



Some Interrelationships Between the TRIPS Agreement and the Convention on Biological Diversity

Introduction

The interrelationships between the Convention on Biological Diversity (CBD) and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) have given rise to a debate on the links between intellectual property rights and the use and conservation of genetic resources. This debate has occupied the international centre stage for almost a decade now. Developing countries tend to view the provisions of the CBD as a means to ensure that the appropriation of genetic resources through intellectual property rights mechanisms - as granted under the TRIPS Agreement - is done in a manner that is not detrimental to their interests. Several provisions under the CBD, such as those that call for protection of traditional knowledge, regulation of access to genetic resources, technology transfer, and fair and equitable benefit sharing, can help further the interests of developing countries. However, resolving the interface between these provisions and those in the TRIPS Agreement, and implementing them at the national level in developing countries in a manner conducive to development, have been very difficult to realize. This is due to both varying national interests that play out in international negotiations and the lack of institutional capacity in developing countries.

This Brief addresses three main issues in the TRIPS-CBD relationship. These are protection of traditional knowledge, technology transfer in the field of biotechnology pursuant to CBD provisions, and the impact of Paragraph 19 of the Doha Declaration on the TRIPS Agreement and Public Health, which calls upon Member Countries to look at the relationship between the TRIPS Agreement and the CBD on protection of traditional knowledge, as well as other emerging developments. These issues have been chosen on the basis of their importance to developing countries and timeliness for policy negotiations on the TRIPS-CBD interface.

Graham Dutfield (page 2) looks at some outstanding issues relating to the protection of traditional knowledge. After highlighting the economic importance of traditional knowledge, he sets out the distinction between positive protection and defensive protection mechanisms. Since each system has relative merits and demerits, the best option for each country might be to choose a combination of the two, keeping in mind the specific characteristics of their indigenous and local communities.

While a number of provisions in the CBD call for the transfer of technology - and several developing countries have taken steps to build local capacity in the biotechnology field - there has not been much progress in building such partnerships on the ground. *Kent Nnadozie* and *Robert Lettington* (page 5) address the implications of the TRIPS-CBD interrelationships for biotechnology-related capacity building and technology transfer and the limitations they place on the implementation process.

On the question of how developing countries can make headway with regard to these issues, *Carlos Correa* (page 8) explores the impact of Paragraph 19 of the Doha Declaration on resolving issues arising out of these interrelationships. He makes the case that little progress has been made on critical issues, including the protection of traditional knowledge, and the origin of disclosure requirements. He also suggests ways in which developing countries can use Paragraph 19 to address these issues more effectively. Such improvements can be very significant in light of the "July Package" of the Doha Work Programme adopted by the WTO Council Decision on 01 August 2004, which reaffirmed Members' continuing commitment to progress in further negotiations in line with the Doha mandates.

Outstanding Issues in the Protection of Traditional Knowledge

Traditional knowledge, and its relationship to the formal intellectual property system, has emerged as a core issue in international negotiations on the conservation of biological diversity, international trade, and intellectual property rights (IPRs). In the past few years, high-level discussions on the subject have taken place at the WTO, the Conference of the Parties to the Convention on Biological Diversity (CBD), and at the World Intellectual Property Organization (WIPO), which has established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). At these fora several developing national governments have adopted the view that traditional knowledge needs to be legally protected and have criticized the formal intellectual property rights system for legitimizing the misappropriation of these resources.

The mainstreaming of this issue is undoubtedly linked to a better understanding of the wealth-generating potential of traditional knowledge. Traditional peoples and communities are responsible for the discovery, development, and preservation of a tremendous range of medicinal plants, health-giving herbal formulations, and agricultural and forest products that are traded internationally and generate considerable economic value. Traditional knowledge also constitutes an input into modern industries such as pharmaceuticals, botanical medicines, cosmetics, agriculture, and biological pesticides.

All this suggests that traditional knowledge plays an important role in the global economy and has the potential to play an even greater one. However, the industrial demand for traditional knowledge should not be overestimated. While enhanced abilities to screen and analyse huge quantities of natural products might suggest that commercial ethnobiology will become more popular, it seems more likely that advances in biotechnology and new drug discovery approaches based, for example, on combinatorial chemistry, genomics, and proteomics will in the long term *reduce* industrial interest in natural products and their associated traditional knowledge.

Solutions to the protection of traditional knowledge in IPR law may be sought in terms of "positive protection" and "defensive protection". Positive protection refers to the acquisition, by the traditional knowledge holders themselves, of an IPR such as a patent or an alternative right provided in a *sui generis* system. Defensive protection refers to provisions

adopted in the law or by the regulatory authorities to prevent IPR claims to knowledge, a cultural expression, or the granting of a product to unauthorized persons or organizations. Two important proposals have come out of international negotiations to provide defensive protection of traditional knowledge through the patent system. The first is to require patent applicants to disclose the origin of genetic resources and associated traditional knowledge relevant to the invention and, according to one variant of the proposal, to provide proof that regulations governing the transfer of the resources and associated traditional knowledge were complied with. The second is to compile databases of published information on traditional knowledge for patent examiners to identify potentially novelty-destroying prior art.

