Project Document

Intellectual Property Rights and Sustainable Development: A Survey of Major Issues

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Introduction

From a broad sustainable development viewpoint, intellectual property (IP) might relate to a number of aspects of a country's social and economic development. Its impact can be felt in industrial, health, education, nutrition, biodiversity and cultural policies. In exploring the issues relating to sustainable development and the important changes that have taken place in the IP landscape, we will focus on issues that are drawing particular attention in major international for and to developments that are taking place in bilateral trade negotiations.

This paper will thus focus on understanding the significance of the World Trade Organization's (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), examine its main features and assess the ways in which it has altered the landscape of IP relations. In doing so the paper explores the key IP issues related to sustainable development, with emphasis on trends and outstanding questions in the international discourse. In this respect, the issues related to access to knowledge, access to health and the relationship between the international IP architecture and the protection of biodiversity and traditional knowledge (TK) has occupied much of the attention of policymakers. This paper accordingly centres its inquiry on these issues. We begin with a short introduction on the purpose and the main disciplines of intellectual property rights (IPRs).

What are IPRs for?

Intellectual property rights are conceived as a tool to reward innovators and creators for their contributions to society, for a statutory period of time. They are intended to provide the necessary incentives for the generation and dissemination of knowledge as well as to encourage the transfer of technology. They cover a wide range of interrelated disciplines, namely:

- Patents, intended to protect and encourage new, inventive and industrially applicable inventions;
- Utility models or petty patents, intended to protect the technical novelty of inventions that usually do not reach the legal standards required for patents;

- Undisclosed information, protecting secrets of commercial value (e.g. technical know-how, data of commercial value, test data);
- Trademarks, protecting signs that distinguish goods or services of one undertaking from those of another undertaking;
- Geographical indications (GIs), identifying a good as originating in a particular territory, or a region or locality, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographic origin;
- Copyrights, intended to protect original works of art, such as music, literature, cinema and other expressions of creativity;
- Industrial designs, protecting the appearance of a product, the ornamental or aesthetic aspect of a useful object. They may consist of the shape, pattern, or colour of the object;
- Integrated circuits (chips), intended to protect the layout design (or topographies) utilized in chips that are essential components in any digital equipment, and have been incorporated into a great variety of other industrial objets, ranging from machine tools to all kinds of household and consumer devices.

The legal rules covering these disciplines tend to be complex and their economic, social and environmental impact is diverse and often difficult to measure. The extent to which these rules advance public policy objectives depends, to a great extent, on how international obligations are implemented, and this is particularly the case with respect to the attainment of sustainable development goals. One of the purposes of this paper is precisely to consider the main features of the international IP architecture and its relationship with sustainable development as it concerns access to knowledge, access to health and biodiversity.

Organization of the study

The study, organized around five chapters, deals mainly with:

- Intellectual property and the international trading system including an analysis of the TRIPS Agreement and the importance of recent bilateral trade agreements including new standards of protection and the strengthening of enforcement measures.
- Access to knowledge and its relationship with the present state of play in IP deliberations. Access and dissemination of knowledge relates to all IP disciplines but discussions have centred mainly in the areas of patents and copyrights.
- The relationship between IP protection, particularly patents and undisclosed information, and access to medicines.
- Genetic resources, biotechnological inventions and traditional knowledge and their interfaces with IPRs.
- Finally, chapter 5 summarizes our main conclusions and findings particularly in the context of the Latin American and Caribbean region.

1. Intellectual property and the international trading system

A. The agreement on trade related aspects of intellectual property rights

The TRIPS Agreement constitutes a landmark in the evolution of IP law. Before TRIPS, countries could differentiate on the patentability of industrial or technological sectors and choose whether to protect processes and/or products. For example, by the time the General Agreement on Trade and Tariffs's Uruguay Round negotiations started (1986), almost half of the patent laws throughout the world excluded pharmaceutical products from patent protection. Switzerland, a technologically advanced country, did not give full protection to pharmaceutical products until 1976. Medicines and food-related products were among the sectors most frequently excluded from patent protection prior to TRIPS.

In contrast to the dispersed nature of legal instruments dealing with IP, the TRIPS Agreement includes, in one single instrument, all the major IP disciplines and sets minimum standards of protection for them. These minimum standards are supplemented by the substantive provisions of, among others, the perennial IP treaties of the 19th century – the Paris and Berne Conventions – which are explicitly imported into TRIPS.

Another major feature is the incorporation in the Agreement of disciplines related to the enforcement of rights. WTO Members are obliged not only to recognize and protect those rights but also to establish mechanisms that guarantee, through administrative, civil and criminal procedures, including border measures, the appropriate means for the domestic enforcement of those rights. Thus, the above-mentioned substantive provisions of the Paris and Berne Conventions are now subject to the enforcement provisions demanded by TRIPS.

However, the most important consequence of TRIPS is the formal incorporation of IP into the international trading system. This means, *inter alia*, that the main foundations of the system –national treatment and most favoured nation treatment (MFN)– should apply to the IP relations between Members.

The national treatment principle, already part of the classical IP conventions, acknowledges the principle of non-discrimination between nationals and foreigners, in the sense that WTO Members should accord foreign IP right holders a treatment similar to that accorded to their own nationals. But, compared for example to the Paris Convention of 1883, the national

treatment principle in TRIPS is expressed as "treatment no less favourable" than that accorded to own nationals, meaning that foreigners could be awarded better treatment than locals.

The MFN principle is an important novelty in the evolution of the international IP architecture. MFN calls for non-discrimination by WTO Members between different foreigners. By this principle, which has very limited exceptions, nationals of different countries should not be treated differently over the protection of IP. One important consequence of this principle is that any advantage, favour, privilege or immunity granted by a WTO Member to a national of any other country – whether a WTO Member or not – is immediately and unconditionally extended to the nationals of all other WTO Members. This principle acquires particular relevance with the rising importance of bilateral trade agreements.

Another major consequence of the full incorporation of IP into the international trading system is the application of the WTO's Dispute Settlement Understanding (DSU) to the TRIPS Agreement (and also the substantive provisions of the Paris, Berne and Rome conventions and the Washington Treaty incorporated in TRIPS). The application of the DSU could justify measures of commercial retaliation, including cross-retaliation in the event of non-compliance with TRIPS obligations.[1] This could be extended not only to violations of the Agreement but also to cases described in the WTO system as non-violation complaint situations.

The TRIPS Agreement sets minimum standards for each type of IP covered by Part II of the Agreement, namely copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits and undisclosed information.[2] As observed above, in the pre-TRIPS landscape countries had the freedom to modulate the manner in which protection was fashioned for each of the IP disciplines. For example, they could exclude certain fields of technology from patent protection and determine the nature and duration of the rights granted. Under TRIPS, countries are obliged to accept at least these minimum standards, but may adopt more extensive protection.

The Agreement at the same time provides for the freedom of implementation of its provisions, in the sense that Members are free to determine the appropriate method of incorporating its provisions into domestic law, within their own legal system and practice. This reflects the notion that the Agreement recognizes flexibilities and discretion in the implementation of its minimum standards. In this context, it is of note that the decision of the WTO panel in the US Section 110(5) of US Copyright Act (Home-style exemption) case refers to the argument made by the United States in its written submission concerning the freedom of implementation in Article 1.1 of TRIPS.[3] In its submission, the US stated:

"Article 1.1 of TRIPS also emphasizes flexibility, and provides that 'Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."[4]

The acknowledgment that Article 1.1 "emphasizes flexibility" is significant. The question of flexibilities in the system has permeated the evolution of the TRIPS Agreement and has been the main bone of contention among governments. This reached a climax in discussions on the

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1 See WTO case United States – Measures affecting the cross-border supply of gambling and betting services. Recourse by Antigua and Barbuda to Article 22.2 of the DSU. WT/DS285/22, p. 1, 22 June 2007, at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds285_e.htm: "Pursuant to Article 22.2 of the WTO's Understanding on Rules and Procedures Governing the Settlement of Disputes (the "DSU"), Antigua and Barbuda requests authorization from the DSB to suspend the application to the United States of concessions and related obligations of Antigua and Barbuda under the General Agreement on Trade in Services (the "GATS") and the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS")".

2 Part II of TRIPS also deals with the control of anti-competitive practices in contractual licenses.

3 United States – Section 110(5) of the US Copyright Act, Report of the Panel, WT/DS160/R, 15 June 2000 ("U.S. – Copyright (Home-style Exemption)"), at para. 6.189 note 167.

4 Ibid. Annex 2.1, First Written Submission of the United States, 26 October 1999, para. 21.

relationship between public health and IPRs that led to the adoption of the Doha Declaration on TRIPS and Public Health in 2001.[5] Contention over this issue remains, as discussed further below.

a) Exhaustion of rights and parallel trade

The doctrine of exhaustion addresses the issue of when the IPR holder's control over the distribution of a specific good ceases. This termination of control is critical to the functioning of any market economy because it permits the free transfer of goods. The basic idea is that once the right holder has been able to obtain an economic return from the first sale or placing a good on the market, the purchaser or transferee of the good is entitled to use and dispose of it without further restriction. Without an exhaustion doctrine, the original IPR holder would perpetually exercise control over the sale, transfer or use of a good or service embodying an IPR, and would control its economic life. From the standpoint of the international trading system, the focus of the exhaustion question is whether it operates on a national, regional or international basis.

A country may choose to recognize that the exhaustion of an IPR occurs when a good is first sold or marketed anywhere outside its own borders (international exhaustion). If exhaustion occurs when a good or service is first sold or marketed outside a country, the IPR holder within the country may not oppose a given importation on the basis of its IPR. The importation of a good for which exhaustion of an IPR has occurred abroad is commonly referred to as "parallel importation", and the goods subject to such trade are commonly referred to as "grey market goods". On the other hand, countries may opt for a national exhaustion regime, whereby a right holder will be able to prevent an importation of a legitimate good if it was streamed into the channels of commerce outside the national territory. Countries that are members of a regional economic group might choose a regional exhaustion regime, as is the case of the members of the European Union (EU), whereby the rights will be exhausted if the goods are sold anywhere within that region.

Exhaustion was one of the most difficult issues that arose during the negotiation of TRIPS (Gervais, 1998). The sole compromise was that each WTO Member would be entitled to adopt its own exhaustion policy and rules. This agreement was framed in Article 6, precluding anything in TRIPS from being used to address the exhaustion of rights in dispute settlement, subject to the TRIPS provisions on national and MFN treatment. This understanding was reaffirmed in the Doha Declaration on TRIPS and Public Health, which stated that in recognizing the flexibilities built into the Agreement, each WTO Member is free to establish its own regime on exhaustion of IPRs (UNCTAD-ICTSD Resource Book, 2005; Watal, 2001).

b) The substantive minimum standards particularly with respect to patents

As detailed above, a major feature of the TRIPS Agreement is the establishment of minimum standards of IP protection. This fundamental aspect of TRIPS differentiates it from previous IP conventions, in the sense that all WTO Members, without differentiation, are obliged to implement and comply with these minimum standards in their national legislation. The Agreement, however, recognizes, through transitional arrangements, some differentiation between categories of countries (i.e. developed countries, economies in transition to a free enterprise economic system, developing countries and least developed countries). The last of these transitional periods expired as of 1 January 2005 for all countries. However, subsequent

[5] See WTO document WT/MIN(01)/DEC/2□, 20 November 2001 at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl _trips_e.htm.

WTO decisions have waived the obligation of TRIPS implementation for the least developed countries (LDCs) until June 2013, in general, and, as a consequence of the Doha Declaration, until January 2016 for pharmaceutical products.

Therefore, the Agreement signified a major cultural change in the international IP system. It raised levels of protection in almost all areas of IP to unprecedented levels, with respect to new rights, the scope of protected subject matter, terms of protection, enforcement and international dispute settlement procedures. However, TRIPS also left considerable room for manoeuvre by providing certain flexibilities.

The flexibilities in TRIPS may take different forms. The Agreement, for example, does not define many of the terms in its provisions, allowing each WTO member to define the meaning of these terms to the extent that they may even help to define what the scope of a specific right will be or which matter will qualify for protection. Another kind of flexibility is given by the provisions in the TRIPS objectives (Article 7) and principles (Article 8), which are very useful for interpretation of the whole Agreement. As we have seen, an additional flexibility in the form of transitional implementation periods was given to developing and least-developed countries. Finally, the most common and probably the most important form of flexibility in TRIPS is that of limitations and exceptions to the rights granted.

Among the substantive minimum standards for all categories of IP covered by the Agreement, probably the most far-reaching changes brought about by TRIPS concern patents and undisclosed information. In all the other areas covered by the Agreement, TRIPS fundamentally imported and expanded the main standards covered already in pre-existing World Intellectual Property Organization (WIPO)-administered treaties.

With respect to patent protection, the Agreement includes a number of important obligations for Member countries that limit the legislative freedom they enjoyed prior to TRIPS.

(i) Patents available in all fields of technology

According to TRIPS, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[6] The Agreement also underlines that patents shall be available and patent rights exercised without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

Whilst stating this principle of non-discrimination with respect to the patentability of inventions in all fields of technology, the Agreement leaves WTO Members the flexibility, within the broad parameters of the provisions of TRIPS, to characterize what an invention is for the purpose of granting a patent. This is, in a way, another manifestation of the flexibilities referred to above. There have been efforts to further harmonize international standards in this area, such as the negotiations in WIPO on a Substantive Patent Law Treaty (SPLT) to which we refer below. An example of the use of this flexibility is the Indian Patent Law of 2005, which defines or excludes a number of acts from the notion of inventions.[7]

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[6] For these purposes the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

[7] See Amir (2007). The relevant section of the Indian law provides: Section 3: The following are not inventions within the meaning of this Act, (d): "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant "Explanation: For the purpose of this clause salts, esters, polymorphs, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance unless they differ significantly in properties with regard to efficacy."

