International Chamber of Commerce
The world business organization

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Patent disclosure requirements relating to genetic resources: will they work?

Highlights

- Objective and measures of the CBD
- Implications of proposals for 'disclosure of origin' and related requirements

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Patent disclosure requirements relating to genetic resources: will they work?

The protection of genetic resources, traditional knowledge and folklore has been under discussion in WIPO since 2000. ICC supports the WIPO process and the principles of prior informed consent and the fair and equitable sharing of benefits from the use of genetic resources and traditional knowledge, as established in the Convention on Biological Diversity (CBD). ICC also supports the goal of preventing the wrongful grant of patents. Nonetheless, there is concern that resources and knowledge are being taken from countries without proper permission or compensation, i.e., that they are being used without agreement to access and without appropriate benefit-sharing as envisioned under the CBD. In consequence, one proposal to combat this "misappropriation" is to require patent applicants to disclose, in respect of genetic resources or their derivatives, the country of source or origin from which they were obtained. Some proposals would also require that the applicant show that he has formal consent from the source of the materials or knowledge, and has agreed to share benefits. Certain countries have already incorporated such requirements in their patent laws. Failure to make a correct disclosure may invalidate the patent.

In ICC's view, all such requirements[1] should be resisted, for the following reasons:

- they hinder rather than promote the objectives of the CBD;
- they are ineffective and would rarely, if ever, contribute to goals of monitoring use of genetic resources and ABS compliance or providing useful information;
- they impose on patent applicants requirements that are unclear and lead to legal uncertainty;
- they impose requirements that are impracticable or impossible to meet;
- they are incompatible with the patent system; and
- alternative approaches exist that can combat "misappropriation" without the drawbacks of a disclosure requirement for patent applications.

The objectives and measures of the CBD

The objectives of the CBD are well-known. They are:

- conservation of biological diversity;
- sustainable use of its components; and
- facilitation of access to genetic resources and the fair and equitable sharing of the benefits from their use.

To promote these objectives, the CBD provides:

- CBD Parties will create conditions to facilitate access to genetic resources for uses by other Parties;
- unless otherwise determined by the Party, such access will be subject to prior informed consent from the Party (or, where appropriate, the holder); and
- where applicable, benefits from such access will be equitably shared on mutually agreed terms.

These objectives and measures are widely accepted and ICC supports them. However, disclosure of source or origin in patent applications does not help to achieve these objectives or make the measures work better.

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[1] *This paper deals only with the origin of genetic resources. Similar but even more difficult issues arise with respect to Traditional Knowledge. Therefore, ICC also is opposed to any disclosure requirement in patent applications relating to TK.*

Why should proposals for 'disclosure of origin' and related requirements be resisted?

- **They would hinder rather than promote the objectives of the CBD**

Disclosure obligations, particularly as a new condition of patentability, have the real potential to deter innovation. The objectives of the CBD include conservation of biodiversity, promotion of access for sustainable use, and the fair and equitable sharing of benefits. New uses require investment. Introducing disclosure obligations in the patent system creates legal and commercial uncertainties for users. This in turn may reduce investment in the use of genetic resources for innovative products, including those needed to address threats to biodiversity, such as climate change. For many sectors, such as agriculture, access and use of genetic resources are critical to the conservation of biodiversity; reducing investment and innovation in this manner would therefore be directly contrary to the objectives of the CBD. Along with investment in research and development, introducing new products to the market may require investment in communication, advertising, supply chains and distribution channels. If investment in innovative products is reduced due to uncertainties and fewer products are developed, there will be less revenue and other benefits to share with the resource providers. Additionally, consumers will be unable to benefit from the use of potentially life-enhancing products. Correspondingly, such lowered benefits reduce the monetary value of genetic resources and so discourage conservation. This runs counter to the objectives of the CBD.

- **They would be ineffective and would rarely contribute to goals of monitoring use of genetic resources or facilitating ABS compliance**

New disclosure requirements will not achieve the objectives of combating “misappropriation” or lack of benefit-sharing or monitoring the use of genetic resources. For example, a disclosure requirement would do nothing to assist in monitoring any use of genetic resources that does not involve patenting. Moreover, the public would gain little information that would help with checking compliance with local ABS laws or determining novelty or inventive step of the invention. For example, it is very difficult to see how such information for genetic resources accessed ex situ could be relevant or useful at all to the general public.