To many countries and non-governmental organizations defensive protection is necessary because the intellectual property rights system, especially patenting, is considered defective in certain areas, and allows companies to unfairly exploit traditional knowledge. It may also be argued that defensive protection may be more achievable than positive protection. This is because some of the most commonly discussed defensive protection measures are basically enhancements to, or modifications of, existing property rights. Effective positive protection will likely require a completely new system, and the active and committed participation of governments.

At least two important questions arise in the negotiation and implementation of legal solutions. First, should initial efforts be devoted to developing a national *sui generis* system, in order to gain experience that makes it easier to determine what a workable international solution should look like? Linked to this is the question of whether a multilateral settlement should be a pre-condition for the effective protection of the rights of traditional knowledge holders within a country. Second, how might concerned countries overcome the limited ability of national *sui generis* systems to protect traditional knowledge (the fact that they have no extra-territorial effect)?

While each country will no doubt come up with good reasons to answer these questions differently, there seems to be a consensus among countries supporting *sui generis* systems of positive protection, and groups representing traditional knowledge holding communities. They agree that the problem with having a national system, in a world where few such systems exist, is that no matter how effective it may be at the domestic level, it can have no extra-territorial effect. Consequently, traditional knowledge right holders would not be able to secure similar protection abroad, and exploitative behaviour in other countries would go on as before.

There may be a way out of this problem. If a number of concerned countries decided to act strategically as a group, some interesting possibilities could emerge. Members of such a group could agree upon harmonized standards and then apply the reciprocity principle so that protection of traditional knowledge would only be extended to nationals of other group members. Of course, the group should not be an exclusive club. Other interested countries should also be able to join, subject to their enactment of similar legislation. As a new category of intellectual property not specifically provided in TRIPS, the members would presumably not have to comply with the most-favoured nation (MFN) principle.

Such a coalition of countries has recently been formed. In April 2002 the Government of India, in co-operation with UNCTAD, held an international seminar on traditional knowledge in which representatives from Brazil, Cambodia, Chile, China, Colombia, Cuba, Egypt, Kenya, Peru, Philippines, Sri Lanka, Thailand, Venezuela, and India participated. At the end of the meeting the group issued a communiqué, which noted that while national sui generis systems "provide the means for protection and growth of traditional knowledge within national jurisdictions", these were inadequate to fully protect and preserve traditional knowledge. But as the participants went on to explain:

the ability of patent offices in a national jurisdiction to prevent bio-piracy as well as to install informed consent mechanisms to ensure reward to traditional knowledge holders, does not ipso facto lead to similar action on the patent application in other countries.

A need was therefore expressed for an international framework for protecting traditional knowledge. The following components of a framework for international recognition of various sui generis systems and customary laws to protect traditional knowledge were suggested:

- a) local protection for the rights of traditional knowledge holders through national level sui generis regimes, including customary laws, and their effective enforcement through, among other mechanisms, the positive comity of protection systems for traditional knowledge;
- b) protection of traditional knowledge through registers of traditional knowledge databases in order to avoid misappropriation;
- c) a procedure to only allow for the use of traditional knowledge in another country - particularly for seeking IPR protection or commercialization - once the competent national authority of the country of origin has certified that the source of origin has been disclosed and prior informed consent, including acceptance of benefit sharing conditions has been obtained; and

- d) an internationally agreed-upon instrument that recognizes such national level protection. This would not only prevent misappropriation but also ensure that national level benefit sharing mechanisms and laws are respected worldwide.

But harmonizing national traditional knowledge protection standards can only go so far. In 1996 the Four Directions Council, a Canadian indigenous peoples' organization, submitted a paper to the Secretariat of the Convention on Biological Diversity, which pointed out that:

Indigenous peoples possess their own locally-specific systems of jurisprudence with respect to the classification of different types of knowledge, proper procedures for acquiring and sharing knowledge, and the rights and responsibilities which attach to possessing knowledge, all of which are embedded uniquely in each culture and its language.¹

For this reason, as the Four Directions Council expressed it:

Any attempt to devise uniform guidelines for the recognition and protection of indigenous peoples' knowledge runs the risk of collapsing this rich jurisprudential diversity into a single "model" that will not fit the values, conceptions or laws of any indigenous society.²

It is therefore inappropriate for countries to come up with a one-size-fits-all sui generis system. New international norms will have to be flexible enough to accommodate this jurisprudential diversity or risk failure. Close collaboration with traditional knowledge holders and their communities is essential in the design of the sui generis system. This point cannot be over-emphasized.

Groups and individuals that have control over their own destinies are far better placed to benefit from legal protection of their knowledge. For example, indigenous groups empowered with rights to control access to their lands and communities have a better chance of preventing misappropriation of their knowledge and negotiating favourable bioprospecting arrangements. But in all too many cases, indigenous groups and traditional knowledge holders suffer from extreme poverty, ill health, unemployment, lack of access to land and essential resources, and human rights violations - factors that undermine full empowerment. As a consequence, human cultural diversity, of which their knowledge is an essential part, is eroding at an accelerating pace as the world becomes more biologically and culturally homogeneous. According to the IUCN Inter-Commission Task Force on Indigenous Peoples:

Cultures are dying out faster than the peoples associated with them. It has been estimated that half the world's languages - the storehouses of peoples' intellectual heritages and the framework for their unique understandings of life - will disappear within a century.³