The TRIPS Agreement, at the same time, establishes general rules on the type of exclusions countries can make to the patentability of inventions:

"Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. (Article 27.2)

Members may also exclude from patentability: diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Article 27.3(a))".

Notably, from a sustainable development perspective, the reference made here to "the environment" is the sole mention of this concept in the Agreement. There is no clear indication in the legislative history of the Agreement as to how it was incorporated in the text. No reference to the "environment" was made in the earlier negotiating texts until its incorporation in the Dunkel draft (1991) that was the basis of the final agreed text. National laws have incorporated this type of exclusion to patentability in the implementation of TRIPS.[8]

A subsequent standard regarding exclusions from patentability is the provision in Article 27.3(b) dealing with biotechnological inventions, including genetic resources, and plant variety protection. We deal with this matter in Chapter 4.

In brief, Article 27 of TRIPS adds to the argument made above that TRIPS radically departed from the system prevailing prior to 1995, where countries could exclude industrial sectors that, for social or economic considerations, were not considered fit for patentability. That was the common practice with respect to products related to medicines and food.

(ii) Rights and exceptions

Another major feature of the Agreement is that it provides for an exhaustive description of the exclusive rights conferred by a patent. These include the right to prevent third parties, who do not have the right holder's consent, from the acts of: making, using, offering for sale, selling, or importing for these purposes, the product (in the case of a product patent) or the product obtained directly by that process (in the case of a process patent). The Agreement adds that the term of protection shall not end before the expiration of a period of 20 years counted from the filing date. The national practices prior to TRIPS varied with some countries recognizing a 20 year patent term and others, such as India, differentiating the term according to sectors. We will see below that in recent free trade agreements (FTAs) the 20 year term may be extended further to take into account delays in the administrative grant of a patent or delays resulting from the marketing approval process of a pharmaceutical product or an agrochemical product.

The exclusive rights conferred to the patent holder are not unqualified. Under most patent laws, such rights may not be exercised with regard to certain acts considered legitimate, for example in relation to non-commercial acts (e.g. private use or scientific research) or for regulatory purposes (e.g. "Bolar exception"). This means that under certain specified circumstances, there may be exceptions to the exclusive rights. In general, the Agreement limits the establishment of such exceptions to those that "do not unreasonably conflict with a normal

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Source: Indian Patent Office at http://www.patentoffice.nic.in/ipr/patent/patents.htm. The Swiss firm Novartis has brought a major case of TRIPS compliance against the Indian government challenging the use of this flexibility. See http://www.ip-watch.org/weblog/index.php?p=657&res=1280_ff.

[8] For instance, see Article 10(IX) and Article 18 of Brazil's Industrial Property Law - Law Nº 9.279, of May 14, 1996 at http://www.sice.oas.org/int_prop/nat_leg/Brazil/ENG/L9279eA.asp#nonpat; and Article 37 of Chile's Industrial Property Law – Ley 19.039 at http://www.bcn.cl/leyes/pdf/actualizado/250708.pdf.

exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties" (Article 30).

Article 30 of TRIPS was the subject of close examination in the WTO case Canada Patent Protection of Pharmaceutical Products.[9] The case was brought against Canada by the EU, questioning the regulatory review exception ("Bolar exception") provided for in Canadian patent law. The Bolar exception in Canada's case recognized that acts by a third party (generic industry) related to the development and submission of information required under the law regulating the manufacture, use or sale of any product, was not an infringement of the patent. The exception, under Canadian law, was also extended to the stockpiling of products intended for sale immediately after the expiration of the patent. The WTO panel, effectively constructing the boundaries of the Article 30 exceptions to patents, found that the stockpiling provision in the Canadian law was inconsistent with international law, but also stated that the exception contained in Canadian law related to testing was "limited" within the meaning of Article 30:

"The exception is 'limited' because of the narrow scope of its curtailment of Article 28.1 rights. As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded. Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner's rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products".[10]

In brief, the Agreement defines the scope of the rights covered by the patent. Those rights could be limited under the conditions set in Article 30 of TRIPS and also by the system of compulsory licensing as follows.

(iii) Compulsory licensing

An important limitation to the exclusive rights of the patent holder relates to the authorization by governments of non-voluntary uses to third parties (commonly known as compulsory licensing). In this context, the Agreement sets up conditions or modalities in case countries allow for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government. The Agreement does not provide for a straightforward recognition of these uses, but acknowledges that Members allowing such licenses in their domestic legislation should comply with a number of conditions. Compulsory licenses are not a novelty in the IP system. They were introduced to the Paris Convention in the Review Conference of 1925. However, a new feature in TRIPS is the specific conditions that govern the granting of a compulsory license.

The main conditions set in TRIPS are:

- The consideration on a case-by-case basis of the individual merits of the request;
- The need for the proposed user to have negotiated previously with the right holder on reasonable commercial terms and conditions for a license to use the invention. This requirement may be waived in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use;

[9] See WTO Case ref. WT/DS114/R, 17 March 2000.
[10] Ibid, para. 7.45

- That the scope and duration of such use shall be limited to the purpose for which it was authorized;
- That such use shall be non-exclusive;
- That any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- That authorization for such use shall be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur;
- That the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- That the legal validity of any decision relating to the authorization of such use and to any decision relating to the remuneration shall be subject to judicial review or other independent review by a distinct higher authority in that Member.

An interesting practical example of the compulsory licensing system related to biotechnological inventions is provided by the European Directive (98/44/EC) to which we refer in subsequent sections of this paper. The Directive provides for compulsory licensing to facilitate the acquisition or exploitation of a plant variety without infringing a prior patent and, conversely, to facilitate the exploitation of a patent without infringing a prior plant variety right. In these circumstances, the breeder or the holder of a patent concerning a biotechnological invention may apply for a compulsory license, for a non-exclusive use of the patent or of the plant variety. In both cases, the Directive provides for a cross-license to the other party.

We return to compulsory licensing in chapter 3.

B. The bilateral trade agreements

A major new development in the IP landscape has been the emergence of a new generation of bilateral free trade agreements that include comprehensive and robust chapters covering IP disciplines. While the main aim of FTAs is increased market access, these agreements contain a number of trade-related regulations, including, besides IPRs, rules on investment, services and government procurement. These agreements adopt different names. For the sake of convenience we refer to these bilateral, trilateral or regional trade agreements collectively as FTAs. The IP obligations in these agreements are notable for expanding the minimum standards of protection and enforcement beyond that which is laid out in the TRIPS Agreement. The main driving force behind this trend has been the US. But the EU and the European Free Trade Association (EFTA) have also been active in negotiating trade agreements with different emphases on IP issues. The EU has recently become more active in this area by launching negotiations on Economic Partnership Agreements (EPAs) – that include IP issues – with six regional groupings of the African, Caribbean and Pacific (ACP) states (Santa Cruz, 2007). Table 1 lists the various FTAs negotiated or currently under negotiation that involve Latin American and Caribbean countries.

TABLE 1
FREE TRADE AGREEMENTS INVOLVING LATIN AMERICAN AND CARIBBEAN COUNTRIES[a]

Country	Negotiated	Under Negotiation
US with	- 1992: NAFTA (Canada and Mexico) - 2003: Chile - 2005: (CAFTA-DR) Central America and Dominican Republic - 2006: Peru; Colombia -2007: Panama	- Free Trade Agreement of the Americas (FTAA); Ecuador;
EU with	- 1997: Mexico -2000: ACP Countries – Cotonou Agreement - 2002: Chile	- Andean Community[b]; Central America; Mercosur[c] - ACP countries
EFTA[d] with	- 2000: Mexico - 2003: Chile	
Canada with	- 1992: NAFTA (Mexico and US) - 1996: Chile - 2001: Costa Rica	
Republic of Korea with	-2005: Chile	- Canada
Japan with	- 2005: Mexico - 2007: Chile-	
Taiwan with	- 2005: Panama	

Sources: www.ustr.gov; http://ec.europa.eu/comm/trade/issues/bilateral/index_en.htm; http://secretariat.efta.int; www.bilaterals.org.
[a] Dates refer in general to the year that the respective agreement was signed
[b] Bolivia, Colombia, Ecuador, Peru
[c] Argentina, Brazil, Paraguay, Uruguay
[d] Norway, Lichtenstein, Iceland, Switzerland

While most developing countries are still struggling to implement the minimum standards detailed in the TRIPS Agreement, these FTAs pose important challenges. Civil society groups have expressed concerns that the TRIPS-plus provisions contained in these agreements raise significant obstacles, particularly with respect to the use of flexibilities in the implementation of these agreements (Oxfam, 2007). It should be noted that these TRIPS-plus provisions do not contravene the Agreement since they legitimately build on its minimum standards. We return to the relevance and implications of the FTAs in IP policy making in the subsequent chapters of this paper.

The developments outlined above are reinforced by the clear determination of more advanced countries to move forward their strategies to strengthen the monitoring of the ways and methods used by countries, particularly developing ones, to implement their commitments and enforce IPRs at the domestic level. The US and the EU have stated this in plain and straightforward language, expressing their intent to bring these matters under the consideration of the WTO Council for TRIPS, whilst persisting in their unilateral measures to identify and publicize specific countries that in their view are not fully compliant with their international obligations (Roffe, 2007). The importance of this angle of the debate on IP issues was highlighted in the Declaration of the G8 Summit held in Heiligendamm, Germany on 7 June 2007.[11]

[11] Available at http://www.g-8.de/Webs/G8/EN/G8Summit/SummitDocuments/summit-documents.html.

2. Access to knowledge

Historically, IP systems have been constructed around the notion that there is a need for state intervention in securing and rewarding innovators and creators for their contributions to society and for the knowledge that is being created. Society prospers, culturally and economically, through innovation and the creation of new ideas. This concept is well expressed in the Constitution of the United States:

"The Congress shall have the power to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries".[12]

In attempting to survey some of the major issues around access to knowledge, this chapter begins with some general considerations as to the role and rationale of the IP system. It follows with observations on the relationship between foreign direct investment (FDI), transfer of technology and IPRs. It deals next with what we characterize as the checks and balances of the system to ensure that IP protection reinforces its contribution to knowledge dissemination. The chapter also considers issues that have arisen in recent FTAs that might affect access to knowledge, particularly with respect to copyright. Finally, it reviews some positive developments in WIPO around the notion of a development agenda and its relation with deliberations on access to knowledge.

A. Access to knowledge at the centre of the IP system

It is implicit that the exclusive rights granted to authors and innovators should also encourage future authors and innovators to use those contributions to further technological and cultural progress. Thus, access to knowledge is at the centre of the IP system. This was well captured in the TRIPS Agreement under its objectives and principles:

"Intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of

[12] US Constitution, Article 1, Section 8, Clause 8.

producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".[13]

According, then, to the TRIPS Agreement, the changes that have taken place in recent years should contribute to the dissemination of knowledge and to improved forms of transfer of technology. In view of their recent implementation, it could be too early to assess this aspect of the impact of TRIPS and TRIPS-plus treaties. For most developing countries TRIPS entered into force in January 2000, since in a number of cases legislative reforms, particularly in Latin America, preceded that date. Furthermore, FTAs are a new vintage and the implementation process has only recently started; some countries have signed but not yet implemented FTAs, such as Costa Rica, which at the time of writing has not yet ratified the Dominican Republic and Central America Free Trade Agreement (DR-CAFTA or CAFTA-DR) with the US. But, even in this case, Costa Rica has already amended its IP regime in line with TRIPS compliance.

Access and dissemination of knowledge then, could be considered as the *quid pro quo* of granting monopoly rights. However, some have raised concerns as to whether the bargain between society at large (benefiting from the knowledge produced and disseminated by IP) and the right holders (benefiting from their time-limited monopoly) is indeed being fulfilled. Although, the issue of access to knowledge is present in all areas of IP, there seems to be a more articulated debate in the area of copyright. But a unifying feature of all the arguments in favour of access to knowledge is the fact that overreaching rights could have adverse consequences in different areas of society, thus obstructing social development. More recently, civil society groups, via the A2K (Access to Knowledge) movement, have related access to knowledge to principles of justice, freedom and economic development.[14]

Certain societal actors are highly dependent on access to knowledge goods. Hence, the activities of, among others, researchers, libraries, educational institutions, people with disabilities, publishers and media rely heavily on a robust public domain and on clear exceptions and limitations to rights. Overreaching rights and even abuses by right holders may defeat the whole purpose of IP of providing incentives for creativity and innovation to further the progress of society, by impeding the use of legitimate exceptions and limitations and delaying the entry of works and inventions into the public domain. Licenses and contracts are often used to restrict the use of exceptions and limitations, and, as we will see below, digital locks (known as technological protection measures or TPMs), although useful to protect works, may also have unintended consequences for the use of legitimate exceptions and limitations and works in the public domain.

For instance, the existing IP system, including the TRIPS Agreement, is based on the assumption that the given state will recognize certain rights for authors and inventors for a certain period of time, after which the works and inventions will fall into the public domain. Some have raised concerns as to whether the terms of protection are too long, and, moreover, whether subsequent extensions of the terms of protection, either unilaterally or through trade agreements, beyond the minimum required by TRIPS may have an adverse effect on the enrichment of the public domain.

In addition to concerns over such extension per se, other problems relate to the implicit encouragement in the TRIPS Agreement of upward harmonization of the terms of protection of copyright, as this issue is subject to reciprocity[15] instead of the general rule of national treatment.

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[13] TRIPS, Article 7.

[14] "The Access to Knowledge movement (also known as A2K) is a loose collection of civil society groups, governments, and individuals converging on the idea that access to knowledge should be linked to fundamental principles of justice, freedom, and economic development". See http://en.wikipedia.org/wiki/Access_to_Knowledge_movement.

[15] Berne, Article 7.8.

