

Towards Effective Disclosure of Origin – The Role of the International ABS Regime

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The disclosure of origin of genetic resources and traditional knowledge, combined with evidence of prior informed consent and benefit-sharing, is one of the most controversial intellectual property-related defensive measures against misappropriation. As existing intellectual property rules are likely to be insufficient to ensure disclosure, international norms in this area could provide a way to address current gaps, provided they are integrated into a broader access and benefit-sharing framework at the domestic, regional and international levels.

A number of provisions within current intellectual property (IP) rules already provide for the disclosure of origin, albeit in a limited manner.¹ A recent survey of patents using biological source material² found that the country/countries of origin of the plant and its traditional uses are usually disclosed in the description where this information is necessary to carry out the invention. However, while this was the case for patents based on ‘rare’ and ‘exotic’ resources, the information was not generally made available for well-known and widespread plants. Moreover, it is ultimately the choice of the applicant whether to disclose the origin of the material.

With regard to traditional knowledge (TK), various countries currently require applicants to disclose prior art to allow for the assessment of the invention’s novelty. Failure to disclose this information could lead to a revocation of the patent. In addition, TK holders have the possibility of claiming joint ownership if their knowledge has contributed to the invention. In both cases, however, the onus is largely on the TK holders to submit a complaint against alleged cases of misappropriation and to show the link between their knowledge and the invention. Such a claim can prove difficult given the limited manner in which prior art is considered in certain countries³ and the fact that much of the knowledge remains unrecorded.

In addition, while a number of national and regional regulatory frameworks already provide for some form of disclosure requirements, the stringency of the requirements vary greatly, ranging from mandatory requirements for disclosure of origin and legal access (i.e. with prior informed consent and on mutually agreed terms as in the Andean community) to disclosure requirements without legal consequence in cases of non-compliance (as in Sweden) to mere encouragement (as in the EU). The different levels of obligation are particularly relevant in cases of transboundary movement of resources when the country providing the resource or TK has to rely on measures in user countries to ensure that its laws are respected, and has no means of recourse to legal action in case of illegal access or breach of an access contract.

Disclosure Requirements – Some Considerations

To what extent international norms for disclosure requirements could play a role in filling some of these gaps in current IP rules will depend on the nature and implementation of such norms. A number of factors need to be considered in this context to ensure that the workability and effectiveness of the system:⁴

Determination of geographical origin: Genetic resources (GR) are sometimes found in more than one country/region or in the case of plant varieties might be result of genetic resources from different sources. The same is true for TK where the attribution of ownership is often not straightforward. Also, the source country that provided the resource might not actually be the same as the country where the resource acquired its distinctive properties. Thus, disclosure requirements will need to account for this multiplicity of sources and, to the extent possible, procedures for tracking the resource and/or TK, in particular if additional requirements for prior informed consent and benefit-sharing are included.

Extent of obligation: The practicality of the requirements will to a large degree depend on the obligation placed on the patent applicant. The most thorough, but at the same time potentially burdensome option would be the origin disclosure of *all* genetic resources and TK used in the invention. Other possibilities include requiring the applicant to make a ‘reasonable effort’ to

determine the source of relevant material or merely disclose what is already known.

Relationship between the GR/TK and the invention: It will be necessary to establish a trigger for the application of disclosure requirements, based on the relationship between the invention and the GR/TK. Such a trigger could be found at various stages in the innovation process, for instance where necessary for the conception, use or replication. It might also be necessary to clarify to what extent and which type of TK is in the public domain, or even revise the concept of ‘public domain’ in the context of TK.

Legal nature and consequences: As mentioned above, disclosure requirements under existing legal frameworks differ widely. Some are voluntary and others mandatory, and there are different consequences for non-compliance. Within patent law, disclosure of origin could be required either as a formality in the patent procedure or as substantive patentability criterion. While the consequences for non-compliance might be similar in both cases, i.e. a refusal of the patent, granted patents are usually hard to overturn on formality grounds unless the failure to comply can be shown to have been fraudulent. Alternatively, a stand-alone disclosure requirement could be introduced linked to the fulfilment of public law, including access legislation. In case of non-compliance, one of the effects could be the suspension of the administrative procedures for the granting of the patent until the requirements of the access legislation have been fulfilled.

The Role of the International ABS Regime

While international norms for disclosure requirements could help set certain minimum standards with regard to the issues outlined above, such requirements are unlikely to be

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effective if they are not integrated into a comprehensive access and benefit-sharing (ABS) system consisting of ABS regulations and access contracts, and the international IP regime. Such a system would be necessary both to set the conditions for access and to provide for legal enforcement within and outside a country's jurisdiction.