This suggests that measures to protect TK and the rights of the holders, custodians and communities need to be implemented with some urgency. As the late Darrell Posey so poignantly expressed it:

*With the extinction of each indigenous groups, the world loses millennia of accumulated knowledge about life in and adaptation to tropical ecosystems. This priceless information is forfeited with hardly a blink of the eye: the march of development cannot wait long enough to even find out what it is about to destroy.*⁴

Yet this tragedy is not inevitable. As Posey explained:

*If technological civilization begins to realize the richness and complexity of indigenous knowledge, then Indians can be viewed as intelligent, valuable people, rather than just exotic footnotes to history.*⁵

It may be reasonably argued that the legal protection of traditional knowledge will further diminish the public domain and is thus undesirable. But it has to be pointed out that not all traditional knowledge is in the public domain. Second, the placement of knowledge into the public domain without the consent of knowledge holders does not in itself extinguish the legitimate entitlements of the holders and may in fact violate them. Third, the question of how traditional knowledge typically enters the public domain cannot be overlooked. It has not been common practice to place traditional knowledge in the public domain, and to disseminate it with the prior informed consent of the knowledge holders, while taking into account their customary laws and regulations on access, use, and distribution of knowledge. All these factors underline the urgent need to develop effective mechanisms to protect traditional knowledge.

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Endnotes

¹ Four Directions Council. 1996. "Forests, Indigenous Peoples and Biodiversity: Contribution of the Four Directions Council"

² Ibid.

³ Inter-Commission Task Force on Indigenous Peoples. 1997. "Indigenous Peoples and Sustainability: Cases and Actions", Utrecht: IUCN and International Books, p. 60.

⁴ Posey, D.A. 2002. "Indigenous Knowledge and Development: an Ideological Bridge to the Future", in Kayapó Ethnoecology and Culture. K. Plenderleith, ed. London and New York: Routledge, p. 59.

⁵ Ibid.

Some Terms Used in this Brief

The Agreement on Trade Related Aspects to Intellectual Property Rights (TRIPS) 1995, is one of the annex agreements to the agreement that established the World Trade Organization in the Uruguay Round of negotiations in 1995. It deals with standards of intellectual property protection that have to be provided by all WTO Members, subject to recognized exceptions.

The Convention on Biological Diversity (CBD) 1993, is an agreement that deals with issues of conservation of biological diversity, the sustainable use of its components and the fair and equitable benefit sharing arising from the utilization of genetic resources (Article 1). It also recognizes the rights of indigenous and local communities over traditional knowledge, innovations and practices, subject to national legislation (Article 8(j)) and the sovereign rights of States to determine access to genetic resources (Article 15). The full text of the Convention is available at www.biodiv.org/convention/articles.asp

The Conference of the Parties (COP) is a bi-annual review mechanism of the CBD.

The Doha Declaration on the TRIPS Agreement and Public health (WT/MIN(01)/DEC/2, 20 November 2001) was proposed by developing countries, and confirms that the TRIPS Agreement should not prevent Members from adopting measures necessary to protect public health, particularly to ensure access to essential medicines. It also expressly recognized the WTO Members' right to use flexibilities embedded in the TRIPS Agreement, such as compulsory licenses and parallel imports to support their public health objectives.

'**Prior art**' is the criteria applied by patent offices to judge novelty, one of the three main criteria of patentability. The idea being, if an invention is novel, the information that forms the basis of the invention should not be available in the public domain. According to The World Intellectual Property Organization, WIPO, "...[t]he term "prior art" generally refers to the entire body of knowledge which is available to the public before the filing date or, if priority is claimed, before the priority date, of an application for certain industrial property titles, principally patents, utility models and industrial designs."

(Source: WIPO, "Progress Report on the Status of Traditional Knowledge as Prior Art", Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Second Session, Geneva, 10-14 Decemeber, 2001).

Implications of the Inter-relationships between TRIPs and the CBD for Biotechnological Capacity Building and Technology Transfer

■ Introduction & Context

The Convention on Biological Diversity (CBD) clearly recognizes that the linkage between Intellectual Property Rights (IPRs) and technology transfer plays an important role in the fulfilment of its objectives. Article 16 (5) acknowledges that "patents and other intellectual property rights may have an influence on the implementation of this Convention". Article 16(2) provides that access to and transfer of technology subject to patents and other IPRs shall be provided on terms "which recognize and are consistent with the adequate and effective protection of intellectual property rights". At the same time, this obligation is subjected to the proviso in Article 16(5) that Parties shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of, and do not run counter to, CBD objectives.

However, a range of views have been expressed on this subject and there has been much debate within the CBD, the World Trade Organization (WTO) and elsewhere on the role of IPRs in the transfer and dissemination of technology to the developing world, whether for biodiversity conservation and sustainable use or for achieving broader development goals. While some view IPRs as an obstacle to transferring technology, others believe that they are a necessary condition for the voluntary transfer of technology.

Although the CBD does not define what technology transfer entails, it recognizes in Article 1 that one of the means of achieving its objectives is through appropriate transfer of relevant technologies, taking into account all rights over those resources and technologies. However, the effectiveness or otherwise of the relevant provisions in the convention is closely linked to the implementation of the WTO agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which largely sets the global minimum standards for the grant and ownership of rights over technological innovation amongst other categories of IPRs.

