International Chamber of Commerce
The world business organization

Discussion paper

Access and Benefit Sharing: Special Disclosure Requirements in Patent Applications

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.

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- 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.

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Discussion paper

Access and Benefit Sharing: Special Disclosure Requirements in Patent Applications

Prepared by the Task Force on Access and Benefit-Sharing

Issue

Proposals have been advanced at the national level, within the Convention on Biological Diversity (CBD), and within forums of the World Intellectual Property Organization (WIPO) and in the World Trade Organization's Council on Trade Related Aspects of Intellectual Property (TRIPS), regarding special disclosure requirements in patents that disclose inventions related to the use of genetic materials. These proposals are largely aimed at enlisting the patenting process to encourage compliance with CBD provisions in the arena of access and benefit sharing. The proposals include mandatory disclosure of "Country of Origin/Source" and proof of "Prior Informed Consent" as conditions of patentability.

General positions of ICC

The following positions of the ICC guide our 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."[1]**

- **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).[2]**

[1] CBD, Article 1
[2] See ICC Policy statement on "TRIPS and the Biodiversity Convention: What Conflict?"

In reviewing the various proposals for patent disclosure, the companies and industries represented within the ICC recognize strengths and weaknesses in each. They have not arrived at consensus regarding any of the specific proposals for disclosure currently under consideration, but do share a general view that such disclosure will not significantly advance the aims of access and benefit sharing. These companies and industries have a common sense of the context out of which these proposals have sprung, and have a consensus on a number of considerations relevant to the proposals. The following discusses that context and the considerations the ICC sees as relevant to any deliberations in this arena.

Context

The Convention on Biological Diversity (CBD) entered into force in December 1993. Prior to that time, access to and use of genetic resources and related traditional knowledge in a particular country were subject primarily to the national regime in that country. The CBD expressly recognized the efficacy of these national regimes by providing that "[s]tates have … the sovereign right to exploit their own resources pursuant to their own environmental policies."[3] Also, the Convention declared as an objective, to promote the "fair and equitable sharing of benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources…."[4] To fulfill this objective, the CBD created expectations (e.g., "endeavor to create conditions to facilitate access"[5]) and imposed obligations (e.g., "access … shall be granted on mutually agreed terms,"[6] and "access … shall be subject to prior informed consent"[7]). Also the Convention provides that "Each Contracting Party shall… [s]ubject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity…."[8] Parties were expected fulfill these expectations and obligations in national frameworks on access and benefit sharing.

In the intervening decade, however, relatively few states have implemented national frameworks for access and benefit sharing. To accelerate implementation of CBD access and benefit sharing provisions, the Parties to CBD adopted the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization" in 2002. These were aimed at helping states to frame national regimes to meet their particular circumstances, but few Parties have adopted frameworks based upon the Bonn Guidelines. Despite the Guidelines, the World Summit on Sustainable Development took note of this issue later that same year and mandated negotiation of a "New International Regime" under the CBD. That negotiation commenced in February, 2005.

[3] CBD, Article 3
[4] CBD Article 1
[5] CBD Article 15, para 2
[6] CBD Article 15, para 4
[7] CBD Article 15, para 5
[8] CBD Article 8, literal (i)

Steps aimed at more systematic advancement of CBD "access and benefit sharing" objectives have been undertaken outside the CBD by both public and private organizations. Most notable is the International Treaty on Plant Genetic Resources negotiated under the auspices of the UN Food and Agriculture Organization. It contains provisions governing access and benefit sharing related to most major agricultural species. A consortium of 12 intergovernmental, non-governmental and private sector institutions developed the Micro-Organisms Sustainable use and Access regulation International Code of Conduct -- MOSAICC, a voluntary code of conduct relating to access to microbial resources and the sharing of benefits arising from access. In addition, some of the major public holders of genetic resources implemented specific policies to ensure that their actions conform to the expectations and obligations of the Convention, (e.g., the U.S. National Institutes of Health, Kew Gardens) as have a number of individual enterprises.

