

This paper is one in a series of briefing papers by the International Institute for Sustainable Development. Each of the papers focuses on an issue of particular importance for sustainable development in the South in the WTO's current round of negotiations—the so-called Doha Development Agenda. The aim of the series is to set out, in brief and uncomplicated style, what is at stake in those negotiations for those concerned with international development and the environment. The full set of papers, and more information about IISD's work on trade and sustainable development, can be accessed on IISD's Web site at <http://www.iisd.org/trade>.

Prepared by IISD for the Swiss Agency for Development and Cooperation (SDC)

## The TRIPS Agreement and Biological Diversity

### 1. Introduction

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is administered by the World Trade Organization (WTO), requires patents to be available for any inventions—whether products or processes, in all fields of technology—that are new, suitable for industrial application and that involve an inventive step. Patents are particularly important in the life sciences and biotechnology sectors because of the expense of doing research in these fields and the rapid pace of innovation. Consequently, life science and biotechnology firms stand to gain from the agreement.

Another important multilateral agreement is the Convention on Biological Diversity (CBD). The CBD, opened for signature at the 1992 Earth Summit, has as its three objectives:

- i. the conservation of biological diversity;
- ii. the sustainable use of its components; and
- iii. the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies.

The guiding principle of the CBD is that states have sovereign rights and responsibilities with respect to the exploitation of their own resources, including biological and genetic resources.

This paper examines the extent to which the two agreements might be in conflict. One view is that the texts of the two agreements are inconsistent and that in order to reconcile them one or the other will have to be revised. A second view is that while there are no inherent inconsistencies, depending on how they are implemented, policy-makers are still likely to encounter problems in reconciling them. A third opinion is that there are no conflicts at all.

In an effort to allow the reader to reach an informed judgment on these questions, this paper addresses four issues that have been at the heart of the debates: private property and national sovereignty; benefit sharing through appropriate access to genetic resources; benefit sharing through appropriate transfer of technology; and intellectual property and traditional knowledge.

### 2. Private property and national sovereignty

It has been argued that TRIPS rules on the scope of patentable material may violate national sovereignty by giving away rights that are accorded states under the CBD. It is therefore important to understand just what can—and what must—be patented under TRIPS.

Article 27.3(b) of TRIPS allows members to exclude from patentability the following:

- plants and animals other than micro-organisms; and
- essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

However, members shall provide for the protection of plant varieties either by patents or by an effective *sui generis*<sup>1</sup> system, or by some combination of the two. Micro-organisms must be patentable, but plants and animals do not have to be.

Where does this leave genetic and biochemical resources, such as plant genetic material or compounds found in animals? Since they are not expressly excluded, patents must in principle be made available for these.

But this is subject to the conditions noted above: they must be new, involve an inventive step and be capable of industrial application. Do these requirements mean that resources existing in nature cannot be patented? In Europe and North America, which have the most experience in the patenting of such natural substances, there has never been a blanket exclusion of inventions simply because they were not human-made. For example, adrenaline was first patented in 1903 and insulin in 1923. From the 1970s, the scope of patent protection was extended first to micro-organisms and then to DNA sequences, plants and animals.

How can such products, some of which are obviously *discoveries*, be protected by patents as if they are *inventions*? The technical explanation is that patent law treats them as if they are chemical substances, and these have been patentable for at least 150 years. Adding value to a discovery is another way to achieve a patent. The patent laws of Europe and North America allow that, while you cannot claim as an invention something as it occurs in nature, it is often possible to do so if you extract it from nature and thereby make it available for industrial utilization

for the first time. A more certain route is to change the substance or life-form in some way, such as by adding something to it (e.g., a gene), subtracting something from it (i.e., purifying it), mixing it with something else to create a new or synergistic effect, or structurally modifying it so that it differs from what it was before. It also appears to be possible in some jurisdictions to get a patent on a natural substance by being the first to describe it in the language of biochemistry and then suggesting an industrial application.

It has been argued that granting patents on isolated biochemical substances or organisms violates the sovereign rights of countries, since such a patent constitutes a property claim over something to which countries may consider they have sovereign rights.

On the other hand, defenders of patents claim that as long as the system operates correctly, it is impossible to patent something as it exists in nature. Therefore, there can be no violation of sovereignty unless a patent is improperly awarded. Critics claim not only that this sometimes happens, but that it is bound to happen because no patent examination system can realistically filter out every spurious application.