- **They are unclear and create legal uncertainty**

There are many outstanding questions concerning proposals to require “disclosure of origin” of genetic resources. Is 'origin', ‘country providing the resources’ or 'immediate source' to be disclosed? How do these terms apply where genetic resources are present in one or more *ex-situ* collections in different countries (e.g., gene banks, botanical gardens, etc.)? What is the 'origin' of a genetic resource? The genesis of any genetic resource is impossible to define technically. How far back should one go in evolutionary time? Frequently, it will be impractical to make detailed investigations due to any number of factors that may be relevant to a particular genetic resource, including, *inter alia*, dispersal of genetic resources through the years, trade flows involving particular resources through intermediaries, and lack of plant-specific record keeping.

If the requirement is to declare the 'country of origin' as defined in the CBD (e.g., possessing the resource *in situ*), what if there is more than one such country? In such a case, is it sufficient to name one such country, or is it necessary to attempt to discover and list all of them, or to trace the parentage of the material to its actual historic source? How is the resource to be defined – specifically or generically? For example, some assert that the “centre of origin” of potatoes as a genus of cultivated crops is the Andean Region in the area now known as Peru[2] – however specific potato varieties have been bred in many countries of Europe and other regions of the world. In addition, the

[2] *See Spooner, DM* et al. *Proc Natl Acad Sci 14694-14699 Oct 11 2005 – summarised at http://www.cipotato.org/pressroom/press_releases_detail.asp?cod=17&lang=en (the website of CIP, the International Potato Centre).*

true origin of the family of plants known as potatoes is uncertain because this is an issue of evolution rather than domestication.

Similarly, how would such requirements apply to genetic resources that have long since been removed from countries of origin and are now distributed by intermediaries as commodities or commercial products? Recognizing that genetic resources can be used in different ways, such as in a step in a process, as a research tool or a catalyst, what uses would trigger a requirement for patent disclosure? Is the disclosure requirement to apply only to *genetic* resources (in conformity with the CBD) or also to *biological* resources more generally? Is it to apply to all materials mentioned in a patent specification or only to those crucial to the invention? Moreover, the very question of what constitutes a "genetic resource" for these purposes has been raised. For example, could information, such as a DNA sequence taken from a publication, trigger a requirement even where no physical genetic or biological resource was accessed? Depending on the answers to these questions, the problems mentioned below can be greatly magnified.

- **They are impracticable and, in many instances, would be impossible to meet**

If what is to be disclosed is not clearly defined, it is impracticable to require it. But even a clear definition does not help if it imposes too great a burden. For example, in many cases, it will simply be impossible to find out whether any country actually possesses particular genetic resources in situ, or to trace back a particular genetic resource transferred many years ago or through multiple intermediaries. A universal requirement for such disclosure cannot work. Some proposals additionally would require evidence of 'Prior Informed Consent' (PIC) of the country of origin or 'source.' The facts show that the concept of origin is impracticable, and such a requirement is not appropriate even for in situ access given that a number of countries do not require such consent. Moreover, others who support such a requirement in principle have not yet provided (nearly two decades after the CBD came into force) any mechanism for obtaining it. Furthermore, some countries have arrangements that in practice make it impossible to obtain PIC within a reasonable time. ICC believes that if a country wants to ensure Prior Informed Consent, the way to do so is to pass national laws to require such consent at the time of access. In addition, to accord with the Nagoya Protocol, the most sensible manner of monitoring and enforcing these laws is to do so as close to the point of access as possible. This can ensure that compliance with ABS rules has been and continues to be achieved. It is not feasible to try to impose requirements after years (perhaps decades) of research have passed, when histories may be impossible to trace.

- **A "source-based" approach is also ineffective**

To address concerns about clarity and practicality, it has been proposed that patent applicants should disclose not origin but immediate source. While one may not know the country where the sample originated, it is said that one usually knows where one got it (e.g., in the case of a potato, from the local supermarket). However, this approach also is inadequate. For example, there is no agreement of what would constitute an appropriate "source". It was made clear in deliberations during the negotiations leading up to the Nagoya Protocol that most developing countries do not believe that an "intermediary country" (i.e., a providing country that is not a country of origin) is an appropriate "source" country.[3]

Even such a strictly limited "immediate source" requirement would require further examination (e.g., would a statement that the materials were accessed from a scientist's private collection and nothing further be satisfactory?). In any case, this approach has been objected to by developing countries as pointless. Such an "immediate source" requirement would only in rare cases provide meaningful

[3] *CBD Article 15 refers to benefit-sharing with respect to "only those [genetic resources] that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with [the CBD]." Several developing countries do not consider "intermediaries" holding genetic resources transferred, e.g., prior to the CBD to have acquired those resources in accordance with the CBD.*

information. Imposing such a requirement for all patent applications involving the use of genetic resources, or even of biological materials, would be quite disproportionate.

