



Policy statement

Should patent applicants disclose the origin of biological materials on which they file patents?
Should they demonstrate Prior Informed Consent (PIC) for their use?

The Convention on Biological Diversity (CBD) was enacted with three objects: promoting conservation of biological resources, use of such resources in sustainable development and equitable sharing of the resulting benefits.

It has been suggested that patent applicants, when filing patent applications concerned with biological resources, should assist the objectives of the CBD by:

- disclosing the origin of those resources;
- providing evidence of Prior Informed Consent that such resources have been accessed in accordance with the provisions of the CBD.

These proposals may be referred to broadly as Source Disclosure.

ICC fully supports the objectives of the CBD. ICC will work within the CBD framework to develop and enhance mechanisms to provide for disclosure of sources from which genetic material is obtained and to ensure compliance with any country PIC requirements. However, imposition of conditions into the complex formal global patent system is necessarily beyond the CBD. Further, given the uncertainties in the larger questions of “origin” of genetic material, using the patent system to enforce such conditions would likely inhibit both the beneficial use of the resources and any sharing of benefits. Such requirements in our view would conflict with Article 15 of the CBD, which requires signatory states to facilitate access.

The CBD is a framework convention, to be implemented by member countries according to their specific needs. ICC insists on the obligation of companies to respect fully the laws of all countries in which they operate. However, the CBD is being implemented by different countries at different rates and in different ways. Some (Philippines, Andean Pact) require PIC before access is granted to genetic resources. Most do not. One country (Denmark) allows unrestricted access, provided the party is in compliance with other applicable property and conservation laws. There is no general rule, and those with specific rules in place are a small minority of CBD members. In these circumstances, there should be **no question of a general requirement for all national Patent Offices to require evidence of PIC** when a patent application referring to biological resources is filed. It would be disproportionate.

Further, the requirements of countries restricting access will differ one from another. It would be difficult or impossible to construct clear general rules to which companies must conform. There is fundamental lack of clarity as to when PIC is required. Suppose the resource has come via a third country? Suppose the resource is common and widely distributed? Suppose the resource does not make a fundamental contribution to the invention patented? Where are lines to be drawn, and what principles are to be applied in drawing them?

However, disclosure of source is a different matter from PIC. Companies generally are willing to voluntarily disclose the source of the material with which they work. ICC is willing to work with the CBD to advance this more systematically. Note however that ‘source’ means the immediate source of the material used. This may not be the ‘country of origin’ in the sense which the CBD uses that term. There will often be practical difficulties as well as legal uncertainties in determining ‘country of origin’. For example, for some material, the accessing and sharing predates any formalised CBD or country requirements, and definitively tracing lineage back to the true point of “origin” simply is not possible.

ICC believes that **Source Disclosure** (to the extent not required by existing patent regulations) **should remain voluntary**. In no case should failure to disclose render the patent invalid or prevent its issue. Further, for specific questions on how the global patent system should deal with origins of genetic resources, **the appropriate forum is WIPO**. Importantly, WIPO has recognised the emergence of such questions and has created a Committee on Traditional Knowledge, Folklore and Genetic Resources specifically to allow countries – all countries – to deliberate them.

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