In other words, the Agreement provides that the "term shall be governed by the legislation of the country where protection is claimed; however, unless the legislation of that country provides otherwise, the term shall not exceed the term fixed in the country of origin of the work" [16]. Normally, as in mostly every other TRIPS (and Berne) provision, a right holder would unconditionally get the same treatment as the nationals of the country where the protection is sought.[17]

Finally, the extension of the terms of copyright cover works that are already copyrighted, contradicting the argument that copyrights are granted to encourage creativity.[18] As we will see, in the case of patents there is already a trend of extending the terms of protection when there have been delays in the granting of the patent, and also when there have been delays in the process of granting marketing approval for pharmaceutical products.

Additionally, the system is based on the premise that certain things may never be protected because the burden on society would be too heavy. The contours of protection are defined by the scope of protection, protected subject matter and rights granted. Therefore, according to TRIPS (the scope of) copyright "shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such".[19] In the case of patents, certain requirements of novelty, inventive step, and industrial applicability must be fulfilled in order to get the statutory 20 years of protection. In the case of trademarks, certain words may never be trademarked (generic terms), while descriptive terms may not be protected, unless a secondary meaning can be proven. Otherwise, the trademark holder would impede its competitors to use the only term to designate their products. In the case of the protection of undisclosed information, WTO Members have decided to protect certain investments on pharmaceutical and agricultural chemical products, but only if a "considerable effort" has been made.

Regarding patents specifically, there are cases where the patent holder does not sufficiently disclose the invention in the patent application (i.e. it cannot be carried out by a person skilled in the art), effectively not allowing others to put the invention into practice and to benefit from that knowledge.[20] There are also cases where patent holders accumulate several 20 year terms of protection for different aspects of a single product. This practice, known as "evergreening", is often seen in the pharmaceutical industry.

Besides some criticism for too-broad and overreaching IPRs, the more positive view of the IP system from the perspective of access to knowledge is that IPRs may contribute, or may be used, in a more pro-competitive manner and with the idea that sharing knowledge will lead to more creation and innovation. The open source movement, Creative Commons licenses, collaborative projects such as Wikipedia,[21] and the use of compulsory licenses are manifestations of this idea. Its most extreme expression could be the copyleft movement, by which authors give up their copyright so that their works fall automatically into the public domain.[22]

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16 Indeed, this was one of the major arguments made in favour of extending the terms of copyrights in the US. See Senate Report 104-315, p.3 at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=104_cong_reports&docid=f:sr315.104.pdf.

17 Among the reasons given in the US to increase the term of protection from life of the author plus 50 years to life of the author plus 70 years, was the fact that some European Union countries had already extended the term to life of the author plus 70 years without automatically extending them to foreigners. Therefore, the effect of increasing the term in the US would be that US authors would gain the same protection as European author in Europe. See http://thomas.loc.gov/cgibin/cpquery/R?cp104:FLD010:@1(sr315).

18 Berne, Article 18.4.

19 TRIPS, Article 9.2.

20 See European Patent Office, Guidelines for Patent Examination, Rules 4.9. and 4.11 at http://legis.obi.gr/ESPACEDVD/legal_texts/gui_lines/e/c_ii_4_9.htm.

21 http://www.wikipedia.org/.

22 http://www.gnu.org/copyleft/.

B. Measuring access to knowledge through patent applications, FDI and licensing of technology

One salient feature of recent IP developments is the extraordinary rise in the number of patent applications throughout the world. According to WIPO statistics,[23] between 2001 and 2004 patent applications averaged 1.5 million per year, compared to 1 million in 1987, the year in which the Uruguay Round was launched. However, more than 80% of the applications are made in Japan, the US, the Republic of Korea, China, the European Patent Office and Germany. Brazil, the largest recipient of patent applications in Latin America and the Caribbean, had fewer than 7000 applications in 2004. Latin American and the Caribbean countries receive, altogether, around 5% of the patent applications made in the world. It should be stressed that most of these applications are from non-residents, mostly from the US, which represents one third of total non-resident applications. In terms of patents actually granted, the region represents fewer than 2% of the patents granted annually around the world. At the same time, the number of applications made by Latin American and Caribbean nationals in the US Patent Office is less than 1% of the total. Thus, in global terms the region is a marginal player with respect to patent applications, both as recipient and as applicant in foreign countries.

With all the necessary caveats, the size of these figures could be indicative of the dissemination of knowledge factor, bearing in mind that patents might contain important technical information than could be used to understand the state of the art in particular fields and to produce new innovations based on the technical information contained in patent applications.

A factor contributing to the rise of patent applications, including in the Latin American and Caribbean regions, relates to the strengthening of IP regimes as evidenced since the launch of the Uruguay Round. This should in theory be a contributing factor to improving the dissemination of knowledge and the transfer of technology. However, this requires further examination.

Relating to the access of knowledge factor, an argument often made in favour of advanced and strengthened IP regimes is that they would improve the foreign investment climate and thus attract more and quality FDI, contributing further to the transfer of advanced technologies generally controlled by transnational corporations. In the case of Latin America, according to the United Nations Conference on Trade and Development (UNCTAD):

Following four years of continuous decline, FDI flows to Latin America and the Caribbean registered a significant upsurge in 2004, reaching $68 billion – 44% above the level attained in 2003… Brazil and Mexico were the largest recipients…Together with Chile and Argentina they accounted for two-thirds of all FDI flows into the region in 2004." [24]

Figures for 2005 confirm the steadiness of FDI flows and their concentration in a few countries. It is interesting to note that the countries of origin of those flows are mainly the US, France, the Netherlands and Spain. With the exception of Spain, the others countries are the main origin of patenting by non-residents in the region.

The available literature is ambivalent on the role IP plays as a factor in FDI. There is some consensus that IP protection plays a positive role in the context of a broader package of policies and incentives. Isolated from other policy instruments, its role is not so obvious. It is often mentioned that on paper a number of African countries provide a high level of IP protection, although their enforcement mechanisms might be weak. Africa in general does not receive significant flows of FDI or transfer of technology, which reinforces the view that

[23] http://www.wipo.int/ipstats/en/.

[24] UNCTAD (2005) World Investment Report.

strengthening IP is not sufficient for these purposes. It is commonly observed that flows of FDI are not necessarily targeted to countries with strong IP systems (China might be a case in point), but that there are other factors that determine the quantity and quality of such flows. FDI flows depend on factors such as costs, size of the market, transaction costs and other factors, such as the local situation in the place of the investment.

The literature also observes that IP protection might be important as a factor for FDI in specific industries which are more sensitive to IP protection and where imitation and copying is less complex, as in the pharmaceutical and chemical sector. Moreover, the IP harmonization process could also make FDI less attractive compared to licensing that could become a more efficient and secure scheme for the transfer of technology. At the same time, it is also observed that the convergence of IP systems through this harmonization process, initiated by TRIPS, could entail that IP as a factor for the localization of FDI and for the transfer of technology could become less relevant. This geographical expansion of IP would allow the transnational firm to serve a particular market via exports and without necessarily a local presence (Maskus, 2004).

In general, scholars are of the view that these issues are still uncharted waters:

*"Economic analysis has come up short of providing either theoretical or empirical grounds for assessing the overall effect of intellectual property law on economic welfare… [E]xpanding intellectual property rights can actually reduce the amount of new intellectual property that is created by raising the creators' input costs, since a major input into new intellectual property is such existing property. This is true in both the patent and copyright areas and makes us sceptical about proposals to enlarge intellectual property rights in those areas. Any further enlargement would increase access and transaction costs and could at the same time weaken rather than strengthen the incentives to create new intellectual property" (*Landes & Posner, 2003).

The strengthening of IP should have contributed to transfer of technology via licensing agreements, as suggested above. One way of measuring this could be the nature of the payments made for concepts such as royalties for patents, trademarks, industrial know-how and copyright. Based on data provided by the *US Bureau of Economic Analysis*, an important rise can be perceived in the payments made to the US in recent years. Since 1986, the year the Uruguay Round was launched, those payments have risen six-fold (CAF, 2005).

This increase in royalty payments could have positive and negative interpretations from the viewpoint of access to knowledge and the transfer of technology. On the positive side, it might reflect a tendency to an expansion in the transfer of technology to the region in the sense that more payments could mean new technology transactions, influenced by the changes made recently in the IP regimens of the region. However, this phenomenon has occurred mainly within firms, namely between parent and subsidiaries and less between independent firms.[25] The counterargument here could be that the strengthening of IP rights has made technology more expensive and difficult to access. This would reaffirm the argument made by some that the TRIPS Agreement and the TRIPS-Plus process would result in a net transfer of resources from developing countries to the technologically most advanced countries, such as Germany, the US and France (UNCTAD-ICTSD, 2003).

[25] See Branstetter.

C. Checks and balances: flexibilities, exceptions and limitations

Access to knowledge could also be tested by the necessary checks and balances that an IP system should have. In this respect, a common form of imitating and upgrading technological skills has been reverse engineering. Many firms and countries employed this technique to industrialize. In the pre-TRIPS era, when the IP system was laxer and more flexible, reverse engineering was easier to achieve. With stronger IP regimes and better modes of enforcement, reverse engineering has become more difficult but not unattainable under the aegis of the new international IP architecture.

The expansion of the IP system to new frontiers, covering new subject matter, could also impinge upon the public domain, i.e. technologies or knowledge not covered by IPRs or whose protection has expired and which is therefore available to interested parties, thus making access to knowledge more difficult.

Linked to this question is the whole issue of flexibilities in the implementation of national IP regimes. The starting point here is that TRIPS –and even more so the new generation of FTAs– has limited countries' ability to exercise such flexibilities. Flexibilities are mainly expressed in the form of exceptions or limitations that can be formulated in national laws. Exceptions and limitations can take a number of forms. For example, in the case of copyright, limitations and exceptions could include those related to the promotion of competition in a given technology to permit interoperability, so that two or more systems can interact (e.g. a computer functioning with software from other companies) or to the efforts of educational institutions to utilize the most effective technological means to communicate with and train students (Okediji, 2004). In the case of patents (as well as in all categories of IP), typical exceptions might include the treatment of the exhaustion of rights (see discussion in Chapter 1 above) and the regulatory exception in the case of pharmaceutical products to allow for the marketing approval of generics before the expiration of a patent, in order that it can reach the market without delay upon expiration of the patent. Another exception commonly used, particularly in developed countries, relates to experimental and scientific use (Garrison, 2006).

The TRIPS Agreement sets general parameters as to the use of exceptions. For instance, Article 30 states that:

"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".

As we have seen a common limitation to the exclusive rights conferred by a patent is the possibility of using the patent without the patent holder's authorization in certain events and under conditions established in national regimes. These are commonly known as compulsory licenses permitted under TRIPS, a subject to which we return in the next chapter.

D. The FTAs and the issue of circumvention of technological measures: their potential impacts on access to knowledge

As noted, the FTAs deepen the process of harmonization started in TRIPS and therefore limit further the use of flexibilities. This is particularly relevant in the field of copyright where the FTAs provide for strict rules against the circumvention of technological protection measures (TPMs) used by authors, performers and the producers of phonograms to protect their works, performances and phonograms protected by copyright and related rights.

The provisions on TPMs go beyond the WIPO Internet treaties of 1996 (the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty), which state only that parties "shall provide adequate legal protection and legal remedies" against the circumvention of TPMs, leaving it to each Party to decide the way in which it will implement the provisions and whether it will apply civil and/or criminal sanctions to infringers.

The FTAs, in general, contain detailed rules aimed at providing adequate legal protection and effective legal remedies to fight against the circumvention of effective technological measures.[26] In a key provision of the CAFTA-DR Agreement, Parties are committed to provide that any person who:

> *"(i) circumvents without authority any effective technological measure that controls access to a protected work, performance, phonogram or other subject matter;*
>
> *(ii) manufactures, imports, distributes, offers to the public, provides, or otherwise traffic in devices, products, or components, or offers to the public or provides services, that:*
>
> a) *are promoted, advertised, or marketed for the purpose of circumvention of any effective technological measure; or*
>
> b) *have only a limited commercially significant purpose or use other than to circumvent any effective technological measure; or*
>
> c) *are primarily designed, produced, or performed for the purpose of enabling or facilitating the circumvention of any effective technological measure, shall be liable… Each Party shall provide for criminal procedures and penalties to be applied when any person, other than a non-profit library, archive, educational institution, or public non-commercial broadcasting entity, is found to have engaged wilfully and for purposes of commercial advantage or private financial gain in any of the foregoing activities (Article 15.5.7 (a)).*"

The terminology of the TPM provisions found in the FTAs draw from the controversial US Digital Millennium Copyright Act (DMCA),[27] which was "nominally intended to bring US law into compliance with the 1996 WIPO Treaties on copyright and the Internet, but in fact went well beyond what those treaties required"(Lemley et al, 2000).

These strong provisions make it a civil and criminal offence to tamper with embedded anti-piracy measures that control access to works and phonograms. They also provide for civil liability, and, when done wilfully and for prohibited commercial purposes, criminal liability for the manufacture, import, distribution, sale or rental of devices, products or components that serve

[26] "Effective technological measure means any technology, device, or component that, in the normal course of its operation, controls access to a work, performance, phonogram, or any other protected material, or that protects any copyright or any rights related to copyright, and cannot, in the usual case, be circumvented accidentally." Article 17.7.5 (f), FTA US-Chile

[27] U.S.C. Title 17 § 1201

the purpose of circumventing TPMs that control access and the exclusive rights in a work or phonogram.[28]

Critics of the TPM provisions of the DMCA argue that they impede lawful uses of works, such as making a copy of a music CD to listen to it on a computer, making a backup copy of a computer program or copying small parts of a DVD movie for the purpose of teaching or criticism. TPMs have also been used to bar the manufacture of competing products, to suppress speech, to limit the first sale doctrine and to fragment markets, such as through regional codes on DVDs[29]. Moreover, the use of TPMs restricts access to works that have already fallen into the public domain. The incidence of these provisions in FTAs has been criticized precisely for limiting access to information technology:

…a series of bilateral trade agreements negotiated by the USA have included DMCA like provisions, and thus made these inordinately high standards a de facto model for global implementation of the WCT [WIPO Copyright Treaty]. The combined effect of private law mechanisms such as torts and contract law, and public law regulation through copyright and other specialized regimes like the DMCA, will lead inevitably to increased difficulty in access to content. In a situation where access to hardware is already an important hindrance to developing countries, adding another layer of impediments, and inevitably raising costs, is problematic for the interests of developing countries in utilizing information technology (Okedji, 2004).