The international ABS regime – mandated by the World Summit on Sustainable Development and currently being negotiated under the Convention on Biological Diversity (Bridges Year 8 No.3, page 12) – can play a constructive role in providing yet another piece in the existing regulatory environment. For instance, the international regime could set up a Clearing House to provide information on access contracts and national and regional laws, which can help patent examiners assess the legality of the claim and whether the conditions attached to the acquisition and use of the GR/TK have been met. Patent examination could also be facilitated through the use of a certification scheme to attest the lawful acquisition of GR and TK, which could be developed and implemented through the international access and benefit-sharing regime.

Moreover, the regime could be used to set minimum standards or guidelines for domestic and regional ABS and IP legislation, while allowing for sufficient flexibility to adapt them to the national context. Such guidelines could be used for the definition of key terms and concepts, including those outlined above. The focus should be on measures and rules in both provider and user countries and could include standard access contracts or material transfer agreements setting out certain conditions for ABS and the filing of relevant intellectual property rights (as being developed in the context of the International Treaty on Plant Genetic Resources for Food and Agriculture).

Finally, the international regime could help monitor and enforce bilateral agreements and national access laws in cases of transboundary movement of genetic resources or use of traditional knowledge outside the jurisdiction. This could be achieved, for instance, by establishing an international obligation to implement national enforcement mechanisms (judicial and criminal) against the illegal access and use of GR/TK.

The regime could also set up a mechanism at the international level to monitor and resolve disputes among governments regarding the implementation of the obligations contained in the international regime.

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ENDNOTES

¹ WIPO. 2003. *Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge*, UNEP/CBD/COP/7/INF/17.

² WIPO/GRTKF/IC/2/15

³ In the US, the law excludes oral communications outside national territory when evaluating prior art for the purpose of determining novelty.

⁴ See, for instance, WIPO 2003; endnote 1.

WIPO Split on Disclosure Requirements

The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) decided in March 2004 to accelerate work on protecting traditional knowledge and folklore, but could not agree on how to proceed on assessing the interrelation of access to genetic resources and disclosure requirements in intellectual property applications.

Delegates agreed to initiate work on identifying policy objectives and core principles for the protection of traditional knowledge (TK) and folklore, which will provide the conceptual framework for future discussions. The Committee will also compile specific policy options and legal elements, as well as a brief analysis of their practical implications. The first draft will be prepared for the Committee's next meeting in November. The initiative will draw, *inter alia*, on a 15 March submission by Egypt on behalf of the African Group, which was widely welcomed as a suitable framework for the Committee's work. The submission outlines objectives, principles and elements of an international instrument (or instruments) on intellectual property in relation to genetic resources and the protection of TK and folklore. One observer noted that although countries continue to differ on the means for providing positive protection at the international level, there appears to be growing acceptance of the usefulness of such protection, marking a shift from the more cautious positions in the early days of the Committee's work.

No Consensus on Assessing Disclosure Requirements

Many developing countries, including Brazil and the African Group, questioned whether the IGC was the appropriate WIPO body to respond to the invitation by the Convention on Biological Diversity (CBD) to assess the interrelation of access to genetic resources and disclosure requirements in intellectual property applications. They expressed concern that hosting the discussions in the IGC would not necessarily ensure that the Committee's work flowed into other discussions at WIPO. Other relevant bodies include the Patent Cooperation Treaty, where Switzerland has submitted a related proposal, or the Substantive Patent Law Treaty, where several developing countries have raised biodiversity-related issues. The IGC discussions mirrored similar debates at the CBD's Conference of the Parties in February, where several developing countries opposed specific references to the IGC (Bridges Year 8 No.3, page 12).

Several delegations also felt that the WTO Council for Trade-related Aspects of Intellectual Property Rights (TRIPs) would be a more appropriate forum for the discussions. They were concerned that a debate in the IGC would distract from or pre-empt a decision by the TRIPs Council on a proposal by a group of developing countries, calling for disclosure requirements and evidence of prior informed consent and benefit sharing related to genetic resources and TK in patent applications (Bridges Year 8 No.3, page 12). Given the lack of consensus on how to proceed with the CBD's request, the Committee decided to forward the issue to the General Assembly for consideration (for a more detailed report, see BRIDGES Trade BioRes, 2 April 2004).