■ Nature of the Obligations for Technology Transfer

Several provisions of the CBD contain technology transfer requirements - including Articles 1 (Objectives), 16 (Access to and Transfer of Technology) and 19 (Handling of Biotechnology and Distribution of its Benefits), as well as articles 12 (Research and Training), 17 (Exchange of Information) and 18 (Technical and Scientific Cooperation). In addition, technology transfer is listed as one of the objectives of the Bonn Guidelines,¹ for ensuring fair and equitable benefit-sharing in the responsibilities of users of genetic resources, as well as providing a type of non-monetary benefit that may be shared. Under Article 16, Parties commit themselves to provide and/or facilitate access to, and transfer to other Contracting Parties, of technologies that are relevant to the conservation and sustainable use of biological diversity. They also endeavour to make use of genetic resources that do not cause significant damage to the environment.

The TRIPS agreement equally recognizes in Article 7 that IPRs should contribute to the "transfer and dissemination of technology." Article 8 states that measures may need to be taken to prevent the abuse of IPRs, including practices that "adversely affect the international transfer of technology". Article 40 includes provisions to prevent anti-competitive practices in contractual licences. Article 66.2 obliges developed countries to provide incentives to their enterprises and institutions to promote technology transfer to least developed countries (LDCs) in order to "enable them to create a sound and viable economic base".

Among the issues raised by both the CBD and TRIPS provisions that have provoked much discussion is whether the objective set out in both agreements that IPRs should contribute to the transfer of technology is achievable, particularly in respect of developing country members. While the provisions on technology transfer in the CBD are quite broad, they leave the implementation up to the Contracting Parties and do not provide legal means for enforcement or compliance. Furthermore, although binding, in actual implementation they tend to be voluntary in nature being based largely on "mutually agreed terms."

While the provisions of the TRIPS agreement spell out certain obligations on the part of members in the implementation of the agreement, they echo the corresponding provisions in the CBD in failing to provide operational stipulations for compliance or for enforcement. This is unlike the provisions that protect rights or seek to enforce other obligations. In this

regard, it has, in fact, been argued that while barriers to investment are coming down rapidly and capital is becoming highly mobile in the ongoing process of globalization, the mobility of other factors of production such as technology is becoming increasingly restricted.² One of the problems identified as being responsible for this is that there are no internationally agreed rules for facilitating transfer of technology despite the fact that it is specifically provided for in these and other recent international agreements - from Climate Change to the International Treaty on Plant Genetic Resources for Food and Agriculture. Notwithstanding these provisions, the issue of technology transfer is extremely complex and the major challenge faced by all parties is how to ensure that these "transfer and diffusion" provisions are given effect and translated into practice.

■ **Transfer and Relevance of Biotechnology**

Biotechnology has given rise to some of the most contentious aspects of the technology transfer debate as well as the CBD-TRIPS nexus. While biotechnology is inextricably linked to international trade, IPRs are critical to the large investments that have driven its development. Proprietary claims cover much of new biotechnologies largely restricting access to them and, therefore, their transfer and use. Furthermore, the use of genetically modified crops and related technologies in developing countries is intensifying the continuing debate on the right of developing countries to have access to technology and to make technology choices. It also raises questions related to Biosafety and the Precautionary Principle, in addition to other complex legal and ethical issues.

The use and application of products and processes of biotechnology is rapidly increasing globally and will continue to be a significant factor in the conservation and use of biodiversity, especially in food and agriculture. However, there is still much debate about the value and appropriateness of biotechnology as a platform, both for the fulfilment of the objectives of the CBD, and for achieving broader development goals, including the transfer of related technologies. The safe and sustainable application of biotechnology depends to a large extent on the capacity of the transferee to understand, adapt, deploy and use the technology to derive the maximum benefits, while minimizing the possible adverse effects. Current modes of transfer of biotechnology are often criticized for not paying due regard to the relevance of the technologies transferred, and the absorptive and adaptive capacity of the recipients. This, it is feared, could lead to adverse results or, at best, end up being a wasteful

venture. It is therefore crucial to fully involve recipient countries at all stages of technology acquisition. To this end, effective and participatory technology transfer can only be achieved if it is demand-driven, based on the needs and circumstances of the recipient, as well as being ecologically and culturally appropriate.

■ **Capacity Building**

A core issue in technology transfer relates to the capacity of countries to adopt and absorb technology, and to maintain the necessary infrastructure for its use and further development. Most potential recipients of modern technology lack the requisite array of capacities, ranging from business, legal and financial expertise, to knowledge in both the social and 'hard' sciences (including genetic engineering). Building capacity for technology transfer requires a comprehensive strategy and a good understanding of the systemic nature of this process. Enhancing human resource capacity is insufficient in itself without the appropriate policy environment and adequate infrastructure for the adoption, adaptation, diffusion and long-term sustainability of technology.

The current programme of work adopted by the seventh meeting of the Conference of the Parties to the CBD (CBD COP-7) held in Kuala Lumpur, Malaysia, is grouped under four programme elements, with capacity building or enhancement being addressed under element 4. Capacity building programmes will be required to be based on needs and priorities identified by countries, to foster enabling environments for technology transfer and cooperation, and in particular with regard to building policy, legal, judicial and administrative capacity.