Only very limited exemptions are permitted to the FTA provisions aimed at providing adequate legal protection and effective legal remedies to fight against circumvention of effective technological measures, an example being for reverse engineering to achieve interoperability between computer programs.

E. Access to knowledge and WIPO

Recent developments in WIPO both directly and indirectly relate to access to knowledge. For instance, in the context of the Standing Committee on Copyrights and Related Rights (SCCR), Chile submitted a proposal in November 2004 to include in the deliberations of the Committee exceptions and limitations for libraries, educational purposes and disabled persons.[30] The proposal has gained support and has led the WIPO secretariat to prepare studies on "Limitations and Exceptions for the Visually Impaired"[31] and on exceptions and limitations for libraries.

In the context of discussions on a Development Agenda for WIPO (see Box 1), member states have agreed on several recommendations dealing in one way or another with the broad issue of access to knowledge. Most importantly in June 2007, members agreed to "initiate discussions on how, within WIPO's mandate, to further facilitate access to knowledge and technology for developing countries and LDCs to foster creativity and innovation and to strengthen such existing activities within WIPO".[32]

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[28] "The DMCA was a bit of law intended to back up the protection of [this] code designed to protect copyrighted material. It was, we could say, legal code intended to buttress software code which itself was intended to support the legal code of copyright". Lessig (2004).

[29] Electronic Frontier Foundation, Unintended Consequences: Seven Years under the DMCA April, 2006. See http://www.eff.org/IP/ DMCA/?f=unintended_consequences.html#Section5.

[30] See WIPO documents SCCR/12/3 at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=34747 and SCCR/13/5 at http: //www.wipo.int/meetings/en/doc_details.jsp?doc_id=53350.

[31] See WIPO document SCCR/15/7 at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=75696.

[32] See http://www.wipo.int/ip-development/en/agenda/pcda07_session4.html.

BOX 1
THE WIPO DEVELOPMENT AGENDA

The 'Development Agenda' proposed in 2004 by Argentina and Brazil aims to make development a crucial element of all negotiations taking place in WIPO and in policy making on intellectual property protection in general. According to the proponents, known as 'the Friends of Development' (FoD) (Argentina, Bolivia, Brazil, Cuba, Ecuador, Egypt, Islamic Republic of Iran, Kenya, Peru, Sierra Leone, South-Africa, the United Republic of Tanzania, Uruguay, Venezuela and the Dominican Republic) WIPO, as a UN agency, should be "fully guided by the broad development goals that the UN has set for itself, in particular the Millennium Development Goals" and take due account of all the pro-development provisions in the TRIPS Agreement and subsequent decisions such as the Doha Declaration on the TRIPS Agreement and Public Health. Argentina and Brazil took the initiative to launch the Development Agenda in 2004 and their proposal was rapidly co-sponsored by 13 developing countries. Notably, eight Latin American countries support the proposed Development Agenda. The original proposal explains that although significant scientific and technological progress has been made over the last century a knowledge gap as well as a digital divide continues to separate the wealthy nations from the poor. They argue that it is of importance not to see intellectual property protection as an end in itself, nor to treat all countries alike in the harmonization of intellectual property laws, but to take due account of different levels of socio-economic development. The FoD proposal identified several ways to achieve this objective. For instance it proposed to develop a treaty on access to knowledge and technology, amending the WIPO Convention to incorporate the development dimension and reforming WIPO norms and practices, including the development of principles and guidelines for norm-setting activities. It also encourages wider civil society participation in the WIPO negotiation process.

In June 2007 WIPO Members recommended, at a working level, to elevate to the WIPO General Assembly the adoption of 45 recommendations to achieve these development goals and to establish consequently a Committee on development and intellectual property.

Source: Puentes, ICTSD, Volume VIII, No.1, March 2007.

With respect to access to knowledge, WIPO members have *inter alia* also agreed to: consider the preservation of the public domain within WIPO's normative processes and deepen the analysis of the implications and benefits of a rich and accessible public domain; take appropriate measures to enable countries to fully understand and benefit from different provisions, pertaining to flexibilities provided for in international agreements; make available advice on the implementation and operation of the rights and obligations and the understanding and use of flexibilities contained in the TRIPS Agreement; consider how to better promote pro-competitive IP licensing practices, particularly with a view to fostering creativity, innovation and the transfer and dissemination of technology to interested countries; and explore IP-related policies and initiatives necessary to promote the transfer and dissemination of technology, to the benefit of developing countries.

3. Access to medicines[33]

The impact of IPRs, particularly patents, on public health policies and access to medicines has been one of the most debated issues to surface in the WTO in recent years. As we will see, with the adoption of the Doha Declaration on the TRIPS Agreement and Public Health, the WTO General Council Decision for the implementation of Paragraph 6 of that Declaration[34] and the subsequent amendment of the TRIPS Agreement, the focus of the discussion has shifted away from the WTO to the regional and bilateral front and the influence of recent FTAs. As far as substance is concerned, the FTAs have added another form of protection to traditional patent rights that is relevant to access to medicines: exclusive rights for pharmaceutical test data submitted to regulatory authorities with the purpose of gaining marketing approval. As we will see in detail infra, TRIPS mandates the protection of data submitted for the registration of medicines against unfair commercial use of that information (thus allowing other fair and reasonable uses), while the FTAs have expanded this protection, baring almost any use of that information unless there is consent from the right holder.

Prominent actors have voiced the concern that provisions on IPRs in FTAs that go beyond the TRIPS minimum standards (i.e. "TRIPS-plus" provisions) may have a serious impact on countries' public health policies. A report prepared for US Rep. Henry A. Waxman forcefully concludes:

"In 2001, the United States joined the international community in adopting the Doha Declaration, which recognized that trade agreements should not impede the efforts of developing countries to obtain essential drugs at affordable prices. Since then, the Bush Administration has negotiated multiple trade agreements with developing countries, including the CAFTA agreement now pending before Congress. Contrary to the principles of the Doha Declaration, the Administration has used these trade agreements to restrict the access of developing countries to low-cost generic drugs. By delaying generic drug approvals, extending patent terms, limiting compulsory licensing, prohibiting parallel importation, and otherwise restricting countries' efforts to improve access to affordable drugs, the trade agreements undermine the safeguards outlined in the Doha Declaration. These agreements may offer advantages to multinational pharmaceutical companies, but they do so at a serious cost to public health in the developing nations" (United States House of Representatives, 2005).

[33] See Roffe & Spennemann (2006).
[34] WT/L/540 of 2 September 2003.

The concern, in brief, is that by signing TRIPS-plus obligations developing countries risk losing the very flexibilities they are granted through the TRIPS Agreement, the Doha Declaration and the Decision on Paragraph 6.

The TRIPS Agreement, as detailed earlier, brought about a number of important changes in the area of patent law. First of all, it introduced the obligation to make patents available in all fields of technology, and for both products and processes.[35] This makes it impossible for WTO Members to exclude or continue excluding, pharmaceutical products from patentability. The Agreement also obliges Members to consider patents without discrimination as to the place of invention, the field of technology or whether the products are imported or produced locally.[36] The latter raises questions on the flexibility countries now have to establish "local working" requirements for patents (providing compulsory licensing or revocation of the patent if the protected product is not produced locally but imported).[37]

A. The flexibilities in TRIPS: the case of compulsory licensing

The TRIPS Agreement leaves WTO Members some discretion for the design of their national patent laws. In particular, the following features are relevant to public health and access to medicines. The TRIPS Agreement:

- Leaves Members the freedom to define whether they will apply a strict criterion of patentability. This is an important tool in preserving a large public domain for follow-on research and the promotion of competing products to help bring down prices;
- Contains no obligation to make patents available for new uses of known patented products ("second uses").[38] This may be a way of avoiding the "evergreening" of patents by seeking an additional full patent term for the same product;[39]
- Contains no obligation to prohibit price controls on patented products;
- Authorizes the control of IPR abuses through competition laws and policies, in particular in licensing agreements;[40]
- Allows for exceptions, under certain conditions, to the exclusive rights conferred by a patent.[41] One relevant exception in the public health field is the early working or regulatory ("Bolar") exception, discussed above (see chapter 1);
- Allows Members to freely determine the substantive grounds for the issuance of compulsory licenses;[42]
- Authorizes Members to determine their own system of IPR exhaustion (national, regional, or international). Through an international exhaustion regime, developing countries may facilitate parallel imports of low-priced drugs from abroad;

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35 See Article 27.1, TRIPS Agreement.
36 Article 27.1, TRIPS Agreement.
37 See UNCTAD-ICTSD (2005), Chapter 25: Patents: Non-voluntary Uses (Compulsory Licenses)
38 For instance, Sildenafil (Viagra) was first patented by Pfizer to treat heart disease. After finding out that it also served to treat impotence, Pfizer filed a second patent for this new use of the same drug. This second patent has been invalidated in some countries because of lack of novelty or because it was found obvious. See:http://www.lockeliddell.com/files/News/ab9ebdd4-621f-4432-a383-1cae37df9ea1/Presentation/NewsAttachment/c5a9d67e-bdd9-4c7e-97e9-1d6efb6314dc/Andrews_Pfizers%20Viagra%20Pate nt.pdf and http://mb.rxlist.com/rxboard/viagra.pl?noframes;read=183.
39 Article 15.8.1(b) of the US – Oman FTA: Each party expressly "confirms that it shall make patents available for any new uses for, or new methods of using, a known product, including new uses and new methods for the treatment of particular medical conditions". See http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Oman_FTA/Final_Text/asset_upload_file715_8809.pdf.
40 See Articles 8.2, 40, TRIPS Agreement.
41 See Article 30, TRIPS Agreement.
42 See Article 31, TRIPS Agreement

- Leaves each Member to employ exclusive or non-exclusive rights (i.e. through rules on unfair competition) to provide protection for pharmaceutical test data submitted to regulatory authorities for marketing approval purposes.[43] There is an important difference between these two approaches, as discussed below.

These TRIPS flexibilities were reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health in 2001:

"In this [public health/access to medicines] connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose".[44]

The WTO General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health[45] even extended the TRIPS flexibilities with regards to compulsory licensing: in essence, the 30 August Decision (Decision on Paragraph 6) waives the exporting country's obligation under TRIPS Article 31(f) to use drugs produced under compulsory license predominantly for the supply of its own domestic market.[46] It also waives the obligation of the importing Member under Article 31(h) to pay an adequate remuneration to the patent holder, where remuneration for the same product has already been paid in the exporting Member.[47]

The issuance of compulsory licenses and the conditions under which they should be authorized have been an important chapter in the deliberations on the relationship between IPRs and access to medicines, and again on the use of flexibilities under TRIPS. This was again reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health. Paragraph 4 of the Doha Declaration acknowledges that:

"…the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

Notwithstanding the Doha Declaration, the use of this TRIPS "flexibility" continues to be controversial. As recently as January 2007, the government of Thailand authorized the use of compulsory licensing to allow generic production of more than a dozen patented medicines unless companies substantially lower the price of their branded products. Previously, the government issued a compulsory license for the AIDS drug *efavirenz* with the intention of first importing a generic version of the medicine from India and later manufacturing it locally. This action by the Thai government has been challenged as "completely unprecedented anywhere in the world" and could result in international firms deciding against marketing their latest drugs in Thailand.[48]

B. The use of flexibilities in the context of FTAs

Free trade agreements include provisions on patents and data protection that go beyond the minimum standards established by the TRIPS Agreement. This is particularly the case of FTAs signed by Latin American countries with the US and notably also EFTA with respect to

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[43] See Article 39.3, TRIPS Agreement. According to another view, this article does not leave Members the discretion to choose, but obligates them to provide for exclusive rights in the test data. For a discussion, see UNCTAD-ICTSD (2005), Chapter 28, Sec. 3.
[44] See paragraph 4 in fine of the Declaration on the TRIPS Agreement and Public Health.
[45] WTO document WT/L/540 of 2 September 2003.
[46] See paragraph 2 of the Decision.
[47] See paragraph 3, second sentence of the Decision.
[48] See "Thailand Continues the Battle for Cheaper Drugs", Bridges, February-March 2007, page 17, at www.ictsd.org.

provisions dealing with data exclusivity. The main TRIPS-plus provisions with relevance for access to medicines, discussed below, relate respectively to: the patent restoration term; patentability criteria; compulsory licensing; parallel imports; regulatory exception; data exclusivity; and the linkage issue.

a) Patent restoration term

Under Article 33 of the TRIPS Agreement, the minimum term of patent protection is 20 years from the filing date. However, the period during which the patentee may actually take advantage of his monopoly rights may be affected in two ways. First, the patent grant may take several years, thus reducing the effective term of protection. Second, in order to market a patented pharmaceutical product, the right holder still needs to gain marketing approval from the responsible regulatory authority, which may also reduce the effective term in which the patentee can benefit from her monopoly rights. This is the rationale behind the FTA provisions that require an extension of the patent term in case the regulatory approval process delays the marketing of the patented product or process, and in cases where the granting of the patent has suffered administrative delays not attributable to the patent applicant. Such an outright extension of the patent term has been criticized as another manifestation of the TRIPS-plus nature of the FTAs that could delay the entry of competing medicines into the market. As discussed below, this trend is being corrected by the US Congress.

b) Patentability criteria

As opposed to the TRIPS Agreement, some FTAs, such as CAFTA-DR, contain a definition of what constitutes "industrial application", referring to the US law concept of "utility" (Roffe, 2004), in the sense that the invention operates according to its intended purpose. This prevents parties from adopting narrower definitions, like the concept of "industrial applicability" as defined in European countries.[49] The difference can be considerable. As opposed to the concept of "industrial applicability", the "utility" approach permits the patentability of business models and purely experimental inventions that do not produce any technical effects and cannot be made or used industrially. This may result in the patenting of research tools needed for the development of competing products (UNCTAD-ICTSD, 2005).

c) Compulsory licenses

Contrary to the FTAs signed with Latin American countries, the US agreements with Australia, Jordan, Singapore and Vietnam limit the grounds for the use of compulsory licenses to cases of anti-trust remedies, public non-commercial use and national emergencies or other circumstances of extreme urgency.[50] The FTAs with Latin American countries do not contain express limitations on the use of compulsory licenses and in side letters[51] to the main agreements refer to the "WTO health solution". The FTA with Chile, for its part, expressly refers to the terms of the Doha Declaration on TRIPS and Public Health in the Preamble to the IP Chapter.

d) Parallel imports[52]

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[49] Article 57 of the European Patent Convention: "Industrial application: An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture". See http://www.european-patent-office.org/legal/epc/e/ar57.html.