Patent-specific considerations in benefit sharing:

As intellectual and capital investment supporting research in fields utilizing genetic resources have increased, the system of intellectual property protections that can aid in securing some measure of return on that investment, particularly the patent system, has become an important tool for a significant segment of genetic resource users. However, the legal uncertainty associated with access to and use of natural genetic resources that has arisen over the past decade has cast a shadow over the patent system and led many of those users to postpone or limit acquisition of new genetic material. Significantly, research and development in the use of alternatives to genetic resources has also advanced over the past decade, particularly through techniques of modern biotechnology that are evolving rapidly in academic centers of excellence and public research institutions around the world, and in the private sector. This has been a factor in the redirection of much research in the pharmaceutical industry toward synthetic molecular compounds rather than naturally occurring ones.

The legal uncertainty that is discouraging investment in naturally occurring genetic resources is reducing opportunities for negotiating mutually agreed terms and for the sharing of any resultant benefits. It is also contributing to an increasingly evident mismatch of expectations regarding the market for and value of in-situ resources, further reducing investment.[9] This vicious spiral is contrary to the interests of both the countries and indigenous communities stewarding in-situ genetic resources, and the community of potential users of such resources.

One key to restoring the mutual benefits of access and benefit sharing envisioned by the CBD is the legal certainty of the patent system in providing assurance to those making significant research and development investments. But assurance also has to be provided to those concerned over allegations of misappropriation of resources – what some have termed "biopiracy." Unfortunately, there is no common definition of this term. It certainly includes access to genetic resources in violation of CBD provisions and attempting to patent existing traditional knowledge and genetic resources in the form received from the provider. It is sometimes claimed to include patenting modified genetic resources and patenting improvements on traditional knowledge. These latter interpretations turn on a fundamental misunderstanding of the principles of patentability in terms of subject matter, novelty and inventive step, and the distinction between tangible physical property and intellectual property.

[9] See ICC Discussion Paper on "Access and Benefit Sharing for Genetic Resources"

When one patents a plant, for example, one does not "own" the plant. One owns some novel invention that is implemented or embodied in the plant through invested research and development. The patent is limited in its term, and also requires public disclosure of the technical character of the invention, to enable future research and development to build upon that invention. The patent process is therefore a key to realizing value from research into genetic resources, both directly and over the longer term.

Considerations related to special patent disclosure requirements

As intergovernmental forums consider various proposals for patent disclosure, they must take into account both the broader context of access and benefit sharing and the specific implications of proposals for the patent system. A practical objective in advancing access and benefit sharing is to facilitate implementing the key principles of the CBD: "appropriate access to genetic resources" and "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources."[10] 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*: While this sector remains a major concern of proponents of disclosure obligations, the reality is that advances in science and technology and the uncertainties around access to natural genetic resources have led this sector to increase its reliance upon synthetic molecules. Many of the major pharmaceutical companies have either scaled-back or discontinued altogether their natural products activities. This reduces demand for (and therefore potential benefits from) naturally occurring resources but potentially still leaves this industry vulnerable to broad, patent-focused initiatives.
  - *Industrial biotechnology sector*: This is a growing sector involved heavily with microbial resources and the development of products that can enable unique properties and the substitution of renewable resources for energy and other natural resource factors of production.
  - *Agricultural sector*: This sector is dominated by use of genetic resources that have been domesticated, bred and traded for hundreds and sometimes thousands of years. It has highly evolved international standards relating to intellectual property protection and is most generally characterized by incremental improvements in adaptations to particular growing environments
  - or nutritional enhancements. It is also subject to the FAO International Treaty on Plant Genetic Resources, which applies particular standards to access and benefit sharing in response to the CBD Access and Benefit Sharing mandates.

[10] CBD Article 1

Each sector has its own suite of circumstances that bear on the use of genetic resources and traditional knowledge and related disclosure proposals. It should also be noted that a number of sectors that are not heavily dependent upon research and development investment, (e.g., cosmetics sector, plant breeding, and the natural remedies sector) are major users of genetic resources and traditional knowledge but do not rely on patents in most cases.