Further, if the substance or organism had not been acquired in accordance with the relevant laws of the source country, and if the latter had not consented to the patenting, such private property claims are arguably a breach of the CBD, according to which: "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies." It can also be argued that, by providing intellectual property rights (IPRs) in such cases, governments are also failing to comply with their obligations under the CBD, in that they fail to recognize national sovereignty.

### **3. Benefit sharing through appropriate access to genetic resources**

The CBD aims to achieve fair and equitable sharing of the benefits arising out of the utilization of genetic resources, on the assumption that this will contribute to the conservation of biological diversity. One of the key means for achieving this objective is establishing systems for access to genetic resources that help ensure fair and equitable benefit sharing. To what extent might this objective be frustrated or supported by the right to patent such resources, as elaborated in the TRIPS Agreement?

Some argue that there is no conflict, but rather synergy, since in the absence of intellectual property protection there would be no benefits to share in the first place. The argument is that patents encourage investment in invention and the research and development needed to turn inventions into marketable innovations. Further, they argue, nothing prevents patents from being used to exploit the market value of an invention in a way

that ensures that the benefits will be shared by many parties. Ownership of the patent could be shared, or it could be held by one party on behalf of the others, in an arrangement that would see them all benefiting from its successful exploitation.

In reality, however, while patents could indeed protect the collective interests of all partners and often do, when it comes to bioprospecting (the search for genetic materials in developing countries, often with the aid of local partners) this very rarely happens. Why is this? In cases where an indigenous community is one of the partners, the problem is that indigenous peoples tend to have a weak bargaining position since they seldom know what legal rights they have under national law and, being poor, would have trouble asserting those rights even if they did. In cases where states themselves are the partners, the problem is that once the resources they have provided leave their borders, it becomes very difficult to prevent recipients from filing patent applications on those resources in foreign jurisdictions without their consent.

### **4. Benefit sharing through appropriate transfer of technology**

The CBD's most explicit link to intellectual property is in the context of technology transfer. Article 16 on access to and transfer of technology requires parties to the Convention to provide and/or facilitate access and transfer of technologies to other parties under fair and most favourable terms. The only technology referred to is biotechnology, though Article 16 is concerned more generally with technologies "that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment."

Access to such technologies must be "on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights." However, Paragraph 16.5 requires the parties to cooperate to ensure that patents and other IPRs "are supportive of and do not run counter to" the CBD's objectives. This wording reflects the profound disagreement during the negotiations on the CBD's text between countries that considered IPRs to conflict with the CBD's objectives and others that saw no conflicts. The key question is: do strong IPRs inhibit or encourage the transfer of these technologies?

Industrial technologies are conventionally transferred through such means as foreign direct investment (FDI), joint ventures and licensing, of which FDI is the main channel. Informal technology transfers can also take place on a large scale and, in those countries in the early stages of industrialization, these may be far greater in number than formal ones.

The relationship between levels of IPR protection and the volume of inward technology flows is complex, and involves many factors whose relative importance varies widely from

one country to another. One argument holds that strong IPRs are a prerequisite for the international transfer of new technologies, at least those that can easily be copied. Companies will be reluctant to transfer technologies that may have cost them millions of dollars to develop to countries where domestic firms can freely adopt the technologies and produce competing goods. The argument goes that the only way companies will feel encouraged to transfer proprietary technologies is if IPR protection is strong enough for them to charge licence fees that reflect the costs of innovation. Alternatively they may operate through FDI or joint ventures, where they maintain more control over their intellectual property.

At the same time, an argument can be made that the *overall* effect of strong IPRs will be to *inhibit* technology transfers. As an intervention in the free market, patents restrict the number of people who could otherwise freely make, use, sell or import the protected products and processes. This enables owners to maintain high prices. Foreign patent owners can use their legal rights either to block access to their technologies or to charge licence fees that are too high for domestic firms. This, the argument goes, inhibits technology transfer and reinforces North-South inequalities. If so, one might argue that the best way for developing country governments to help domestic firms and public institutions acquire technologies might be to weaken patent rights, for example by allowing compulsory licensing<sup>2</sup> on licensee-friendly terms.

In the final analysis, much uncertainty remains as to the effects of IPRs on technology transfers to developing countries. But there is empirical evidence to suggest that these effects depend on the level of development of a country—less developed countries gain less from strong IPRs—and the behaviour and absorptive capacity of individual firms. They also depend on the specific technological fields involved. It is worth noting that while patents are very important in biotechnology, many of the technologies relevant to the conservation and sustainable use of biological diversity are already in the public domain, either because the patents have expired or because they were never IPR-protected anyway. These include various environmentally-friendly, on-farm management techniques such as integrated pest management, as well as tissue culture and some of the early genetic engineering technologies such as recombinant DNA.