[50] See e.g. Article 4, paragraph 20 of the USA - Jordan FTA

[51] Side letters are documents signed by the parties to the main agreement, with the purpose of clarifying certain aspects of the text. Technically they should have the same legal status as the main text. See a USTR document from July 2007 clarifying several aspects of an immigration understanding contained in a side letter to CAFTA at http://www.ustr.gov/assets/Trade_Agreements /Bilateral/ CAFTA/Briefing_Book/asset_upload_file650_13202.pdf.

[52] For a discussion on parallel imports and exhaustion of IPRs, see chapter 1, supra.

Under the US FTAs with Australia, Morocco and Singapore, the patent holder is authorized to prevent parallel imports through the use of contracts or other means.[53] This limitation is not included in the FTAs with countries from the Latin American and Caribbean region. A US House of Representatives report prepared for Rep. Henry Waxman warns on this trend:

"…making this policy permanent in trade agreements prevents countries that do not currently restrict parallel importation from reconsidering their national policies. Even in the United States there is great support for a form of parallel importation: both the house and the Senate have measures that would allow the importation of lower-priced patented drugs from Canada. The trade agreement language would make it difficult for the United States or other nations with current restrictions on importation to revisit their national policies."

e) The regulatory exception

Article 30 of the TRIPS Agreement, as discussed elsewhere, authorizes Members to provide, under certain circumstances, limited exceptions to exclusive patent rights. One of these exceptions, as endorsed by a WTO panel (see chapter 1) and available in many domestic laws (Garrison, 2006), is the authorization for third party competitors to use patented subject matter to generate information required to support an application for marketing approval of a pharmaceutical or agricultural chemical product (also known as the "Bolar exemption"). The purpose of this exception is to accelerate the market entry of generic competitors immediately after the expiry of the respective pharmaceutical or agrochemical patent. As marketing approval may be time consuming, the generic producer is given the opportunity to submit a substance still under patent protection for approval during the patent term, to ensure regulatory approval is granted at the expiration of the patent term. Otherwise, delays in the approval of competing products would amount to a *de facto* extension of the exclusivity period accorded by the patent. This regulatory exemption is recognized in all of the US FTAs.

f) Protection of undisclosed information

Related to patent protection of pharmaceutical and chemical entities, Article 39.3 of the TRIPS Agreement prescribes that:

"when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use".

The so-called pharmaceutical "research-based industry" considers the protection of data submitted for the registration of medicines to be of considerable economic magnitude. The rationale is that the manufacturer has invested, often heavily, in the research necessary to develop the relevant data (Meitinger, 2005),[54] and where patent law fails to provide protection (e.g. because the active component was shortly to be out of patent, or because the drug was based on a combination of known substances used in a novel manner) the secrecy of the testing work would provide the only barrier against a generic competitor rapidly producing and registering an exact copy of the drug. From a public health perspective, however, the early entry of generic competition is also considered an important policy objective, whose realization is facilitated by

[53] See e.g. Chapter 15, Article 15.9.4 of the USA - Morocco FTA, and Chapter 17, Article 17.9.4 of the USA - Australia FTA.
[54] It is argued that the estimated clinical costs per approved new drug exceed 50% of its total development costs.

regulations that allow health authorities to rely on existing test data to approve subsequent applications for generic products (UNCTAD-ICTSD, 2005).

The original intention of the main advocates of TRIPS in the Uruguay Round was the establishment of an exclusive right in the form of an economic protection of test data for a given number of years. In a submission made by the US in 1990, which was joined by the EC and Switzerland, it was proposed that:

"Contracting parties which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secret for the commercial or competitive benefit of the government or of any person other than the right holder except with right holder's consent, on payment of the reasonable value of the use, or if a reasonable period of exclusive use is given to the right holder" (cited by Watal, 2001).

The Agreement did not fully recognize this new right but instead established that undisclosed information should be protected against unfair competition, leaving a number of uncertainties as to the appropriate implementation of this provision. The original intention, to recognise an exclusive protection of test data for at least five years from the date of approval of the pharmaceutical product, was first introduced in the North American Free Trade Agreement (NAFTA) and has been further elaborated and included in free trade agreements concluded by EFTA countries and the US with a number of developing countries.

The US FTAs introduce this new regime, providing that once a company has submitted original data on a pharmaceutical product, regulatory authorities shall not permit competing producers to rely on that data for a period of five years from the date of marketing approval (ten years in the case of agricultural chemical products).[55] This provision effectively requires generic producers to come up with their own test data, which very often is not economically feasible or may be considered unethical. It thus provides the data originator with a further period of exclusivity. It is important to note that this exclusivity may apply to non-patented pharmaceutical or agrochemical products, thus creating a new form of monopoly not required by TRIPS (Abbott, 2004).[56]

The CAFTA-DR agreement, as well as those more recently signed with Colombia, Panama and Peru, expressly maintains the possibility of requesting marketing approval at any time during the five-year period. Where the data originator requests domestic approval at the end of the five-year exclusivity period generated by his earlier request abroad, another term of protection of five years will be triggered, extending protection effectively to 10 years (15 in the case of agrochemicals) (Correa, 2000; Abbott, 2004). As discussed below, in a recent development in the US, the FTAs with Colombia, Panama and Peru have been revised to take into account many criticisms made as to the effects of these types of provision on access to medicines.

g) Linkage between regulatory procedures and patent rights

While the above observations may concern non-patented pharmaceutical and agrochemical products, most of the FTAs also contain a provision that can have an important impact with respect to patented pharmaceutical and agrochemical products. For instance, Chapter 15, Article 15.10.3(a) of CAFTA provides that:

"3. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product

55 See, e.g., Chapter 15, Article 15.10.1(a) of CAFTA

56 The same author observes that such exclusivity renders illegal the registration of generic drugs for public non-commercial use.

that was previously approved, such as evidence of prior marketing approval in the Party or in another territory, that Party:

(a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and

(b) if the Party permits a third person to request marketing approval of a product during the term of a patent identified as claiming the product or its approved use, it shall provide that the patent owner be informed of such request and the identity of any such other person."

In other words, the decision by regulatory authorities to grant marketing approval is made dependent on the will of the patent holder, thus linking the separate realms of safety and efficacy regulations and patent rights. Besides the difficulties created for regulatory authorities to determine the validity of patents, this provision has been interpreted as potentially precluding governments' options for using compulsory licenses to increase the availability of low-priced pharmaceutical products (Abbott, 2004). Since marketing approval is independent of patent law, the third party authorized to produce a patented product under compulsory license would arguably depend on the patentee's consent or acquiescence for the actual marketing of the product (UNCTAD-ICTSD, 2005). Chile, in its FTA implementing legislation, has provided that once a compulsory license is issued, the associated test data may also be used.

C. Recent developments in US policies

On 10 May 2007, the terms of an agreement between Congress and the US administration on the pending FTAs with Colombia, Peru and Panama were made public. The agreement would allow the ratification of these FTAs provided that changes are incorporated on three counts, namely on basic labour standards, environmental issues and access to medicines. Of the latter, the agreement calls for amendments in five areas:

a) Data exclusivity. It is suggested that in cases where data exclusivity for new chemical entities relies on marketing approval in the US, provided Colombia, for example, grants approval within six months of an application by a person that produced the original data, the five year exclusivity should begin when the drug was first approved in the US (a so-called "concurrent period"). This important change takes care of one of the criticisms of the CAFTA-DR, referred to above, of extending the exclusivity period for an added five years;

b) Patent extensions. Parties "may" extend the term of a patent to compensate for unreasonable delays in the patent or marketing approval process. In other words the mandatory obligation to compensate for those delays is transformed into an option for the parties. But the FTAs also provide that a party should endeavour to process patent and marketing approval applications expeditiously, with a view to avoiding unreasonable delays.

c) Linking drug approval to patent status. The agreement here is straightforward, calling for the FTA texts to be amended so that there is no "linkage" between drug regulatory agencies and patent issues, and in particular no requirement that the drug regulatory agency withhold approval of a generic until it can certify that no patent would be violated if the generic were marketed. However, the agreement does prescribe that a party would be required to provide procedures and remedies (judicial or administrative proceedings, including injunctions), for adjudicating expeditiously any patent infringement concerning validity or disputes that arise with respect to a

product for which marketing approval is sought. Transparency in these processes is also advocated. Parties to the FTA could choose to implement the "procedures and remedies" obligation through a linkage system, but in these cases they should make available: i) an expeditious administrative or judicial procedure to challenge the validity or applicability of the patent (so as to break the ex-officio "link" in appropriate cases), and ii) effective rewards for successfully challenging the system as already provided in US law. In other words, the agreement tries to balance the rights of patent holders with opportunities for generic producers to challenge patented products that might impinge the entry into the market of competing products.

d) Side letter on Public Health. As mentioned previously, some of the FTAs include side letters that refer to the Doha Declaration on TRIPS and Public Health. The agreement prescribes that they should be made part of the text of the FTA by i) affirming the parties commitment to the Doha Declaration; ii) clarifying that it does not prevent the parties from taking measures to protect public health; and iii) including an exception to the data exclusivity obligation for measures to protect public health in accordance with the Doha Declaration.

e) Economic Development. An important final element of the agreement is the provision that the FTA could include a provision calling for a periodic review of the implementation and operation of the IP chapter, and giving the parties an opportunity for further negotiations. The parties could agree to consider, *inter alia*, whether any changes in the level of economic development in the territory of the other party would support amendments to the IP chapter.

These developments are a sign of an important shift in US policies, that in many respects takes into account the criticisms faced by FTAs on account of their impact on the use of TRIPS flexibilities and on their actual impact on public health. The agreement of May 2007 has featured in revisions to the FTAs signed with Peru and Panama and ultimately with Colombia. The revised treaties, compared to those signed by CAFTA-DR, provide for additional flexibilities in the implementation of the FTAs. A major issue for those countries will be the proper use of the policy space left open by the new versions of these agreements. A further line of enquiry could be the possible implications of this new deal on third countries already party to an FTA with the US, as in the cases of CAFTA and Chile.

4. Genetic resources: biotechnological inventions, genetic resources, traditional knowledge

Access to genetic resources and its relationship with IP has been a controversial aspect in multilateral deliberations, particularly in the WTO and WIPO. At the root of the controversy is the contentious provision of the TRIPS Agreement that:

"*Members may also exclude from patentability: plants and animals other than microorganisms, 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 system or by any combination thereof*". (Article 27.3 b)

Article 27.3(b) of TRIPS describes inventions that Members may exclude from patentability while, at the same time, specifically obliging Members to protect microorganisms and certain biotechnological processes. The final drafting of this provision reflects differences and uncertainties among countries over the scope of protection to be given to such inventions and the concerns regarding the patentability of life forms. The Agreement also provides for a review of this provision, which has become one of the key issues currently under consideration in the WTO Council for TRIPS.

In the review process of Article 27.3 (b), developing countries, in particular, have presented their views on the possible implications of this provision with respect to the protection of living organisms and on the need to reconcile TRIPS with the Convention on Biological Diversity (CBD).

TRIPS leaves flexibility for Members to adopt different approaches on the patentability of inventions relating to plants and animals, but requires the protection of microorganisms – though, as with other terms in TRIPS, such as the concept of invention itself, the meaning of microorganism is not defined, leaving some space for flexibility. TRIPS also obliges Members to introduce some kind of protection for "plant varieties" which most developing countries did not protect before the adoption of the Agreement. This obligation "has raised concerns in some of those countries about the impact of IPR protection on farming practices (particularly the re-use and exchange of seed by farmers), genetic diversity, and food security)" (UNCTAD-ICTSD, 2005).

TRIPS does allow for the exclusion from patentability of "plants and animals" in general. Consequently, Members may exclude plants as such (including transgenic plants), plant varieties (including hybrids), as well as plant cells, seeds and other plant materials. They may also exclude animals (including transgenic) and animal races. For example, the European Directive,[57] in line with TRIPS, excludes from patentability: plant and animal varieties; and essentially biological processes for the production of plants and animals.

The TRIPS Agreement, however, states that Members "shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof".

The option of patent protection is straightforward. But the Agreement leaves the content of "an effective *sui generis* regime" open to interpretation. It might suggest the breeder's rights regime, as established in the UPOV Convention (International Union for the Protection of New Varieties of Plants) (see Box 3 below), that could have been the intention of some negotiators during the Uruguay Round, but the text does not contain any such references. The possibility is also open to combine the patent system with a breeders' rights regime, or, indeed, to develop other "effective *sui generis*" forms of protection.

The remainder of this chapter will be devoted to analysis of the major developments that have taken place in the deliberations in WTO and WIPO on these issues, focussing on the review of the biodiversity provision of the TRIPS Agreement, the protection of life forms, the relationship between TRIPS and the CBD and the debates surrounding the protection of traditional knowledge. We will return to examine further how the FTAs concluded between the US, EU and EFTA on one side, and a number of developing countries on the other, relate to these questions.

