



TRIPS Should Not be Re-opened to Mandate Special Disclosure Requirements in Patent Applications

Prepared by the Commission on Intellectual Property and the Commission on Biosociety

A. ICC believes that it is premature to consider amending the TRIPS Agreement to provide for special disclosure requirements in patent applications.

1. In its Discussion Paper of May 25, 2005, "Access and Benefit Sharing: Special Disclosure Requirements in Patent Applications," ICC cautioned that patent disclosure proposals should take into account the broader context of access and benefit sharing and the specific implications of such proposals for the patent system and innovation. Attached as an Annex is the Summary of the May 25, 2005 Discussion Paper.
2. No consensus has yet developed as to whether special patent disclosure requirements are a desirable objective, nor on definitions of key terms. While some countries strongly support these requirements, others vigorously contest them in all three multilateral fora dealing with the issue (WTO TRIPS Council, WIPO and the Convention on Biological Diversity).
3. These discussions should be allowed to come to fruition before the issue is taken into a renegotiation of the TRIPS Agreement.
 - a) More technical work should be undertaken and a consensus developed in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. WIPO is the multilateral forum charged with the technical discussion of intellectual property issues and should be the locus of deliberations by technical experts on the implications of disclosure obligations associated with patent applications. While the slow pace of progress is understandably frustrating for some, the Committee has made real advances in identifying the technical issues. These must be better understood before a TRIPS amendment is considered.
 - b) The CBD is considering the linkage of disclosure requirements to the patentability of inventions stemming from genetic resources in its negotiations on an Access and Benefit Sharing scheme and much work remains in that body on the scheme's scope, nature and key elements.

4. More experience is needed to see how well the current national systems work.
 - a) More analysis is needed to determine the impact of special patent disclosure requirements already found in national laws on the rate of bioprospecting.
 - b) More analysis is needed to determine the extent to which patent applicants already provide source information in their applications when it is materially relevant to the application.
5. Unnecessary burdens on innovators, such as disclosure requirements beyond existing requirements, run the risk of deterring innovations and technical progress.

B. As a general matter, ICC believes that the TRIPS Agreement should not be re-opened at this time.

1. There has not been sufficient experience with the implementation of the TRIPS Agreement to warrant a re-opening of the text. While we are celebrating this year the tenth anniversary of the WTO TRIPS Agreement, the agreement has actually been implemented for less time. Developed country Members of the WTO were not obligated to apply the TRIPS provisions until January 1, 1996, while developing country Members were given until January 1, 2000 to do so. Some developing countries, including India and Egypt, were only obligated to provide patent protection for pharmaceutical and agrochemical products as of January 1, 2005. The least developed country Members of the organization have, as a general matter, until January 1, 2006 to apply the agreement in their national laws and were given until 2016 to implement the pharmaceutical-related provisions of TRIPS Article 70.9. Most WTO Members have either only had five years of experience in meeting the obligations of the TRIPS Agreement or have yet to implement the agreement at the national level. ICC thus believes that it is premature to re-open the Agreement.
2. A good number of countries that are currently obligated to implement the TRIPS Agreement have, in fact, not done so. ICC believes that, rather than reopening the TRIPS agreement, technical assistance should be provided to these countries in order to build up their capacity to implement the TRIPS Agreement expeditiously and properly .
3. ICC is of the opinion that the built-in processes found in TRIPS Article 71 are the most appropriate ways of amending the Agreement. Article 71.1 calls for the biennial review of the TRIPS Agreement by the TRIPS Council, while Article 71.2 provides for an additional process for amending the TRIPS Agreement to reflect higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO.

ANNEX

Access and Benefit Sharing: Special Disclosure Requirements in Patent Applications

25 May 2005

Summary

Issue

Proposals have been advanced at the national level, and within intergovernmental forums, to mandate disclosure of “Country of Origin/Source” and/or proof of “Prior Informed Consent”.

General positions of ICC

The following guide ICC’s overall view of such proposals.

- ICC fully supports the aims of the CBD and its recognition of sovereign rights of states to control access to their own genetic resources pursuant to national policies; and supports in particular the objectives of the Convention calling for “sustainable use (of the components of biological diversity) and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.”
- ICC supports efficient and effective utilization of intellectual property protections as necessary and appropriate to stimulate innovation in use of genetic resources, to enhance the value of those resources, and to facilitate the equitable sharing of benefits from the use of those resources.
- ICC believes that there is no inherent conflict between the obligations in the CBD and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

ICC does not have consensus regarding any of the specific proposals for disclosure currently under consideration, but does have a general view that such disclosure will not significantly advance the aims of access and benefit sharing; and has consensus on a number of considerations relevant to the proposals.

Considerations related to special patent disclosure requirements

The Intergovernmental forums considering proposals for patent disclosure must take into account the broader context of access and benefit sharing and the specific implications of proposals for the patent system. To that end, the ICC offers the following.

- Consideration of proposals for special patent disclosure need to expressly recognize the differing implications for the three major sectors engaged in modern biotechnology research.
 - Pharmaceutical sector;
 - Industrial biotechnology sector; and
 - Agricultural sector.
- Workable national frameworks are essential to any meaningful access and benefit sharing advances.
- National frameworks need to recognize the role of academic and other research institutions and other providers of ex-situ genetic resources as key participants in any overall scheme of access and benefit sharing and regulate them accordingly.
- Any scheme relating to access and benefit sharing, whether connected to patents or otherwise, poses different challenges with respect to new in-situ access versus resources already ex-situ, particularly resources removed from the country of origin.
- Implications of disclosure obligations associated with patent applications should be deliberated in the forum in which the countries invest their technical expertise in implementing the patent system, WIPO.
- Disclosure obligations beyond existing requirements, particularly as a new condition of patentability, risk deterring innovation.
- Disclosure of “Prior Informed Consent” is not appropriate.
- Any consideration of disclosure obligations needs to recognize the distinction between “Disclosure of Country of Origin” versus “Disclosure of Source”:
- Any consideration of disclosure obligations needs to distinguish between human and other genetic resources.
- Any consideration of disclosure obligations needs to distinguish between biologic and genetic resources to be consistent with CBD.
- Any consideration of disclosure obligations needs to carefully examine both the potential for unintended consequences, and relationship between cause and effect