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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.

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Traditional Knowledge and Patentability

1. Introduction

Traditional knowledge is information, skills, practices and products—often associated with indigenous peoples—which is acquired, practiced, enriched and passed on through generations. It is typically deeply rooted in a specific political, cultural, religious and environmental context, and is a key part of the community's interaction with the natural environment.

At the global level, minimum standards and criteria for patent protection are established by the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement). Although the TRIPs Agreement does not directly address traditional knowledge, the subject matter requirements and the nature of the rights conferred to patent owners do have implications for indigenous groups in the protection of traditional knowledge. These are further explored below.

Article 27 of the TRIPs Agreement requires member countries to make patents available for innovative products or processes in all fields of technology, provided that the minimum criteria of novelty, inventiveness and industrial applicability are satisfied. Article 27.3(b) also requires protection for plant varieties, either under a patent system, or through other *sui generis* protection.[1] In industrialized economies, patents are a tool for rewarding innovative endeavours with a profitable temporary monopoly, and the patent grant serves as a powerful incentive to undertake research and to commercialize its results. Since the TRIPs Agreement allows members to grant patents, plants and other life forms, a strong incentive exists for research to be conducted in biodiversity-rich areas of the world, particularly since plant-based therapies, domestic seeds and their associated research and inventive effort have emerged as an important element of the success of modern medical/agricultural biotechnology. It is here that the incentive effects of patent rights connect most directly with traditional knowledge, which includes medicinal/agricultural practices based on knowledge of the natural environment—especially plants—to treat members of the community, usually as part of survival, common uses, rituals and sacred practices.

2. What are the issues?

There are two main issues in the relationship between the TRIPs Agreement and traditional knowledge.

a. Property Rights, the Culture of Ownership and Traditional Knowledge

Within some indigenous groups, traditional knowledge is systematized and regulated by certain members of the group. Frequently, however, traditional knowledge is not "owned" by anyone, in a Western sense of the word. It is used and developed for the benefit of the entire community, and the idea of exclusive proprietary use of such knowledge for individual profit is objectionable to many traditional knowledge holders.

Further, opponents of patent protection for traditional knowledge have argued that such protection will ultimately undermine the processes by which the knowledge has historically been acquired, preserved and used in the indigenous community. That is, the historical basis for development of traditional knowledge was an understanding that it would be used for the community's benefit. The concepts of individual profit and exclusive ownership may erode that understanding, resulting in the arrested development of the knowledge base. The same concern has been raised with respect to the protection of traditional knowledge through copyright and trademarks.

b. Appropriation of Traditional Knowledge

Another issue at the intersection of traditional knowledge and TRIPs-style patent protection is the appropriation of traditional knowledge by researchers, scholars and institutions from outside the community with neither the consent of the community, nor agreements to share benefits arising from the use of the knowledge. These actors are usually, but not always, from the developed world. Even when access to traditional knowledge has been authorized, the critical issue is whether the communities that are the source of that knowledge have been compensated at all and, if so, whether the levels of compensation were fair. Too often they are not fairly compensated, though they are the primary source of at least *some* of the intellectual capital and raw materials used in developing the patentable product or process.

Traditional communities are generally at a disadvantage when dealing with "bioprospectors"—those who search for and harvest medicinal plants, agricultural plant varieties and genetic resources for commercial purposes, and who require the communities' help and knowledge. Often the communities have no understanding of the commercial value of the knowledge they are asked to disclose, nor do they have the skills to negotiate fair

terms for such disclosure should there be an opportunity to share in the economic benefits of any resulting commercialization of the knowledge.

It should be noted that valuable services may be rendered whether or not a patent is ultimately granted. For example, traditional knowledge may simply inform researchers of what might not be a viable research path. However, even such negative knowledge has some economic value since it can give a firm a head start in the research phase of product development. Judicial decisions in some developed countries have recognized the value of these so-called "blind alleys" in calculating monetary damages for misappropriation of proprietary interests.

3. Alternatives to the TRIPs model

The TRIPs Agreement is only one of many existing institutional models for addressing the protection and fair treatment of traditional knowledge. Indeed, one of the key difficulties in advancing this objective is the multitude of actors and institutions that have partial, sometimes overlapping approaches and mandates, and the lack of coordination among them. The WTO was discussed above, and this section deals in more detail with the new Treaty on Genetic Resources for Food and Agriculture, the UN Food and Agriculture Organization (FAO) and the Convention on Biological Diversity. Others include the World Intellectual Property Organization (WIPO) (addressing legal options for the defensive and positive protection of traditional knowledge), the World Health Organization (issues of traditional medicine), the United Nations Educational, Scientific and Cultural Organization (addressing protection for folklore and cultural heritage), the United Nations Conference on Trade and Development (addressing the protection of traditional knowledge in relation to the TRIPs Agreement) and the United Nations Sub-Committee on Human Rights (examining human rights implications of the TRIPs Agreement, including issues of traditional knowledge protection). If the goal is an effective and fair multilateral system, this scattering of institutional responsibility will be one of the foremost obstacles.