■ **Modes of Technology Transfer**

Without doubt, the process of generation, sharing and dissemination of technology is complex and sometimes costly. Finding appropriate new mechanisms, including bioprospecting arrangements, through which technologies can be successfully and effectively transferred is an ongoing challenge for parties to the both the CBD and TRIPS. The conditions under which bioprospecting contracts contribute to technology transfer, for instance, need to be systematically documented. The complexity and the rapid nature of developments in technology, especially biotechnology, means that finding the appropriate means as well as the right technologies to fit the needs of each recipient is equally challenging. In respect of technologies protected by IPRs, there are several formalized means of transfer, including foreign direct investment (FDI), joint ventures, through wholly owned subsidiaries, licensing, technical-service arrangements, joint R&D

arrangements, technical assistance, training, information exchanges, sales contracts, and management contracts. While licensing has been one of the more traditional routes through which technology transfer occurs, it has been reported that FDI in one form or another accounts for over 60 percent of technology transfer flows to developing countries.

Transfer of technology was one of three priority areas discussed at the CBD COP-7. The COP adopted decisions that put forward elements of a work programme on facilitating the transfer of and access to technology. This programme of work spells out a number of strategic considerations to be taken into account in its implementation by the various actors. The elements stress the need to create enabling environments, including appropriate IPR regimes, for the transfer as well as absorption, adaptation and diffusion of technologies. As stated, the language of the CBD in respect of technology transfer is generally vague and this vagueness tends to permeate the decisions of its Conference of Parties. As a result the programme of work still lacks the enforcement or compliance mechanisms required to give them effect. The positive affirmation of principles in a number of areas is largely qualified or diluted by provisos or made subject to parties' discretion. This situation has always been rationalized on the grounds, *inter alia*, that technology is mostly privately held (usually protected by IPRs) and therefore governments cannot make rules requiring or compelling its transfer. Typically, the result is a largely voluntary or discretionary set of stipulations.

■ Major Obstacles to Technology Transfer

There are major obstacles preventing the full realization of the transfer of appropriate technologies that can fulfil the goals and objectives of the CBD as well as implement the relevant provisions of the TRIPS agreement. Of considerable import is the impact of private interests, which play a significant role in the positions of governments during negotiations and in the course of national implementation of the relevant agreements. An often cited explanation for the difficulty in facilitating technology transfer is the fact that technology is mostly in private hands and governments cannot compel holders to transfer or share it contrary to their national laws. It could be recalled that the existing technology transfer provisions in Article 16 of the CBD were some of the most contentious articles during the negotiations. The USA, for instance, initially refused to sign the Convention largely due to concerns about the effects that these provisions might have on IPRs under its national laws. In practice, however, private corporations do adopt

many restrictive policies and measures on transfer of technology being generally wary of transferring technology in ways that might decrease their competitive advantage in any way.

A number of other constraints affect the transfer of technologies, including limited financial resources, institutional and policy constraints, human resources problems, limited access to information on environmentally sound technologies and knowledge. Other significant factors include the controversies surrounding certain types of technologies, especially biotechnology, and their potential effect on the environment, particularly the conservation and sustainable utilization of biodiversity. In the final analysis, however, a key challenge is the fact that the relevant obligations with respect to technology transfer (under the CBD as well as TRIPS), are not operational, largely due to the absence of any compliance and enforcement mechanisms.

Current international rules governing the protection of rights over technologies are critically important for developing countries. The strengthening of IPRs under the TRIPS Agreement is a sensitive issue at the centre of a highly polarized debate. On the one hand, fears have been expressed that genetic resources originating in developing countries are being used in the development of new biotechnology-based techniques and products, to which access would subsequently be restricted by IPRs. On the other hand, it is argued that strengthened IPRs would increase the flow of technologies and products from developed to developing countries, as well as provide new incentives for local research and innovation. It is also argued that strong intellectual property protection will provide new incentives for local research and innovation. Although the impact of IPRs on development continues to be widely debated, the promise of technology transfer, for the most part, has not been met. In light of this, there are indications that many developing countries no longer consider technology transfer to be a useful mechanism, due to the lack of identifiable progress under the other two treaties.

■ Conclusion

A considerable gap exists between the intentions expressed in the provisions of various international agreements with respect to technology transfer, and their effective implementation. There is need for a technology transfer framework that addresses the entire technology development and transfer chain - from the initial development of technology to its use and diffusion. Such a framework should, first, recognize the values, needs and capacities of recipients. Second, it should facilitate the development of assessment tools that will strengthen local decision making capabilities, particularly with

regard to biotechnology. Third, it should provide for the sharing of the biological technologies, science, and tools required (and their associated skills and knowledge) based on needs and actual circumstances of recipients.

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Endnotes

¹ Bonn guidelines on access to genetic resources and fair and equitable sharing of benefits arising out of their utilization.

² See the Report of the International Commission on Intellectual Property Rights (CIPR) set up by the UK Government available at www.iprcommission.org.

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Intellectual Property after Doha: Can Developing Countries Move Forward Their Agenda on Biodiversity and Traditional Knowledge?