- **They are not compatible with the patent system**

The patent system aims to promote innovation. For this purpose, incentives in the form of exclusive rights granted for a limited time are offered for new inventions in exchange for a public disclosure of the invention. Patent applications are examined by patent offices primarily for the fundamental criteria of novelty, inventive step and industrial application. Other causes of invalidity are possible, such as that the applicant has filed the patent application without permission of the inventor, but all such requirements relate directly to the subject matter of the invention. Patent offices, or courts when considering patent issues in litigation, do not normally consider other regulations which may have some relation to an invention (e.g., safety or health rules, taxes to be paid on commercial sales of products, etc.). Similarly, patent law or examination is not the right means to control requirements about origin of genetic resources used in developing products. Moreover, the TRIPS Agreement prohibits such additional conditions on patentability. In addition, the proposed requirements are specifically targeted to biotechnology and other life sciences using genetic resources and, therefore, would not be consistent with the principle in the TRIPS Agreement that patents be made available without discrimination based on field of technology.

- **Alternative approaches can more effectively combat "misappropriation"**

The major failure in dealing with "misappropriation" is that many countries concerned about such matters have not implemented meaningful ABS legislation in respect of genetic resources, whether held in-situ or ex-situ. Such legislation must be enacted at the national level. The recently concluded Nagoya Protocol should encourage this. The Nagoya Protocol envisions a "check point" mechanism, such as a central ABS authority, that would monitor the transfer of genetic resources at the point of access – and also calls for "proportionate and effective" mechanisms for Parties to assess whether genetic resources being used in their jurisdictions have been accessed with PIC and mutually agreed terms to share benefits.

In addition, there are several proposals before the WIPO Intergovernmental Committee that can contribute in the intellectual property context. For example, the draft guidelines on contractual practices, if agreed as part of an international instrument, would facilitate implementation of benefit-sharing terms in the IP context to directly complement Article 6(g) of the Nagoya Protocol. In addition, the proposal by Japan for a "One-Click Database Search System", composed of a WIPO portal site in combination with existing or yet to be developed databases in WIPO member states containing information about genetic resources, could ease concerns about the inappropriate patenting of genetic resources. These proposals should be further studied and, if agreed, could constitute the core of an international instrument, which builds on the objectives and principles articulated by WIPO members. However, patent disclosure will do little to advance these notions, and yet would have significant negative consequences.

In conclusion, disclosure obligations relating to genetic resources will have few intended and many unintended consequences.

The International Chamber of Commerce (ICC)

ICC is the world business organization, a representative body that speaks with authority on behalf of enterprises from all sectors in every part of the world.

The fundamental mission of ICC is to promote trade and investment across frontiers and help business corporations meet the challenges and opportunities of globalization. Its conviction that trade is a powerful force for peace and prosperity dates from the organization's origins early in the last century. The small group of far-sighted business leaders who founded ICC called themselves "the merchants of peace".

ICC has three main activities: rules-setting, dispute resolution and policy. Because its member companies and associations are themselves engaged in international business, ICC has unrivalled authority in making rules that govern the conduct of business across borders. Although these rules are voluntary, they are observed in countless thousands of transactions every day and have become part of the fabric of international trade.

ICC also provides essential services, foremost among them the ICC International Court of Arbitration, the world's leading arbitral institution. Another service is the World Chambers Federation, ICC's worldwide network of chambers of commerce, fostering interaction and exchange of chamber best practice.

Business leaders and experts drawn from the ICC membership establish the business stance on broad issues of trade and investment policy as well as on vital technical and sectoral subjects. These include financial services, information technologies, telecommunications, marketing ethics, the environment, transportation, competition law and intellectual property, among others.

ICC enjoys a close working relationship with the United Nations and other intergovernmental organizations, including the World Trade Organization, the G20 and the G8.

ICC was founded in 1919. Today it groups hundreds of thousands of member companies and associations from over 120 countries. National committees work with their members to address the concerns of business in their countries and convey to their governments the business views formulated by ICC.
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