- **Workable national frameworks are essential to any meaningful access and benefit sharing advances.** National frameworks are necessary to clearly define rights and responsibilities for consultation and negotiation of access and benefit sharing agreements, and in establishing general conditions that either invite or discourage interest in resources. National frameworks that provide clarity regarding rights to the resources and traditional knowledge in question and legal certainty regarding the integrity of any such agreements are essential.

- **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.** The line between academic and commercial research is blurring. To ensure appropriate consultation and mutually agreed terms for access and benefit sharing for any resources that may find their way to commercial use, national schemes must extend to all who seek access to genetic resources.

- **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.** Almost all of the genetic resources being used in research and development today have been long-since legally extracted from their in-situ conditions and from their countries of origin (e.g., those in large botanical gardens). It may not be possible to document the origin of these resources, as they may have been accessed without benefit of national frameworks or expectations of mutually agreed terms.

- **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.** The expertise assembled by the countries in WIPO is necessary in determining 1) whether disclosure in conjunction with patent applications is appropriate and, 2) if so, in what manner this could most efficiently and effectively be done. The extension of WIPO cognizance in this arena is already manifest in its Committee on Genetic Resources, Traditional Knowledge and Folklore. Current discussions on a proposed "Development Agenda" for the organization promise to deliver greater clarity in how WIPO can best respond to the range of concerns imbedded in disclosure proposals.

- **Disclosure obligations beyond existing requirements, particularly as a new condition of patentability, risk deterring innovation**. Patent applicants are required to fully disclose the technical nature of their inventions. This already existing disclosure requirement is intended to promote innovation by discouraging investment in duplicative research and by promoting investment in significant improvements of existing inventions.

Requirements to disclose the origin, source or provenance of genetic resources associated with the invention claimed in a patent application do not promote innovation. If such requirements are imposed as a new condition of patentability, they may actually cloud such patents even where information is supplied in good faith, as that would create a new avenue for legal challenge to patents.

- **Disclosure of "Prior Informed Consent" is not appropriate.** The reality is that few countries have implemented regulatory regimes requiring such consent, effectively making it impossible to prove compliance in many cases.

- **Any consideration of disclosure obligations needs to recognize the distinction between "Disclosure of Country of Origin" versus "Disclosure of Source":** The source from which genetic material was obtained is normally a matter of record in academic and commercial endeavors. However, the notions of 'origin" or "country of origin" are far more obscure in their implied criteria. Even if the criteria are clarified, the relevant facts may well be impossible to ascertain with any degree of certainty in many circumstances.

- **Any consideration of disclosure obligations needs to distinguish between human and other genetic resources.** The CBD does not pertain to human genetic resources. The ethical and legal distinctions between use of human and non-human genetic resources are significant and need to be respected in any provisions relating to patenting.

- **Any consideration of disclosure obligations needs to distinguish between biologic and genetic resources to be consistent with the CBD**. The expectations and obligations of CBD with respect to access and benefit sharing are limited to genetic resources.

- **Any consideration of disclosure obligations needs to carefully examine both the potential for unintended consequences, and relationship between cause and effect:** The aim of any implementation provisions in CBD-driven access and benefit sharing must be both proper access to resources to enable generation of benefits, and orderly, equitable sharing from such benefits. Failure to take both access and benefit sharing into account in designing any regime risks frustrating both of those fundamental objectives. Any initiative that increases the complexity and legal risk of the patent system carries the potential to discourage use of natural genetic resources under that system, and therefore reduces the potential for benefits to be shared.

Industry, academic and institutional researchers, the countries and local and indigenous stakeholders all are in the midst of a significant transition. We are moving from a pre-CBD era largely dominated by varying country regimes with only spotty attention to access and benefit sharing, to a post-CBD era in which the interests of rights-holders in countries of origin will be more clearly defined and more consistently respected, and in which the benefits accruing from use of genetic resources will be more equitably shared. The pace of that transition and the breadth of societal benefit realized will be in significant part determined by attention to the considerations outlined above. Industry stands ready to explore them in more depth.