A. Deliberations in WTO

With respect to genetic resources, the most relevant IP issue has been the relation between the TRIPS Agreement and the CBD and, in this context, discussions on the disclosure of origin of genetic resources and associated traditional knowledge (TK) in patent applications. The debates on disclosure of origin have revolved around several positions, ranging from solutions through contracts, to amendments of specific international agreements. As detailed in this section and the following, four concrete proposals have been tabled in the WTO and WIPO respectively.

The built-in mandate in the TRIPS Agreement to review Article 27.3(b) was expanded by the Doha Ministerial Declaration to include the relationship between the TRIPS Agreement and the CBD and the protection of TK and folklore.[58] Therefore, discussions on biodiversity issues in the WTO have centred on these three issues, with most attention given to the relationship between TRIPS and the CBD. Of the latter, the disclosure of origin of genetic resources and associated TK in patent applications to combat their misappropriation has been the central issue at hand.

[57] See the European Directive on legal protection of biotechnological inventions of 1998 (98/44/EC).

[58] Paragraph 19 of the Doha Ministerial Declaration states: "We instruct the Council for TRIPS, in pursuing its work program including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension." See WTO document WT/MIN(01)/DEC/1.

a) The Review of Article 27.3(b): the various issues under consideration, including the protection of life forms

As mentioned earlier, Article 27.3(b) contains a review process that actually began in 1999. The debates have revolved around several issues, one of them being the relationship between TRIPS and the CBD, which has since become almost the sole biodiversity issue discussed in the WTO. Other matters discussed in the review process include:

- What are effective *sui generis* systems for the protection of plant varieties;
- Whether concepts such as microorganisms, plants and animals should be defined;
- The protection of traditional knowledge associated with genetic resources; and
- Whether the exceptions related to life forms should be eliminated, qualified or strengthened.

One of the most heated debates has been on the latter issue of exceptions to life forms, between those for and against providing patent protection for inventions based on plant and animal life. Positions range from proposals to amend the TRIPS Agreement in order to prohibit the patenting of any life forms, including microorganisms and non-biological and microbiological processes,[59] to those that propose extending patent protection to all inventions, including plants and animals. India and Kenya, the latter generally speaking on behalf of the African Group of countries, have been the main exponents of the case against patent protection of life forms, whereas Singapore and the US have stated that they consider exceptions to patentability unnecessary. Australia, Canada, China, the Republic of Korea and the EC have put forward arguments in favour of preserving Article 27.3(b) as it is. In other words, the preservation of Article 27.3(b) would allow the patentability of all types of life forms, but at the same time enable WTO Members to except plants, animals and essentially biological processes from patent protection. As noted above, this is precisely what the European Directive on the legal protection of biotechnological inventions does. The Directive recognizes the patentability of biotechnological inventions that are new, involve an inventive step and capable of industrial application, even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. It excludes plants and animal varieties and essentially biological processes but recognizes the patentability of inventions related to plants or animals "if the technical feasibility of the invention is not confined to a particular plant or animal variety". It also allows for the patentability of "inventions which concern a microbiological or other technical process or a product obtained by means of such process".[60]

The main arguments against the patentability of plants and animals have been that:[61]

- Living things should not be patentable because they are discoveries and not proper inventions;
- The differentiation between plants and animals on the one hand and microorganisms on the other is artificial;
- Patenting of life forms is in itself unethical;
- There are implications for access to, and the cost of, the re-use and exchange of seeds by farmers as well as displacement of traditional varieties and depletion of biodiversity;

[59] See WTO document IP/C/W/404 of the African Group of June 2003.
[60] Articles 3 and 4 of Directive 98/44 of 6 July 1998.
[61] See WTO document IP/C/W/369/Rev.1.

- Excessively broad patents may be granted, which do not fully meet the criteria for patentability;
- The associated costs for the revocation of such patents;
- Current international agreements protect the interest of innovators but do not adequately protect the countries and local communities that supply the genetic material and traditional knowledge.

On the other hand, the main arguments favouring the patentability of plants and animals expressed in the context of WTO deliberations are that:[62]

- With respect to ethical concerns, Article 27.2 of the TRIPS Agreement would adequately take into account ethical concerns as far as patent law is concerned;[63]
- Biotechnological inventions, including plants and animals, should be accorded the same patent protection as inventions in other fields, to promote private sector investment in inventive activities and to contribute to solving problems in areas such as agriculture, nutrition, health and environment;
- Patent protection for plants and animals facilitates the transfer of technology and the dissemination of state of the art research, by providing incentives to licensing and discouraging confidentiality and trade secrets arrangements;
- Patent disclosure requirements can facilitate the operation of laws aimed at protecting public morality, health and the environment.

b) The relationship between TRIPS and the CBD

The issue of the relationship between the TRIPS Agreement and the CBD was mandated for discussion in the TRIPS Council by the Doha Ministerial Declaration. However, this relationship is also being discussed in parallel "dedicated consultations" as an outstanding implementation issue under the Doha Declaration and the Hong Kong Ministerial Declaration.[64] The Hong Kong mandate – to intensify TRIPS-CBD consultations – has been carried out under the supervision of the Director General of the WTO, who has to report to the meetings of both the General Council and the Trade Negotiations Committee (TNC).

The debates in the TRIPS Council are often seen as being of a more technical nature than those held in the "dedicated consultations", which are rather seen as part of the broad political context of a package deal comprising different issues and interests at stake. The discussions revolve around the question of whether there is a conflict between TRIPS and the CBD. Given that TRIPS is an agreement recognizing private rights and permitting the appropriation of genetic

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62 See WTO document IP/C/W/369/Rev.1

63 TRIPS Article 27.2 states that: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."

64 Paragraph 39 of the Hong Kong Ministerial Declaration states the following: "We reiterate the instruction in the Decision adopted by the General Council on 1 August 2004 to the TNC, negotiating bodies and other WTO bodies concerned to redouble their efforts to find appropriate solutions as a priority to outstanding implementation-related issues. We take note of the work undertaken by the Director-General in his consultative process on all outstanding implementation issues under paragraph 12(b) of the Doha Ministerial Declaration, including on issues related to the extension of the protection of geographical indications provided for in Article 23 of the TRIPS Agreement to products other than wines and spirits and those related to the relationship between the TRIPS Agreement and the Convention on Biological Diversity. We request the Director-General, without prejudice to the positions of Members, to intensify his consultative process on all outstanding implementation issues under paragraph 12(b), if need be by appointing Chairpersons of concerned WTO bodies as his Friends and/or by holding dedicated consultations. The Director-General shall report to each regular meeting of the TNC and the General Council. The Council shall review progress and take any appropriate action no later than 31 July 2006." See WTO document WT/MIN(05)/DEC.

resources through the patenting of life forms, it is argued that it could run counter to the sovereign rights of countries over their resources, as provided for in the CBD. Additionally, it is also argued that this appropriation could conflict with one of the main objectives of the CBD, namely the "fair and equitable sharing of benefits arising out of the utilization of genetic resources".[65]

The CBD requires each contracting party to implement several measures in order to ensure the in-situ and ex-situ conservation of genetic resources. Additionally, it recognizes the authority of national governments to determine access to genetic resources, subject to national legislation. Under the CBD, access, where granted, shall be on mutually agreed terms and subject to prior informed consent of the contracting party providing the genetic resources and on the basis of benefit sharing arrangements. Box 2 provides a summary of the key features of the CBD as it relates to IPRs.

BOX 2
THE CBD

The CBD provides that States have the "sovereign right to exploit their own resources" and that they will, "subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices". Additionally, the CBD states that each party "shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties"[66]…"on mutually agreed terms" and that such access "shall be subject to prior informed consent of the Contracting Party providing such resources".[67] Finally, those using the genetic resources shall share "in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources".

Source: The Convention on Biological Diversity (CBD), concluded in 1992, available at http: //www.cbd.int/doc/legal/cbd-un-en.pdf

The relationship between TRIPS and the CBD has given rise to different opinions, ranging from those considering the two agreements to be compatible, to those considering that there is an inherent conflict between the two international agreements. This conflict has been associated with the possible granting of IPRs, based on or consisting of genetic resources, without observing the prior informed consent and benefit sharing obligations established by the CBD. The different views on the TRIPS-CBD relationship could be summarized as follows: a number of developed countries find no inconsistencies between the two treaties while several developing countries highlight the need to reconcile the two agreements, possibly by means of a formal revision of TRIPS.

The main concern of developing countries is that TRIPS does not require patent applicants, whose inventions incorporate or use genetic material or associated TK, to comply with the obligations under the CBD. As pointed out, the CBD subjects access to genetic material to prior informed consent from, and equitable benefit sharing with, the party providing the genetic resources. Developing countries have repeatedly voiced concerns about possible misappropriation of their genetic resources by developed country patent applicants.

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[65] See CBD Article 1, "The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and 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, taking into account all rights over those resources and to technologies, and by appropriate funding".

[66] CBD Article 15.2.

[67] CBD Article 15.5.

In general terms, in order to address these concerns, developing countries have proposed an amendment to TRIPS so as to require applicants for a patent relating to biological materials or associated traditional knowledge, to disclose, as a condition for obtaining the patent: (i) the source and country of origin of the biological resource; (ii) any related TK used in the invention; (iii) evidence of prior informed consent from the authorities under the relevant national regime; and (iv) evidence of fair and equitable benefit sharing under the relevant national regime.

The opinion of supporters of the disclosure requirement, not only developing countries, is that such an obligation would reaffirm the principles of the CBD, particularly with respect to prior informed consent and equitable benefit sharing, but also in terms of the consistency that must exist between the access and transfer of technology relevant to biodiversity and IPRs as provided for in the CBD.[68] The biggest differences between proponents of disclosure are with respect to the legal effects of non-disclosure. Broadly, some argue in favour of sanctions within the IP system (e.g. revocation of the patent) whilst others favour sanctions outside the IP system (e.g. punitive damages) which would leave the patent intact.

The attempt to reinforce CBD obligations through TRIPS is opposed by a number of developed countries that see no conflict between TRIPS and the CBD. For example, in the view of the US, the proposed disclosure requirement is not an appropriate solution. It advocates that members should instead focus on national solutions outside the IP system, which directly address the specific issues of prior informed consent, equitable benefit sharing and erroneously granted patents. They suggest that countries could, *inter alia*, promote the use of organized databases to help examiners assess prior art in patent filings, require that information concerning patentability be provided and use post-grant opposition or re-examination systems as an alternative to litigation.[69]

Most importantly, the US has promoted the use of contracts between the authorities administering the genetic resources and those interested in using them (e.g. bioprospectors and researchers), thus fulfilling the requirement for prior informed consent. Additionally, contracts could regulate other matters, such as the transfer of benefits, the mandatory disclosure of relevant information (including the contract) if the invention is patented, and periodical reports on the use of the genetic resources. As we will see, this has been considered an adequate approach in the FTAs between the US and, respectively, Colombia and Peru (see box 4 below).

Specific proposals made on disclosure requirements in the WTO

Norway has submitted a proposal in the WTO supporting an amendment to the TRIPS Agreement by introducing a mandatory obligation to disclose the origin of genetic resources and TK in any patent application, be it national, regional or international.[70]

The obligation would consist of disclosing the "supplier country (and the country of origin, if known and different) of genetic resources and traditional knowledge", and "if the country of origin is unknown, that fact must be disclosed". This would also apply to TK, even if it were not directly related to genetic resources. It should be noted that the CBD deals with only the

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[68] Article 16.2 of the CBD provides: "Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favorable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below".

[69] See IP/C/W7469 (13 March 2006).

[70] See WTO document WT/GC/W/566, TN/C/W/42 and IP/C/W/473 of 14 June 2006, submitted to the General Council, the TNC and the TRIPS Council.

TK associated with genetic resources. Applicants would also be obliged to disclose whether prior informed consent had been obtained.

In Norway's view, the amendment would provide that patent applications should not be processed unless the required information has been submitted. However, conversely to the approach of developing countries, non-compliance with the disclosure obligation discovered post-grant would not affect the validity of the patent. According to Norway the disclosure requirement would not constitute a substantive patent criterion. In this context, TRIPS would be amended by the introduction of a new provision in the Agreement following the general provision on disclosure requirements (Article 29).[71] Moreover, Norway also supports making corresponding amendments to both the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT) in the framework of WIPO.

As with Norway, a group of developing countries, the most active *demandeurs* of the disclosure requirement, submitted a proposal in the WTO in July of 2006.[72] This proposal, cosponsored by Brazil, China, Colombia, Cuba, Ecuador India, Pakistan, Peru, South Africa, Thailand, Tanzania and Venezuela, also suggests incorporating a new article after the general disclosure requirement provision (a new TRIPS Article 29bis). According to this proposal, the disclosure requirement should include:

- An obligation to disclose the country providing the biological resources (a broader concept than genetic resources) and/or associated traditional knowledge;
- From whom in the providing country the resources were obtained, and, as known after reasonable enquiry, the country of origin;
- Information of evidence of compliance with legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge.

Contrary to the Norwegian proposal, the legal effects of non-disclosure would be that the request for application would not be further processed, and that patents would be revoked or rendered unenforceable when the applicant knowingly (or having reasonable grounds to know) failed to comply with the obligation.

Two other proposals for disclosure requirements have been submitted in WIPO, by Switzerland and the EC respectively, as discussed below.

c) The protection of traditional knowledge and folklore

Finding solutions to the protection of traditional knowledge is not straightforward. Dutfield identifies two main forms of protection: positive and defensive.

"Positive protection refers to the acquisition by the TK 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 a product being granted to unauthorized persons or organizations" (Dutfield, 2006).

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[71] Article 29: "1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application. 2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants".

[72] See WTO document WT/GC/W/564, TN/C/W/41 and IP/C/W/474 of 5 July 2006, submitted to the General Council, the TNC and to the TRIPS Council. This proposal, as of June 2007, has received the support of the African Group.