■ Doha Outcomes

The outcome of the Doha Ministerial Conference reinforced the feeling, among developing countries, that the WTO system was flexible enough to respond to some of their demands on critical issues related to intellectual property protection. On the one hand, the Ministerial Declaration on the TRIPS Agreement and Public Health addressed concerns about access to medicines and gave comfort to South Africa, Brazil, Thailand and other countries, which had been under pressure by developed countries to ignore the flexibilities allowed by the Agreement to protect public health.

On the other hand, paragraph 19 of the Ministerial Declaration (WT/MIN(01)/DEC/1) addressed developing countries' repeatedly voiced concerns about "bio-piracy" and the potential inconsistencies between the system of appropriation under the TRIPS Agreement and the principles of the Convention on Biological Diversity (CBD)¹. The Ministers instructed the Council for TRIPS to examine, inter alia, the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. This mandate called for an examination of these issues through three different avenues, namely: (i) the review of Article 27.3(b); (ii) the review provided for under Article 71.1²; and (iii) negotiations foreseen in paragraph 12 relating to the implementation of various aspects of the WTO rules (see, e.g. Hepburn, 2002). Moreover, paragraph 31 also mandated 'negotiations', inter alia, on the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs), such as the CBD.

Discussions relating to biotechnology and genetic resources had started in 1999 as the TRIPS Agreement required Members to review Article 27.3(b) by that date.³ However, progress was blocked by an apparently semantic, but indeed substantial divergence. Developing countries aimed at a "review" of that provision so as to narrow down the scope of patentability in biotechnology and reduce or exclude the appropriation of biological resources. The African Group, for instance, proposed

the non-patentability of any life form (see IP/C/W/163, November 8, 1999). On their part, developed countries wanted to maintain the status quo in TRIPS, and limit any review to the implementation of the provision by Member Countries.

The Doha Ministerial Conference gave an apparent new impetus to the treatment of these issues. In light of the broad mandates adopted, developing countries expected that action in WTO on biotechnology and biodiversity issues could finally be taken. They were also reassured by the wording in paragraph 19, in fine, of the Declaration indicating that "the work programme of the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 ("Objectives") and 8 ("Principles") of the TRIPS agreement and should take into account the development dimension".

Despite the expectations created by the Ministerial Declaration, the Council for TRIPS has achieved very little after Doha. This paper concentrates on a number of unresolved issues relating to biotechnology/biodiversity and traditional knowledge ⁴.

■ Review of Article 27.3(b)

No "review" of Article 27.3(b) has taken place so far. While several analyses and proposals have been made about the possible content of a sui generis regime for plant varieties (see, for instance, IPGRI, 1999), developed countries have made use of bilateral agreements to impose commitments on developing countries to protect plant varieties under the UPOV Convention (see, for instance, Drahos 2003). Table 1 provides examples of such bilateral commitments.

Table 1: Bilateral agreements establishing TRIPS-plus requirements on the protection of biotechnological inventions and plant varieties

Type of agreement	Trade agreements	Development cooperation,	IPR agreements
Bilateral	Chile-USA (2004) Chile must adhere to UPOV 1991 and undertake "reasonable efforts" to develop legislation to make available patent protection for plants	EU-Bangladesh (2001) Bangladesh must endeavour to join UPOV (1991 Act)	Switzerland-Vietnam (1999) Vietnam must join UPOV (1991 Act)
	US-Jordan (2000) Jordan must implement Articles 1-22 of UPOV (1991 Act)	EU-Morocco (2000) Morocco must join UPOV (1991 Act) by 2004	US-Nicaragua (1998) Nicaragua was obliged to implement and join UPOV (1978 or 1991 Act)
	US-Vietnam (1999) Vietnam must implement the provisions of UPOV and "promptly make every effort to accede" (1991 Act). Further, Vietnam must provide patent protection on all forms of plants (and animals) that do not fit the UPOV definition of "variety", as well as "plant or animal inventions that could encompass more than one variety"	EU-Tunisia (1998) Tunisia must join UPOV (1991 Act) by 2002. In addition, Tunisia "shall provide suitable and effective protection of intellectual, industrial and commercial property rights, in line with the highest international standards."	US-Trinidad & Tobago (1994) Trinidad & Tobago was obliged to implement and join UPOV (1978 or 1991 Act)
	EU-South Africa (1999) South Africa shall "ensure adequate and effective protection of intellectual property rights in conformity with the highest international standards". Under this agreement, such rights include patents on "biotechnical inventions". South Africa must "undertake to improve, where appropriate, the protection provided for under TRIPS"	EU-Palestinian Authority (1997) The Palestinian Authority agreed to "grant and ensure adequate and effective protection of intellectual, industrial and commercial property rights in accordance with the highest international standards"	US-Sri Lanka (1991) No exclusions from patentability for plants and animals
	US-Cambodia (1996) Cambodia must join UPOV		
	US-Mongolia (1991) No exclusions from patentability for plants and animals		
	US-China (1979) China committed to provide the equivalent level of patent protection to US nationals in China as they would receive in the US		
	US-Singapore (2003)		
	US-Chile (2003)		
	US Central America and Dominican Republic (2004)		
Regional and sub-regional	EU-ACP (Cotonou Agreement, 2000) Without prejudice to their negotiating position in multilateral fora, the 77 African-Caribbean-Pacific (ACP) countries must provide patent protection for biotechnological inventions.		
	US-Mexico (NAFTA, 1994) Mexico assumed the obligation to join UPOV (1978 Act)		

Source: Updated from GRAIN, 2001

In particular, recent bilateral free trade agreements (FTAs) between the USA and developing countries oblige the Parties to make efforts to provide patent protection for plants. Article 15.9.2 of the Central American Free Trade Agreement (CAFTA), for instance, provides that "any Party that does not provide patent protection for plants by the date of entry into force of this Agreement shall undertake all reasonable efforts to make such patent protection available". The FTA between USA and Chile stipulates a period of four years during which efforts will be made to grant plant patents (Article 17.9.2).