Two alternate existing models to protecting and fairly treating traditional knowledge are surveyed in this section: the Convention on Biological Diversity (CBD) and the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture.

a. The Convention on Biological Diversity

There is an ongoing debate about the relationship between the patent requirements of the TRIPs Agreement and the substantive obligations of the Convention on Biological Diversity (CBD). The CBD, among other things, provides for the sovereign rights of a country over its plant and animal life, as well as its genetic resources. The CBD also provides that access to genetic resources should be subject to prior informed consent of the authorities of the countries (including the consent of traditional communities) and that there should be fair and equitable sharing of the benefits that flow from the commercialization of traditional knowledge or products that incorporate traditional knowledge.

These last two provisions in particular are not provided for in the TRIPs Agreement. In the course of the ongoing review of the Agreement's Article 27.3(b), it has been suggested that a precondition for granting of a patent should be a proof of the existence of prior informed consent and benefit-sharing agreements where the patent involves the use of traditional knowledge, as well as a the disclosure of origin of biological resources used or incorporated in patents for products or processes.

Most of these proposals have come from developing countries, but there is no consensus among them on the wisdom of renegotiating 27.3(b), since there are a number of risks as well as potential benefits. For example, the current negotiations could well result in the deletion of the exceptions to patentability and narrowing down of definition of what is to be understood as a *sui generis* system. In such cases most developing countries would agree that they were worse off than under the flexible ambiguity of the existing language.

Developed countries have objected to these proposals, arguing that they would unduly burden the patent process and that the TRIPs Agreement is the wrong forum for this type of protection for traditional knowledge. In part this argument stems from a conviction that traditional knowledge is not and should not be covered by the TRIPs Agreement. Countries supporting this position identify a number of obstacles to intellectual property protection for traditional knowledge, including the difficulty of identifying ownership (most traditional knowledge is held by the community at large), the long period of time the knowledge has existed (intellectual property rights are protected for a limited time), and the requisite legal standards for intellectual property protection (such as novelty and non-obviousness in patent law) which some traditional knowledge may not easily satisfy. The counter-argument is that, administrative difficulties notwithstanding, TRIPs *should* cover traditional knowledge which, like intellectual property, is the product of intellectual activity, innovation, creativity, ingenuity and a rudimentary form of R & D.

More generally, opponents of traditional knowledge protection in the TRIPs Agreement argue that the basis for intellectual property protection is increasingly utilitarian, while traditional knowledge protection would have to account for the social and religious aspects of that knowledge base in the traditional community. Thus, the argument is that the goals of the CBD can be facilitated by protecting traditional knowledge differently from modern intellectual property, rather than viewing the goals of the CBD and TRIPs in a holistic fashion.

b. The International Undertaking on Plant Genetic Resources and the International Treaty on Genetic Resources for Food and Agriculture

In 1983, the International Undertaking on Plant Genetic Resources (IU), a multilateral instrument administered by the Food and Agriculture Organization (FAO), declared that plant genetic resources and plant-related innovations are the common heritage of mankind. The IU preserves the principle of open access to international gene banks which hold seeds in trust for public benefit. These gene banks provide access to samples in their collections for research purposes, but preclude users from acquiring intellectual property rights in any materials distributed. The strong emphasis placed on intellectual property rights in leading developed countries to stimulate research and encourage private investment in creative activity prevented those countries from signing the IU.

In 2001, a new treaty on plant genetic resources was created: the International Treaty on Plant Genetic Resources for Food and Agriculture (IT). This treaty, which is supported by many developed and developing countries, establishes a new system of access to seeds of specified food and feed crops that comprise the bulk of human nutrition. In exchange for access to these seeds, private parties who create commercially viable products from these banks must pay a percentage of their profits into a trust account, unless the product is made freely available for use in further research and breeding. The funds from the trust account are to be used to facilitate benefit-sharing to farmers in developing countries, and the conservation of plant genetic resources. In this regard, this new treaty accords "public domain" status to specific genetic material and seeks to establish a means to preserve the earth's genetic riches.

The new IT treaty addresses traditional knowledge issues in several respects. First, it provides for farmers' rights and their traditional knowledge in farming practices. Article 9.2 of the IT treaty provides that it is the responsibility of national governments to take appropriate measures to protect farmers' rights which include, *inter alia*: "(a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture; (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture." It is, however, unclear whether these rights are undercut by the TRIPs Agreement in light of the next paragraph: "Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-seed/propagating material, subject to national law and as appropriate."

