Level

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On the eve of the WTO Ministerial Conference in Hong Kong, developing countries are pushing for a mandate to negotiate a broad international disclosure requirement for genetic resources and traditional knowledge under patent law. The relevant discussions, however, are stalled. Are there any alternatives to an 'all-or-nothing' scenario at Hong Kong?

The discussions on genetic resources and traditional knowledge (TK) have shown a need for measures that increase transparency in access and benefit-sharing. One such measure is the requirement to disclose certain information regarding genetic resources and traditional knowledge in patent applications. The majority of least-developed and developing WTO Members want to amend the WTO's TRIPS Agreement to include an obligation for Members to introduce a broad disclosure requirement in their national laws. In contrast, developed WTO Members either consider the World Intellectual Property Organisation (WIPO) to be the competent forum, or oppose international disclosure obligations altogether. Consequently, there is a continuing impasse at the WTO.¹

An Alternative Way Forward

In order to support the process, and because it has an interest in balanced patent protection for biotechnological inventions, Switzerland – not a *demandeur* on these issues – has presented specific proposals for amendments to international patent legislation.² The proposed amendments to WIPO's Patent Co-operation Treaty (PCT) would explicitly enable the national legislator to require patent applicants to declare the source of genetic resources and the associated TK in patent applications, if the invention is directly based on the resources or knowledge in question. The proposals would also grant applicants the possibility of satisfying this requirement at the time of filing an international patent application, or later during the international phase. This declaration of source would be included in the publication of the international patent application in order to render it accessible to the public at the earliest stage possible.

Additionally, Switzerland has proposed to establish a list of government agencies competent to receive information on patent ap-

plications containing a declaration of source. Patent offices receiving such applications would be obliged to inform, in a standardised letter, the competent government agency that the respective country has been declared as the source, thus further enhancing the transparency function of the disclosure requirement.

The proposals have four policy objectives: They would (1) increase *transparency* in access and benefit-sharing, (2) allow providers of genetic resources and traditional knowledge to *trace* their resources or knowledge in patentable inventions, (3) assist in the establishment of *technical prior art* with regard to inventions relating to genetic resources or traditional knowledge, and (4) increase mutual *trust* among the various stakeholders involved.

Replies to Comments on the Proposals

These proposals have been discussed in a number of international fora, and different opinions have been expressed. Some commentators were concerned that the proposals would:

- make it optional for the national legislator to introduce the disclosure requirement;
- not be reflected in the TRIPS Agreement; and
- not require evidence of prior informed consent (PIC) and benefit-sharing.

When drafting the proposals, these and other points were carefully considered, the aim being a balanced, timely, effective and practical solution.

Optional Introduction at National Level

The *demandeurs* propose to make it *mandatory* for the national legislator to introduce this requirement in national law, one of their main objectives being to target the major players in the field of patents. In contrast, the proposals by Switzerland would *explicitly enable* the national legislator to introduce the disclosure requirement at the national level. When comparing these approaches, the optional approach offers at least three main advantages:

- Much faster international consensus is likely to be achieved on an optional approach, thus making it possible to reach a timely resolution; in contrast, the mandatory approach entails the risk of blocking progress at the international level.
- The optional approach would explicitly enable interested countries to introduce a disclosure requirement in their national legislation, and would allow them and the international community to gain experience without prejudice to further international efforts. This would be particularly useful for those countries that have a positive attitude towards disclosure requirements.
- The optional approach would not oblige developing countries, especially the least-developed among them, to introduce the requirement in their national laws. This takes into account the difficulties these countries might face with such an obligation, since their patent authorities are likely to lack the necessary legal and technical capacity to apply the requirement in practice. It appears, however, that many developing countries are not fully aware of the new obligations that a mandatory approach would place upon them.

In this regard, proposals have been made to oblige only industrialised countries to introduce a disclosure requirement in their national laws. Any such solution, however, would unduly open the door for abusing this measure and would thus weaken its effectiveness. Furthermore, this solution would hardly be acceptable to industrialised countries.

It is also important to note that many European countries have already introduced a disclosure requirement in their national legislation or plan to do so. For example, the draft revised Swiss patent law to be submitted to Parliament in 2005 contains provisions in this regard.³ In addition, the proposed establishment of a list of competent government agencies and the inclusion of the declaration of the source in the publication of international patent applications would bring results very similar to a mandatory approach.