The discussions in WTO have principally revolved around "defensive protection". As we will analyze below, the deliberations in WIPO have been more comprehensive in nature and with greater emphasis on forms of "positive protection".

As detailed above, the debate in the WTO is tied to the relationship between TRIPS and the CBD, focusing on amendments to TRIPS in order to incorporate a requirement to disclose the use of traditional knowledge in patent applications. A question that has surfaced in the WTO regarding patents that comprise traditional knowledge is that of countries that do not recognize TK transmitted orally or through use outside their jurisdictions when considering the novelty of an invention (e.g. US and Japan). Because this information is often not documented, examiners would not be aware of it when examining a patent application.

Approaches that have been suggested in the WTO to tackle the protection of traditional knowledge include the establishment of an "absolute" novelty criteria (as opposed to a "relative" criteria), by which any prior use or publication, anywhere in the world, would bar the patentability of the invention. The development of databases has also been proposed to prevent the issuance of patents that rely on information that should have been considered during the examination of prior art. To this effect, Japan submitted a proposal in WIPO to consider the establishment of a database of genetic resources and TK.[73]

Some of the counterarguments that have been advanced to the development of such databases have been that:

- Databases would still not accommodate TK and prior art transmitted orally;
- They would not account for equitable benefit sharing with communities and indigenous people who are the holders of TK;
- The inclusion of TK in public databases would only increase the problem of biopiracy as the information would be easily accessible for further misappropriation, and:
- Databases would have limited use because there would be no obligation to consult them.

B. Deliberations in WIPO

a) General developments

Issues related to biodiversity in WIPO have been addressed mainly in the context of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Furthermore, issues related to biodiversity and genetic resources have also been broached to a lesser extent in the Standing Committee for the Law of Patents (SCP) in the context of negotiations on the SPLT, in the Working Group on Reform of the PCT, and finally, in the discussions on a WIPO Development Agenda (see Box 1 above).

In the context of the Development Agenda, and in addition to the general discussions, the issues of genetic resources and TK have risen in two specific proposals made by developing countries. The first relates to the adoption of "an internationally binding instrument on the protection of genetic resources, traditional knowledge and folklore in the nearest future". The second proposal relates to "work on any initiative intended to facilitate the implementation of technology-related provisions of Multilateral Environmental Agreements (MEAs), so as to ensure that countries where biological, traditional or other environmental resources originate from, participate in the process of research and development".

[73] This document was also submitted in the TRIPS Council. See WTO document IP/C/W/472 of 13 June 2006.

Regarding the discussions on an SPLT in WIPO, the issues of genetic resources and the environment found their way into several articles under consideration in the Draft SPLT.[74] For instance, concerning general exceptions, the draft provides that neither the treaty nor the regulations should limit the freedom of contracting parties to "take any action it deems necessary for the preservation of essential security interests or to comply with international obligations, including those relating to the protection of genetic resources, biological diversities [sic], traditional knowledge and the environment".[75] Regarding the grounds for refusal of a claimed invention, draft Article 13.4 would allow parties to "require compliance with the applicable law on public health, nutrition, ethics in scientific research, environment, access to genetic resources, protection of traditional knowledge and other areas of public interest in sectors of vital importance for their social, economic and technological development". Finally, the draft provides for similar grounds for invalidation or revocation of a patent.[76]

The US, Japan and the European Patent Office (EPO),[77] submitted a joint proposal to the SCP in May 2004, suggesting discussions focus on reaching an agreement on an initial four issues (definition of prior art, grace period, novelty and non-obviousness/inventive step) before the SCP could then turn to discuss other issues such as those related to genetic resources.[78] The proposal met with the forceful opposition of developing countries, who are seeking a more comprehensive approach to the treaty, which has lead to a stalemate in the SPLT negotiations at the time of writing.

The discussions around the SPLT have thus been most controversial, particularly with the general opposition of developing countries to using the SPLT as a platform for further substantive harmonization of patent law. In many respects the initiative behind the WIPO Development Agenda finds its origin in the concerns arising from the SPLT discussions.

b) The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)

The IGC was established in 2000, after Colombia submitted a proposal (Vivas, 2001) during negotiations on the PLT,[79] which sought to incorporate, among others, a requirement to "specify the registration number of the contract affording access to genetic resources and a copy thereof whereby the products or processes for which protection is sought have been manufactured or developed".[80] The proposal was supported by many developing countries and was rejected by

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74. See WIPO document SCP/10/2.

75 See Articles 2.2 and 2.3 of the Draft SPLT. WIPO document SCP/10/2.

76 See Article 14.3 of the Draft SPLT. WIPO document SCP/10/2.

77 See WIPO document SCP/10/9.

78 The proposal did mentioned discussion on disclosure requirements but did not take into account that the draft treaty included several other "public interest" provisions.

79 The aim of the Patent Law Treaty (PLT) of 2002 is to harmonize and streamline formal procedures in respect of national and regional patent applications and patents, and thus to make such procedures more user-friendly. With the significant exception of the filing date requirements, the PLT provides maximum sets of requirements, which the Office of a Contracting Party may apply. This means that a Contracting Party is free to provide for requirements that are more generous from the viewpoint of applicants and owners, but are mandatory as to the maximum that an Office can require from applicants or owners. Source WIPO, http://www.wipo.int/treaties/en/ip/plt/summary_plt.html, as of 12 April 12, 2007.

80 The proposal by Colombia was submitted to the Third Session of the Standing Committee on the Law of Patents, in September 1999. It read: "1) All industrial property protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired legally; 2) Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin". See WIPO document SCP/3/10 at http://wipo.int/meetings/en/details.jsp?meeting_id=3824.

most of the developed countries on the grounds that it "related to issues of substantive law and was therefore not appropriate for inclusion in the draft Treaty".[81]

With its mandate renewed for two years at the 2005 WIPO General Assembly, the IGC held its eleventh session in July 2007.[82] To date, the IGC has discussed extensively the issues of traditional knowledge and traditional cultural expressions (TCEs or folklore) and has even considered detailed draft provisions on objectives and principles for the protection of TK and TCEs, with the view of adopting an international instrument.[83] The nature of such an instrument is a major source of disagreement. The IGC has been deliberating for some years, most of all towards an outcome on the issues of TK and folklore. The outcome could take diverse forms, including a "binding international instrument or instruments; a non-binding statement or recommendation; guidelines or model provisions; authoritative or persuasive interpretations of existing legal instruments; and an international political declaration espousing core principles and establishing the needs and expectations of TCE/TK holders as a political priority".[84]

On the other hand, work on genetic resources has been lagging behind, with some preparatory progress made.[85] Although developing countries favour an internationally legally binding instrument for the protection of genetic resources, the opinion in the IGC has been that the Committee should focus on the more advanced work on TK and TCE, while avoiding duplication with work carried out in the WTO and the CBD on the issue of genetic resources. For those developing countries that have made proposals in the context of the WTO there is an inherent preference to deal with these questions there, where any resultant commitments would have more "teeth" that those that might result from negotiations in WIPO. This in a way reflects the position adopted by developed countries during the Uruguay Round, who sought to move discussions on IP out of WIPO for consideration in the new WTO system.

As mentioned earlier, Japan submitted a proposal to the IGC in April 2006 to consider the establishment of a database of genetic resources and TK.[86] Japan saw an easily accessible database, which would be available to patent examiners in any country, as a tool to prevent the issuance of erroneous patents. By creating such a database, it us argued, examiners would not have to deal with countless documents on TK when performing searches; prior art transmitted orally could be documented; and the problems of providing documentation in accessible languages could be solved by attaching a summary, in a widely used language, to the documents written in foreign or indigenous languages.

With respect to the disclosure requirement discussed in the context of the WTO, the EC submitted a proposal to the IGC on a mandatory disclosure of the country or source of origin of genetic resources.[87] The proposal by the EC would apply to all patent applications, whether international, regional or national. Therefore, it would necessitate amendments to the PLT, the PCT and regional agreements, such as the European Patent Convention (EPC). The obligation

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81 See Report of the Third Session of the SCP at http://wipo.int/edocs/mdocs/scp/en/scp_3/scp_3_11.doc.

82 The 11th session of the IGC agreed to renew its mandate again and forwarded its decision to the 2008 General Assembly for approval.

83 See WIPO/GRTKF/IC/11/5(c), 26 April 2007.

84 See "Options for giving effect to the international dimension of the Committee's work" (WIPO document (WIPO/GRTKF/IC/10/6).

85 For instance, the IGC developed a database of contractual practices concerning intellectual property, access to genetic resources and benefit-sharing; a questionnaire on contracts and licenses; a Draft Technical study on Disclosure Requirements related to Genetic Resources and Traditional Knowledge (later forwarded to the Secretariat of the CBD); Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing; and elaborated a complete document on issues relating to genetic resources and disclosure requirements in response to an invitation from the CBD. Further, Members have tabled specific proposals on the issue of protection of genetic resources and traditional knowledge

86 See WIPO document WIPO/GRTKF/IC/9/13 at: http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_9/wipo_grtkf_ic_9_13.doc

87 See WIPO document WIPO/GRTKF/IC/8/11 at: http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_8/wipo_grtkf_ic_8_11.doc.

would consist of disclosing the country of origin of the genetic resources, if the invention was directly based on specific genetic resources, and if the country were unknown to the patent applicant then the source of origin would have to be disclosed. Additionally, the applicant would be obliged to disclose TK associated with the genetic resources, but there would be no obligation to disclose proof of prior informed consent and equitable benefit sharing. The information would be submitted in a simple, standardized form, and the patent offices would communicate the fact that there has been a disclosure to a centralized body (e.g. the Clearing House Mechanism of the CBD). In case an applicant does fail to comply with the obligation, by not submitting any information or by submitting incomplete information, then sanctions outside the patent system would be applied. Thus, there would be no effects on the validity of the patent.

The EC proposal in the IGC differs from the proposal made by developing countries in WTO in three main respects. Firstly, it only requires disclosure of the origin of genetic resources, not of prior informed consent and equitable benefit sharing. Secondly, the EC opposes the revocation of the patent in the event that the origin is not disclosed. Instead, sanctions would be established outside the patent system, whereas developing countries favour the revocation of the patent. Thirdly, the EU advocates the amendment of the PCT, PLT and other treaties, but not the TRIPS Agreement. At present, the member countries of the EU are guided by the principle stated in the European Directive on biotechnological inventions:

"Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents".[88]

The proposal by the EC has similar consequences and effects to that made by Norway in the context of the WTO with the aim of amending the TRIPS Agreement, as discussed above.

In brief, and to underline the point, in comparing the corresponding parallel exercises in the WTO and in the WIPO-IGC, a general observation is that while WTO initiatives deal with "defensive" measures addressing possible misuses of genetic resources and associated TK, the WIPO exercise also tries to provide "positive" responses and options for TK protection. At the present juncture in negotiations, and in view of the intrinsic difficulties of providing universally acceptable solutions to the questions raised by the protection of TK in terms of "private rights", defensive measures might prove a more realistic approach. A difficulty arising in this area is the need to reconcile the preservation of indigenous groups and their communal control of ancestral knowledge and practices, on the one hand, whilst granting exclusive property rights to that knowledge on the other. There are, however, scholars that consider this feasible through, for example, the recognition of a new *sui generis* system of IPRs:

"Accommodating IPRs to this subject matter is primarily a learning process. As farmers adopt and familiarize themselves with the concepts of real and movable property rights, they might grow accustomed to the concept of property in intangible knowledge goods that underlies intellectual property systems. Because IPRs can potentially enhance farmers' standing, bargaining powers, respect and incomes, these proposals seem likely to attract attention and support from rural communities" (Cottier & Panizzon, 2005).

c) The Working Group on Reform of the Patent Cooperation Treaty (PCT)

The Patent Cooperation Treaty is a WIPO global protection treaty, which makes it possible to seek patent protection for an invention simultaneously in each of a large number of PCT member countries by filing an "international" patent application. Such an application can be filed by

[88] See preambular paragraph 27 of the EC Directive on the legal protection of biotechnological inventions (98/44/EC).

anyone who is a national or resident of a PCT contracting state. It is generally filed with the respective national patent office but the applicant can also do so through WIPO's International Bureau in Geneva.

In the context of the Working Group on the Reform of the PCT, Switzerland tabled a proposal in May 2003 on the disclosure of origin of genetic resources and traditional knowledge.[89] The Swiss proposal consists of amendments to the PCT Regulations and the PLT to enable parties to these treaties to request the disclosure of source of genetic resources and/or TK incorporated in the invention, if the invention is directly based on those genetic resources and/or TK. The opportunity for disclosure would be within the international phase, and, in the event that disclosure was inadequate, domestic legislation would preclude the completion of the application at the national phase. The Swiss proposals were reiterated at the 2006 meeting of the Working Group,[90] but were subsequently withdrawn at the 2007 meeting in order to avoid further delays to the work of the Group.[91] They are being analyzed at the IGC.

Regarding sanctions, Switzerland proposes that if the applicant does not comply with the national disclosure obligations, the application may be refused or considered withdrawn. In cases where the patent has already been granted, sanctions would not include revocation, unless the respective national law provided for revocation in fraudulent cases.

Discussions in the PCT Working Group revolved around whether the Group was the appropriate forum to discuss the issue of disclosure, given that other fora such as the IGC, the TRIPS Council and the CBD were dealing with the same topic. Opinions differ as to how this question should be tackled within the context of the PCT. They range from discussing it as complementary to deliberations in other organizations, to considering that it is not appropriate to address the issue at all within the PCT.