The paralysis in WTO, hence, does not mean a preservation of the pre-TRIPS status quo, but the expansion of the standards of protection on plant varieties promoted by developed countries, as illustrated by the fact that 34 out of a total of 54 UPOV members (as of 15.1.04) acceded after 1995.

■ The TRIPS-CBD Interface

The CBD is generally viewed by developing countries as being supportive of their interests, especially as it provides for prior informed consent and benefit sharing in cases of commercial exploitation of genetic resources. Few developing countries have, however, implemented access regimes for such resources, and among these a majority have reaped almost no benefits, essentially due to complex procedures or poor implementation mechanisms (see Correa, 2003b). One of the main concerns of developing countries is the tension between the CBD's recognition of sovereign rights over the exploitation of genetic resources, and the possibility, offered by the TRIPS Agreement, of patenting biological materials, including genes.⁵ Although no normative collision between the two treaties was found under a strict interpretation of the provisions of the CBD and the TRIPS Agreement, their implementation may lead to conflicts, as the appropriation of genetic resources may effectively undermine the CBD objective to promote the sharing of genetic resources on a global scale.

This tension has been addressed - specifically in relation to Plant Genetic Resources for Food and Agriculture (PGRFA) - by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) adopted in November 2001. The Treaty aims at the conservation and sustainable use of such resources and the fair and equitable benefits arising out of their use, in harmony with the CBD. While the ITPGRFA covers all PGRFA, it establishes a Multilateral System (MS) of Access and Benefit-sharing for PGRFA of an agreed list of 35 food crops, and 29 forage genera. Under the MS, PGRFA can be accessed to and exchanged free of charge if they are to be solely used for research, breeding or training purposes. Further, according to

Article 12.3(d) of the Treaty recipients of materials in the MS "shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System".

Developing countries have proposed to deal with the TRIPS-CBD interface in WTO through an obligation to disclose in a patent application the origin of claimed biological materials (and the associated knowledge). According to some proposals, such an obligation should include not only information about origin but also about the applicant's compliance with national access laws. It should also include effective, fair and equitable benefit sharing arrangements under the relevant national regimes.⁶

The adoption of such an obligation may constitute the first step in the development of a misappropriation regime⁷ aimed at avoiding the monopolization of biological materials and related traditional knowledge. The disclosure of origin may fulfil three main functions relevant to the operation of the patent system:

- (a) It would improve the substantive examination of patent applications involving biological materials and traditional knowledge. The provision of that information may, in effect, facilitate the determination of prior art by providing useful information to the patent examiners. In some cases, it may simplify the process of searching the databases on traditional knowledge (currently being established). The information supplied would help to identify possible cases of misappropriation of biological materials and facilitate actions to challenge the validity of wrongly granted patents.
- (b) It would also improve the determination of inventorship by the patent office or courts. Although a patent is granted (according to the "first to file" system) to the first person to apply for it, he/she should be entitled to the patent on the basis of an act of invention, or as a legitimate successor in right to the inventor. Inventorship is a basic element in patent law and there are no limitations under the TRIPS Agreement with regard to means to determine it.
- (c) The disclosure of origin may, in some cases, facilitate or permit the actual execution of the invention, such as where a biological material is endemic to a specific location.

In addition to these possible functions within the patent system, if the information to be provided encompassed (as proposed by some developing countries) a declaration or evidence about compliance with national access laws, the disclosure obligation may have a significant role outside the patent system. It would, in effect, help countries supplying biological materials to: (a) promote

compliance with access legislation, where applicable, and (b) keep track of the commercial exploitation of such materials for the purposes of benefit sharing.

These two functions are important in achieving the principles and obligations of the CBD, as well as the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization" (Bonn Guidelines), in particular paragraph 16(d).⁸

Failure to provide information about the origin of biological materials and traditional knowledge may, like other requirements under patent law, be deemed sufficient ground for refusal of a patent application. In addition, the revocation of a grant would be justified, if it were proven that the invention failed to meet the patentability requirements or the applicant was not the true inventor.

While the USA rejects the idea of establishing such an obligation, the EU and its Member States agree on the concept but argue that "failure to disclose, or the submission of false information should not stand in the way of the grant of the patent and should have no effect on the validity of the patent, once it is granted".⁹ On its part, Switzerland sees merits in establishing a disclosure of origin requirements only with regard to applications under the Patent Cooperation Treaty and as a facultative requirement that domestic law may impose upon applicants.¹⁰

At the Committee on Trade and the Environment (see Vivas, 2002) several Member States sought to transfer the objectives and principles of the CBD into the relevant WTO Agreements. In this context, Member States have presented their national experiences regarding the implementation of the CBD but have failed to reach agreement on recommendations for future action.