Once the proposed disclosure requirement is introduced at the national level, it would be *mandatory* for patent applicants to disclose the source, and failure to disclose or wrongful disclosure would carry the sanctions currently allowed for under the PCT and the Patent Law Treaty (PLT), including the refusal of the patent application. Sanctions outside of the patent system could also be imposed, including criminal sanctions. The draft revised Swiss patent law, for example, would impose fines of up to CHF 100,000 and allow judges to publish their rulings.

The Role of the TRIPS Agreement

Switzerland proposes to apply the disclosure requirement to international patent applications as well. Its proposals would also afford applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase, and would include this declaration in the publication of international patent applications. Accordingly, Switzerland proposes to amend the PCT. Through reference, the proposals would also apply to the PLT and thus to national and regional patent applications.

In contrast, any amendment of the TRIPS Agreement would *not* apply to international patent applications, and would thus not bring the same results as an amendment of the PCT. Furthermore, since the relevant provisions of the TRIPS Agreement (Articles 27.1, 29.1 and 62.1) should provide for adequate flexibility with regard to a requirement to disclose the source, there is no need to amend the TRIPS Agreement. Moreover, the PCT approach has a considerable advantage of time: amending the PCT Regulations could likely be carried out quickly, whereas amending the TRIPS Agreement would probably require considerable time. This notwithstanding, it may be conceivable to reflect the Swiss proposals in the TRIPS Agreement at a later stage.

Evidence of PIC and Benefit-sharing

In our view, the proposals by Switzerland on the declaration of the source and the establishment of a list of competent government agencies would allow the providers of genetic resources and traditional knowledge to verify whether the applicable national legislation on access and benefit-sharing has been complied with. It is thus not necessary to also require evidence of PIC and of fair and equitable benefit-sharing in patent applications. In addition, such requirements would raise a number of legal and technical concerns, including the following:

- Patent authorities would need easy access to the – likely differing – national legislations on access and benefit-sharing in a language familiar to them. Up to now, however, only few countries have actually implemented such legislation and designated the competent national authorities. The patent authorities would also have the complex task of analysing and applying this legislation. Moreover, they lack the necessary legal and technical competence to determine the veracity of the evidence provided.
- In contrast to the Convention on Biological Diversity (CBD), the FAO International Treaty for Plant Genetic Resources for Food and Agriculture does not require PIC; accordingly, burdensome distinctions would be necessary between patent applications where the PIC-requirement applies and where it does not apply.
- Patent authorities are not in a position to determine whether the sharing of benefits is 'fair and equitable'. Moreover, at the time of filing patent applications, no monetary benefits will have arisen yet, and the commercial success of the invention is generally unknown. The applicant is thus unable to provide the required evidence when filing a patent application.

Conclusions

The proposals submitted by Switzerland to WIPO present a practical and result-oriented way forward. They could be introduced in a timely manner. Disclosing the source can be seen as

the 'entry point' of the access and benefit-sharing system in the patent regime and would strengthen mutual supportiveness between the two regimes.

The proposed disclosure of the source would allow parties to contract on access and benefit-sharing to verify whether the other contracting party is complying with its obligations. This would not only assist in and simplify the enforcement of these obligations, but would also permit verifying whether prior informed consent has been obtained and whether provisions have been made for fair and equitable benefit-sharing.

The proposed way forward would enable countries to fulfil their international obligations, in particular those arising out of the TRIPS Agreement, the PCT, the PLT, the CBD and the FAO International Treaty, and would provide one means to implement these international agreements in a mutually supportive way. Since no modifications to the TRIPS Agreement would be necessary, they provide further evidence of the flexibility of this agreement. And finally, the possibility to require the declaration of the source would also support the determination of prior art with regard to traditional knowledge, as it would simplify searching the TK databases that are increasingly being established at the local and national levels.

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ENDNOTES

¹ See generally, e.g., www.ip-watch.org/weblog/index.php?p=86&res=1024&print=0.

² The Swiss submissions to WIPO and WTO can be found at www.ige.ch/E/jurinfo/j105.shtm#6 and www.ige.ch/E/jurinfo/j1101.shtm#5. For a more detailed summary of the Swiss proposals see http://www.iprsonline.org/icts/docs/DOO6_Addor.pdf.

³ The draft for a revised Swiss Patent Law can be found at www.ige.ch/E/jurinfo/documents/j10017e.pdf.