Second, it is unclear whether traditional knowledge is subject to information databases on plant genetic resources which are part of the new multilateral system. If they are, then traditional knowledge with respect to genetic resources may have been cast into the public domain under the terms of the treaty. If so, proposals to protect traditional knowledge either through the grant of intellectual property rights, or through a *sui generis* system, will have to occlude knowledge which is covered by the IT system (assuming the treaty is ultimately ratified).

Third, the new IT treaty does not specifically provide for benefit sharing to go to the indigenous communities directly. Although the objective is for farmers in developing countries to benefit from the system, it is not clear what mechanism will ensure that this in fact occurs.

4. Other models

A variety of other legal mechanisms for the protection of traditional knowledge have been proposed. Prominent among these are proposals for a *sui generis* regime consisting either of a benefit-sharing system or a "misappropriation model." The benefit sharing system would require some of profits made from the commercialization of traditional knowledge to be remitted to the "owners" of the knowledge. A misappropriation model would imply the revocation of patents and other intellectual property rights over traditional knowledge obtained without the consent of the title holders of that knowledge.

Ongoing patent harmonization efforts at the World Intellectual Property Organization (WIPO) may make it difficult to address the protection of traditional knowledge using the patent system. The Substantive Patent Law Treaty currently under negotiation will represent a multilateral agreement on the granting of patents. There is currently a controversy over whether it should contain requirements on disclosure of origin, and general exceptions from patentability based on preserving public interest (to be decided by national level authorities). If this is not addressed during negotiations (a definite possibility) it will eliminate—at least in the foreseeable future—the possibility of national-level requirements that patent applicants disclose the origin of plants or other genetic material, and certify prior informed consent for use of traditional knowledge. Further, countries that now include this provision in their domestic patent laws may be forced to strike the provision as a condition of membership in the treaty.

5. Implications for sustainable development

Sustainable development in the context of traditional knowledge and patents has both institutional and substantive aspects. With regard to substantive issues, the developing countries' ability to regulate access and use of genetic resources and protection of traditional knowledge is critically important to development on a number of levels. It is a prerequisite to the economic returns that may accrue under benefit-sharing

arrangements—arrangements that may allow traditional communities the financial resources to choose to maintain their traditional lifestyles. Depending on the arrangement in question, it may also end up by paying traditional communities to maintain biodiversity by acting as stewards.

On the institutional side, the shape of the actual benefits sharing arrangements will be key. It was argued above that certain types of arrangements, depending on the community where they are introduced, may have the effect of stifling the traditional process of informal innovation, which would work against the benefit of the community as a whole. In general, any system of benefit sharing will have impacts on the existing social structures and the distribution of power and resources within them. The fact that traditional societies have a multitude of different social structures makes this consideration difficult to address when designing a benefits sharing system, but no less important from a sustainable development perspective.

Some developing countries have already enacted domestic laws dealing with the protection of traditional knowledge. There are also important legislative efforts that have taken place at regional levels. As well, the Plan of Implementation of the World Summit on Sustainable Development (WSSD) (paragraph 42(j)) calls on countries to, "subject to national legislation, recognize the rights of local and indigenous communities who are holders of traditional knowledge, innovations and practices," and "develop and implement benefit-sharing mechanisms on mutually agreed terms for the use of such knowledge, innovations and practices."

However, without some international agreement that recognizes and affords protection to this body of knowledge, unilateral efforts alone will not sufficiently harness the value of traditional knowledge for development objectives. In fact, even multilateral arrangements between developing countries will not suffice, since the exploitation of the knowledge and resources takes place largely in developed countries. The absence of an international agreement will affect opportunities for developing countries and traditional communities to control, manage and benefit from traditional knowledge. This was recognized to be the case for genetic resources as a whole in the WSSD Plan of Implementation, which called on countries to negotiate, under the framework of the CBD, "an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources."

It has been widely recognized that the issues of traditional knowledge and patentability need to be addressed as a key component of sustainable development. The complications of many ongoing overlapping processes, and the complexity of the issues involved, do not diminish the final value of addressing those issues in a comprehensive manner, and in a way that promotes equity, social values and environmental integrity.

Endnote

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.

The International Institute for Sustainable Development contributes to sustainable development by advancing policy recommendations on international trade and investment, economic policy, climate change, measurement and indicators, and natural resource management. By using Internet communications, we report on international negotiations and broker knowledge gained through collaborative projects with global partners, resulting in more rigorous research, capacity building in developing countries and better dialogue between North and South.

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