■ Protection of Traditional Knowledge

Paragraph 19 of the Doha Ministerial Declaration identifies the need for protecting traditional knowledge, and not merely analysing its content or relation with the TRIPS Agreement. Similar to other issues, no progress can be found here.

The World Intellectual Property Organization (WIPO) established in 2000 an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGCGRTKF). Its mandate is to discuss (a) access to genetic resources and benefit sharing; (b) protect traditional knowledge; and (c) protect expressions of folklore. The fact that this Committee is examining traditional knowledge-related issues has been mentioned in WTO debates by developed countries as a reason not to address the issue in WTO.¹¹ The WIPO General Assemblies (22 September to 1 October 2003,

Geneva) decided to prolong the mandate of the Committee. It was requested to accelerate its work and to focus, in particular, on the international dimension of intellectual property and genetic resources, traditional knowledge and folklore. Given the resistance by developed countries to agree on a negotiating mandate, vague language was used to indicate that "no outcome of [the Committee's] work is excluded, including the possible development of an international instrument or instruments". The mandate also states that discussions in the Committee should be without prejudice to the work in other fora. This may be regarded as a concession to developing countries, who did not want to be blocked in other fora (notably the WTO) with the argument that studies on these issues are still pending in WIPO (see BRIDGES 2002).

■ Conclusion

In March 2004, several developing countries submitted to the Council for TRIPS a checklist of some of the issues to be addressed in the context of the mandate contained in paragraph 19. The US and Japan opposed the checklist arguing that there is no conflict between the CBD and the TRIPS Agreement and that there is no need to amend the TRIPS Agreement. The European Union and other developed countries like Switzerland said that they could accept the checklist, with reservations, and that in order to avoid duplication of work the TRIPS Council should wait for decisions on these matters at the WIPO.

This discussion clearly exemplifies the state of play in WTO. There are no signs that the current stalemate can be overcome in the short term. Developing countries, however, should not abandon their efforts to reconcile the TRIPS Agreement with the CBD. They need to act coherently in different fora and neutralize the forum "shopping game" by developed countries. A review of the conventions administered by WIPO should be initiated to assess how they may be modified to introduce a disclosure obligation in parallel to a possible amendment to the TRIPS Agreement.

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Endnotes

¹ Countries identified a number of issues to be examined under this heading. For example: the need to reach a clear understanding in the interim that patents inconsistent with Article 15 of the CBD shall not be granted; that the period given for implementation of the provisions of Article 27.3(b) shall be five years from the date the review is completed; and to amend this article taking into account the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources.

See the footnote to the heading 'Outstanding Implementation Issues' and document Job(01)/152/Rev.1, available at http://www.ictsd.org/ministerial/doha/docs/imp_iss.pdf.

2 Article 71.1 refers to the review of implementation of the Agreement and to its "review in the light of any relevant new developments which might warrant modifications or amendments".

3 Article 27.3 (b) requires the protection of micro-organisms, non-biological and microbiological processes for the production of plants or animals, and plant varieties, but leaves flexibility for Members to adopt a "sui generis system" on the latter, as well as to exclude the patentability of inventions relating to plants and animals.

4 For a more comprehensive picture of post-Doha developments, the implementation by the General Council of paragraph 6 of the Declaration on the TRIPS Agreement and Public Health should also be considered. (see, e.g., Correa, 2003a).

5 However, the TRIPS Agreement does not obligate parties to grant patents on genes as such, and some countries (e.g. Argentina, Brazil) deem genes, even if isolated, as not constituting an "invention".

6 See, e.g., "The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge" (Brazil on behalf of the delegations of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe), IP/C/W/356, 24 June 2002, para. 10.

7 There has been extensive documentation of IPRs being sought over resources "as they are", without further improvement (e.g., US patent No. 5,304,718 on quinoa granted to researchers of the Colorado State University; US Plant patent No. 5,751 on ayahuasca, a sacred and medicinal plant of the Amazonia) and on products based on plant materials and knowledge developed and used by local/indigenous communities, such as the cases of the neem tree, kava, barbasco, endod and turmeric, among others (see, e.g., Correa 2001).

8 See also paragraph 46 of Decision VI/10 and paragraph 1 of Section C of Decision VI/24 adopted by COP6.

9 "Review of article 27.3(b) of the TRIPS Agreement, and the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge and folklore. A concept paper". Communication from the European Communities and their Member States, IP/C/W/383, 17 October 2002, para. 55.

10 Article 27.3(b). "The relationship between the TRIPS agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge". Communication from Switzerland", IP/C/W/400, 28 May 2003, fn. 5.

11 For instance, the EU and its Member States have stated that they "support the development of an international model for the legal protection of traditional knowledge" and expressed their hope that the issue be taken up by the WIPO Intergovernmental Committee in cooperation with the CBD, and that "once a model is in place, attention can then be focused on how and to what extent the protection of traditional knowledge can be included in the TRIPS Agreement" (IP/C/W/254, 3.4.01).

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FUTURE TECHNOLOGY POLICY BRIEFS

Future UNU-INTECH Technology Policy Briefs will address innovation and development issues relating to Drug Research, Biotechnology and Bioprospecting

Comments, criticisms, and suggestions on this Brief are welcome. Please contact Padmashree Gehl Sampath (sampath@intech.unu.edu)



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