The debates over IPRs and technology transfer often overlook the fact that the private sector plays a key role in technology transfer, not least because it holds the vast majority of patents worldwide. Yet it is governments that are required to implement the CBD. Therefore, while governments can act as *facilitators* by, for example, helping to provide financial incentives, funding and appropriate technical assistance so that developing countries are in a position to receive and make best use of technologies transferred to them, the *providers* of technologies will

mostly be companies. Since few developed country governments have been active in this regard, the technology transfer provisions of the CBD have been inadequately implemented.

## 5. Intellectual property and traditional knowledge

Article 8(j) of the CBD requires the parties to do three things:

- i. 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;
- ii. promote their wider application with the approval and involvement of the holders; and
- iii. encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

The language is somewhat vague but has nonetheless provoked much discussion on the relationship between traditional knowledge (TK) and TRIPS, which does not actually mention TK at all. Despite this, many critics of TRIPS have argued that its IPR rules legitimize the misappropriation of traditional knowledge, including knowledge related to biodiversity.

It is undeniable that traditional knowledge is not currently protected by formal IPRs such as patents, copyright and trade secrets. But it is a step beyond that to assert that TRIPS is actually *harmful* to the rights and interests of indigenous peoples and traditional communities. Does this charge ring true?

This question is dealt with in greater depth in another brief in this series, but the heart of the matter is the issue of balance. While TRIPS offers unprecedented protection to formal innovations (such as the outputs from corporate research laboratories), it offers none whatsoever to traditional knowledge (such as seed varieties improved by generations of farmers, or community-held knowledge of medicinal applications of plants). Thus, scientists have been able to patent certain compounds found in a plant called hoodia, which has traditionally been used by certain groups of San (Bushmen) people as an appetite suppressant. But the indigenous groups that showed the scientists how to use the plant were in no position to assert property claims to this knowledge through the intellectual property rights systems. Arguably, this imbalance is unfair both to the traditional knowledge holders themselves and to those developing countries where the presence of such knowledge could potentially provide competitive advantages for their economies.

Aggravating this situation is the broad scope of patentability, discussed above; the patent system nowadays seems to require little in the way of improvement to naturally-occurring

resources for them to become protectable inventions. In effect, the resulting regime—coupled with the prevailing economic incentives—encourages misappropriation of indigenous peoples' knowledge. Businesses have been known to be aggressive in claiming ownership of resources they falsely claim to have discovered or invented, and in defending their rights once these have been granted.

## 6. Implications for developing countries

The preceding sections have made it clear that developing countries have a stake in reconciling the goals of the TRIPS Agreement and the CBD, such that IPRs work in the service of sustainable development and the preservation of biological diversity.

One of the most significant proposals in this vein, put forward by developing country WTO members, is to require patent applicants to disclose the source of biological or genetic material and associated traditional knowledge upon which the claimed inventions were derived, and to provide documentary evidence of compliance with the access and benefit sharing regulations of provider countries (such as regulations on prior informed consent). Such a system, it is argued, would reduce the potential for "biopiracy," or the taking of genetic material or use of traditional knowledge without consent, and would facilitate the CBD-mandated sharing of the benefits of commercial exploitation.

Mandatory disclosure would probably work well for resources with health applications, especially pharmaceuticals. The pharmaceutical industry generally bases its new drugs on single compounds, and tracing the sources of these is not partic-

ularly difficult. But it would not work as well for plant varieties, which can be patented in some countries. Plant genetic material may come from numerous sources, some of which may no longer be identifiable because of the lack of documentation and the length of time between its acquisition and its use in breeding programs.

Another avenue by which IPRs might better serve conservation of biological diversity in developing countries is through projects aimed at sustainably utilizing the components of biological diversity. Well-designed patent regimes could, at least in theory, help such countries add value to their genetic resources, rather than sell them as raw materials to be processed elsewhere. Two ways to achieve such value added would be to (i) bring to market lucrative, new science-based products; and (ii) more effectively identify, develop and market high-value primary and semi-processed products. In addition, trademarks and geographical indications may serve as useful legal tools to promote the marketing of new products based on genetic resources such as foods and beverages. Most developing countries have little experience in using these IPRs and would have much to gain from technical assistance in both intellectual property policy-making and in the use of IPRs as marketing tools.

### Endnotes

- 1 A *sui generis* system implies a special system. *Sui generis* means "of its own kind." In this case it would be a system specifically designed to protect plant varieties.
- 2 Compulsory licensing is the compulsory transfer of patent rights at a price set by the government.

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