

FEASIBILITY OF NATIONAL DISCLOSURE OF ORIGIN REQUIREMENTS

Is it feasible for countries to adopt national disclosure of origin (DOO) requirements, requiring patent applicants to (1) disclose the source of genetic resources used in an invention, (2) disclose the source of traditional knowledge used in the invention, and/or (3) to provide evidence that the provider gave prior informed consent and received a share of benefits? DOO requirements could be direct (mandatory and enforceable through loss of patent rights), indirect (mandatory but enforceable only through means other than the patent system), or voluntary/permissive. The feasibility of DOO requirements may be assessed in terms of compatibility with existing international treaties, compatibility with national legislation, political viability domestically and internationally, consistency with rules and customs of patent practice, and ease of implementation. Measured this way, direct DOO requirements encompassing (1), (2), or (3) above may be more problematic than indirect or voluntary approaches. All approaches may impose implementation costs and concerns.

Disclosure in the CBD

DOO requirements can be traced to two provisions in the Convention on Biological Diversity (CBD): Article 15 established the basis for access and benefit sharing (ABS) agreements.¹ Article 8(j) required Parties to protect traditional knowledge.² The informed consent and benefit sharing provisions have led to much discourse at the international level, and many countries have promulgated laws or regulations that specify the permitting requirements for people seeking access to genetic resources. The Bonn Guidelines, adopted by the CBD Conference of the Parties in 2002, provided voluntary guidelines on improving ABS agreements, and recommended that Parties encourage disclosure of origin as a mechanism to track compliance with ABS requirements.³ Such mechanisms are being considered by committees of the World Trade Organization (WTO)⁴ and the World Intellectual Property Organization (WIPO).⁵

Implementing disclosure requirements at the national level

As a general matter, to implement DOO requirements, a country would need to pass national legislation amending patent laws, and promulgate regulations for the national patent office to follow. Further, countries would have to avoid entering into multilateral or bilateral agreements that preclude DOO requirements. To satisfy principles of jurisprudence, DOO laws would need to be clear, comprehensible, and fair. Such laws would have to specify many details, including: the circumstances triggering a disclosure requirement; the timing, content, format, and level of detail required from the applicant; and the consequences of a failure to disclose. An optional system might include incentives such as a discount in official fees.

DOO requirements directly tied to patent rights, for example, would add as a requirement for patentability that for every patent application based on genetic resources or traditional knowledge

¹ "Access to genetic resources shall be subject to the prior informed consent of the Contracting Party providing such resources...." Art. 15.5. Access "shall be on mutually agreed terms." Art. 15.4.

² Parties shall "respect, preserve and maintain" traditional knowledge of traditional and indigenous communities, and "encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations, and practices."

³ See CBD COP 6, Decision VI-24, at p. 268, Access and Benefit Sharing as Related to Genetic Resources, A. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising Out of Their Utilization (Bonn Guidelines), available at <http://www.biodiv.org/doc/decisions/COP-06-dec-en.pdf>

⁴ These include the Committee on Trade and Environment and the TRIPS Council.

⁵ The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

obtained anywhere in the world, the applicant must identify where the material was obtained, the person or organization providing it, and any traditional or indigenous knowledge that was employed, and the applicant must have entered into an ABS agreement with the appropriate rights-holder, and must provide a copy of the agreement. Failure to satisfy any of these requirements would result in rejection of a patent application, or invalidity of a patent that was erroneously allowed to issue.

Factors that would limit the stringency of a DOO law include: (a) permitting retroactive cure for any provision that was not satisfied initially; (b) accepting the applicant's certification that all applicable ABS requirements were satisfied (instead of requiring copies of ABS agreements, and (c) requiring disclosure only for genetic resources and traditional knowledge obtained from within the country that has a DOO law. On the last point, for example, an applicant (Peruvian or not) seeking a Peruvian patent might only need to provide disclosure of origin information for genetic resources or traditional knowledge whose source was within Peru. Alternatively, a regional framework such as the Andean Community could provide that an applicant seeking a patent from any country in the Community would need to provide disclosure regarding resources or knowledge obtained from any of them.

Arguments against DOO requirements

Four main arguments have been raised against DOO requirements: (1) inconsistency with international treaties as a matter of law; (2) inconsistency with domestic laws; (3) opposition by particular countries; and (4) impracticality and other negative domestic public policy consequences. The first argument was addressed in a paper prepared for Public Interest Intellectual Property Advisors, concluding that most forms of DOO requirements would be consistent with international treaties.⁶ However, DOO requirements in a particular country would need to apply to applicants from all countries, and could not preclude the filing of national phase PCT applications. As to the second argument in principle DOO rules are not necessarily incompatible with domestic laws in the US and elsewhere, although this issue depends on the specifics. The third argument is a political issue not addressed here.

The fourth argument, impracticality and domestic consequences, remains a crucial issue for countries to address in reaching decisions about DOO requirements. For example, for countries that lack a practical ABS regimes, a strict DOO requirement might be impossible to satisfy, precluding genetic resources patents.⁷ National patent offices are generally under-funded and are already required to examine extremely complex technical and bibliographic information, so they may lack capacity to handle additional DOO requirements. DOO requirements would burden patent applicants in the life sciences over applicants in other technologies. Finally, other measures outside patent law, like civil or criminal sanctions, might be a better use of resources to improve compliance with ABS regimes. All these policy and procedural concerns need to be addressed for a DOO regime to succeed.

Final Considerations

As international consideration of DOO requirements moves through discussions involving the CBD, WIPO, and WTO, countries may wish to commission intellectual property professionals to draft model legislation for a range of specific DOO requirements. This would help focus attention on the key issue -- whether DOO requirements are an effective way to achieve the ultimate goals of promoting conservation of biological and cultural diversity, in balance with innovation and technology transfer. The specifics of draft model legislation could also help build a consensus about consistency with international treaties and domestic laws, and the policy merits of particular options.

⁶ Joshua D. Sarnoff, Consistency with Patent Law Treaties of Application Disclosure Requirements Regarding Origins of Genetic Resources and Traditional Knowledge, Discussion draft of June 23, 2004 available at http://www.piipa.org/DOO_Memo.doc. This memorandum includes a comprehensive study of the relevant treaties.

⁷ IP/C/M/46, Council for Trade-Related Aspects of Intellectual Property Rights - Minutes of Meeting - Held in the Centre William Rappard on 1 - 2 December 2004