Notably, the Swiss proposals are consistent with amendments being sought in its domestic patent law. A new provision of the Swiss Patent Act would require patent applicants to disclose the source of a genetic resource, "insofar as the invention depends" directly on the resource. The Act also obliges the applicant, if they are unaware of the origin of the resource, to state so. This amendment to the Swiss law has met with the objection of the international industry group BIO for contravening the TRIPS Agreement by allegedly adding an additional technological-specific requirement to the patentability of biotechnological inventions and raising new potential grounds for the invalidity of patents.[92]

C. The Free Trade Agreements (FTAs)

As we have seen, the FTAs signal an important development in the evolution of the IP system. With respect to the issues discussed in this chapter, one can detect a tendency to include TRIPS-plus provisions, among others, in the areas of patents and plant breeders rights. On the issue of the protection of genetic resources and TK, there have also been developments in the FTA texts, though not with the far reaching implications of some of the patent provisions. Organizations such as Oxfam International, however, have denounced "the double standards" in these agreements:

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89 See WIPO documents PCT/R/WG/4/13; PCT/R/WG/6/11; PCT/R/WG/7; and WIPO/IP/GR/05/INF/4.
90 See Swiss Federal Patent Office available at http://www.ige.ch/E/jurinfo/j105.shtm, as of 12 April 2007.
91 at http://www.wipo.int/edocs/mdocs/pct/en/pct_r_wg_9/pct_r_wg_9_8.doc.
92 See ICTSD, Bridges BioRes, Vol.7, No. , 13 April 2007, available at: www.ictsd.org.

"While they extend the monopoly rights of large corporations, they offer no such protection for the vast amounts of knowledge held by farmers in developing countries" (Oxfam, 2007).

As mentioned above, in recent FTAs concluded between the US, EU and EFTA on one side and a variety of developing countries on the other, the 1991 Act of the UPOV Convention has been listed as one of the international treaties that parties should subscribe to in the near future as the modality of protection for plant varieties. Article 27.3(b) of the TRIPS Agreement, as discussed, obliges countries to prescribe protection of plant varieties either by patents, by an effective *sui generis* system of protection or by a combination of both. UPOV as a *sui generis* option is not referred to in the Agreement. The FTAs oblige countries to opt for the 1991 version of UPOV, which is seen as less flexible and more stringent than its previous incarnations (see box 3).

BOX 3
UPOV

UPOV provides a framework for the protection of plant varieties. The Convention was first signed in 1961 and revised in 1972, 1978 and 1991. It entered into force in 1968. It established the International Union for the Protection of New Varieties of Plants, based in Geneva and associated with WIPO. There are two versions of the Convention: UPOV 1978 and UPOV 1991. In both versions, the breeders' right may be subject to two exceptions: the "breeders' exemption" and the "farmers' privilege". The rights of breeders both to use protected varieties as an initial source of variation for the creation of new varieties and to market these varieties without authorization from the original breeder (the "breeder exemption") is covered in both versions of the Convention. One difference is that the 1991 version states that the original breeder's right also extends to varieties which are essentially derived from the protected one. The intention is that breeders should not be able to acquire protection too easily for minor modifications of extant varieties. This provision is also intended to ensure that patent rights and breeders rights operate harmoniously.

In the 1978 version there is no reference to the right of farmers to re-sow seed harvested from protected varieties for their own use (often referred to as the "farmers' privilege"). Thus countries that are members of the 1978 version are free, but not obliged, to uphold the farmers' privilege. In this respect, the 1991 version is more specific. Whereas the scope of the breeders' right includes production or reproduction and conditioning for the purpose of propagation, governments can use their discretion to decide whether to uphold farmers' rights. The Convention (Article 15) provides for an optional exception that allows parties "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, [to] restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or [an essentially derived] variety". This means that parties under UPOV 1991 can continue to uphold the farmers' privilege as long as their national plant variety system provides for it. If the national legislation does not feature provisions on the farmers' privilege, this presumably means there is no such privilege and that farmers cannot re-sow harvested seed even on their own farms.

Source: UNCTAD-ICTSD (2003).

UPOV's plant breeders' rights regimes have been criticized on the grounds that they better respond to conditions prevailing in industrialized countries and that as such risk undermining the food security of communities in developing countries. This, according to activists in the NGO community, may occur as a result of:

- Encouraging cultivation of a narrow range of genetically-uniform crops, including non-food cash crops, with the possible consequences that people's diets will become nutritionally poorer and crops will be more vulnerable to outbreaks of devastating diseases;

- Limiting the freedom of farmers to acquire seeds they wish to plant without payment to breeders, and thereby impoverishing them further;
- Restricting the free circulation of plant genetic resources, which is generally considered essential for the development of new plant varieties (UNCTAD-ICTSD, 2003);
- Increasing the market power of seed suppliers, pushing up the prices and enabling international firms to capture a larger segment of the profits from farming than poor farmers themselves (Oxfam, 2007).

In FTAs with the US, countries undertake further commitments to make efforts to introduce legislation concerning the patenting of plants. For example, and although Chile is a member of the 1978 UPOV Convention, the FTA between Chile and the US provides for a "best endeavour" clause for both parties to undertake reasonable efforts, through a transparent and participatory process, to develop and propose legislation –within four years of the entry into force of the agreement– to provide patent protection for plants which are new, involve an inventive step, and are capable of industrial application. In the CAFTA-DR Agreement, plants and animals may be excluded from patentability, but any party that does not provide patent protection for plants by the date of entry into force of the agreement shall undertake all reasonable efforts to make such patent protection available. In addition, according to the same agreement, any party that provides patent protection for plants and animals as of, or after, the date of entry into force of the agreement shall maintain such protection. In other FTAs, such as the one between the US and Morocco, there is a straightforward obligation for the parties to grant patents to inventions on animals and plants.

Another standard provision in US-forwarded FTAs that goes beyond TRIPS is that patents can only be revoked or cancelled on grounds that would have justified a refusal to grant the patent initially. Apparently then, the only causes for revocation or cancellation of a patent would be that the patent was not new, did not entail an inventive step or was not industrially applicable. However, other conditions of revocation have been incorporated in the different agreements, such as inequitable conduct, misrepresentation, the insufficiency of or unauthorized amendments to the patent specification, or nondisclosure of the invention. The question arises as to whether parties may incorporate substantial requirements at the domestic level on the disclosure of origin of genetic resources and associated TK. As explained above, the FTAs constitute a departure from the TRIPS Agreement but are built on its fundamental principles. As such, the disclosure of origin at the domestic level is in principle TRIPS compliant. Indeed, as mentioned the Swiss government is amending its patent law precisely to include such a requirement. In its recent report, Oxfam is of the view that in FTAs with the US, including CAFTA-DR, Peru and Colombia, "governments will no longer be able to reject a patent application because a firm fails to indicate the origin of a plant or show proof of consent for its use from a local community" (Oxfam, 2007). This assertion is reflected by a provision in the FTA between the US and Peru, that resembles the other treaties, with the exception of the FTA with Chile:

"16.9. Each Party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be carried out by a person skilled in the art, without undue experimentation, as of the filing date and may require the applicant to indicate the best mode for carrying out the invention known to the inventor as of the filing date.

"16.10. With the aim of ensuring that the claimed invention is sufficiently described, each Party shall provide that a claimed invention is sufficiently supported by its disclosure if the

disclosure reasonably conveys to a person skilled in the art that the applicant was in possession of the claimed invention as of the filing date".

The extent to which these FTA provisions would inhibit the possibility of introducing disclosure requirements at the domestic level remains a matter of interpretation. But if that was their effect, as Oxfam suggests, there would be large political ramifications, especially for a country like Peru that has been a main proponent of amending TRIPS to accommodate a disclosure requirement.

In another recent development, highlighted above, side letters were included in FTAs recently negotiated by the US with Colombia and Peru, respectively, recognizing the importance of TK and biodiversity, "as well as the potential contribution of traditional knowledge and biodiversity to cultural, economic, and social development". The side letters reaffirmed the importance of obtaining prior informed consent and the equitable sharing of benefits. However, the understanding reached by the parties recognized that these objectives could be adequately addressed by mutually agreed contracts between users and providers. Box 4 reproduces the contents of the understanding with Colombia.

BOX 4
UNDERSTANDING REGARDING BIODIVERSITY AND TRADITIONAL KNOWLEDGE

The Parties recognize the importance of traditional knowledge and biodiversity, as well as the potential contribution of traditional knowledge and biodiversity to cultural, economic, and social development.

The Parties recognize the importance of the following: (1) obtaining informed consent from the appropriate authority prior to accessing genetic resources under the control of such authority; (2) equitably sharing the benefits arising from the use of traditional knowledge and genetic resources; and (3) promoting quality patent examination to ensure the conditions of patentability are satisfied.

The Parties recognize that access to genetic resources or traditional knowledge, as well as the equitable sharing of benefits that may result from use of those resources or that knowledge, can be adequately addressed through contracts that reflect mutually agreed terms between user and providers.

Each Party shall endeavor to seek ways to share information that may have a bearing on the patentability of inventions based on traditional knowledge or genetic resources by providing:

- publicly accessible databases that contain relevant information; and

- an opportunity to cite, in writing, to the appropriate examining authority prior art that may have a bearing on patentability.

Source: USTR at http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Colombia_FTA/Final_Text/asset_upload_file953_10182.pdf.

Besides reference to the issue of biodiversity and TK in side letters or understandings in the case of Colombia and Peru, not many FTAs have incorporated provisions on the protection of TK and folklore. However, Panama and Taiwan probably reached the most extensive provisions on this topic in their FTA, signed in 2003.[93] The innovative provisions of this agreement refer to the protection of genetic resources, traditional knowledge and folklore. Although the provisions on these issues are quite strong, they do not provide for a requirement of disclosure of origin of genetic resources. Still, they provide a framework against misappropriation of genetic resources, for the legitimate access to genetic resources and for equitable benefit sharing. The parties to

[93] See text of the Panama - Taiwan FTA at http://2005.sice.oas.org/Trade/PanRC/PANRC_e.asp.

this FTA also agreed to develop a mechanism for the mutual recognition of plant varieties.

Finally, the EU has concluded a very limited number of FTAs that include IP chapters, but has recently announced that it will engage in new negotiations. Of these, it is currently negotiating Economic Partnership Agreements with six regional groupings of the ACP countries. A proposal to one of these sub-groupings surfaced at the end of 2006 and included comprehensive IP provisions, including issues related to the CBD.

According to this proposal, the parties would "underline the importance of acceding to the Convention on Biological Diversity (CBD) and agree that, in line with Article 46.2 of the Cotonou Agreement, the patent provisions of this Title and the Convention on Biological Diversity shall be implemented in a mutually supportive way".[94] As we can see, this issue is closely related to discussions in the WTO on the relation between the TRIPS Agreement and the CBD, and more specifically on whether there is a conflict between the two treaties or whether they can be interpreted in a mutually supportive way. The EU has also incorporated Article 8(j) of the CBD into its proposal:

"Subject to their national legislation the Parties 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 and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices".[95]

[94] See proposal to CARIFORUM countries at http://www.bilaterals.org/IMG/doc/EC_non-paper_on_IPRs_text_for_EPA.doc.
[95] Ibid.

5. Concluding observations

A. The complexities of the IP landscape

The incorporation of trade-related IP disciplines in the final outcome of the trade negotiations of the Uruguay Round signalled a major change in IP law making. The TRIPS Agreement not only incorporates IP within the international trading system but also introduces the concept of minimum standards of protection for each of the IP categories it deals with. The transformation brought about by TRIPS is particularly significant for developing countries. The "bottom up" approach to IP that characterised pre-TRIPS systems allowed each country to calibrate their IP regimes to their national interests.

The TRIPS Agreement should not only be assessed on the basis of the changes it brought to the international IP architecture, but also by the legitimacy it has given to new initiatives with broad and profound consequences for further processes of IP harmonization. Building on the minimum standards principle of TRIPS, a new generation of bilateral and regional FTAs containing IP provisions have been signed in recent years, deepening the process of harmonization initiated by TRIPS.

As observed in this paper, the WTO and WIPO have been the major institutions overseeing changes in the IP landscape at the multilateral level. However, in addition to the WTO and WIPO, there are a variety of organizations dealing with specific IP matters. Today, a number of intergovernmental bodies include IP-related questions in their work programmes, as is the case of the United Nations Education, Science and Culture Organization (UNESCO), the Convention on Biological Diversity (CBD) and other UN agencies, such as the United Nations Conference on Trade and Development (UNCTAD) and the United Nations Development Program (UNDP).

The work of, respectively, the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) has been of particular relevance. The WHO has engaged actively in questions related to IP and health, particularly in the report of its Commission on Intellectual Property Rights, Innovation and Public Health,[96] and the follow-up work of its Intergovernmental Working Group on Public Health, Innovation and Intellectual

[96] See: http://www.who.int/intellectualproperty/en/.

Property (IGWG).[97] Most importantly, the 2007 World Health Assembly (the highest decision-making body of the WHO) adopted Resolution 60.30 on Intellectual Property, Innovation and Public Health.[98] The Resolution requests the WHO Director General:

"[…] (2) to provide as appropriate, upon request, in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products,1 and to implement the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments; […]

"(4) to encourage the development of proposals for health-needs driven research and development for discussion at the Intergovernmental Working Group that includes a range of incentive mechanisms including also addressing the linkage of the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products and a method for tailoring the optimal mix of incentives to a particular condition or product, with the objective of addressing diseases that disproportionately affect developing countries."

For their part, FAO members spent a number of years negotiating an International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) that finally entered into force in June 2004.[99] Among others, the treaty provides that state parties should take measures:

"to protect and promote Farmers' Rights, including: (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; and (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture".

Given the crosscutting and interrelated nature of the issues under consideration, the involvement of so many institutions covering these matters highlights the challenges and complexities facing developing countries in managing and sustaining coherence in international and national IP policies.

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97 The IGWG was established by the World Health Assembly in 2006, by Resolution 59.24, which set "an intergovernmental working group open to all interested Member States to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission [on Intellectual Property Rights, Innovation and Public Health]; such strategy and plan of action would aim, inter alia, at securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area"; see: http://www.who.int/gb/ebwha/pdf_files /WHA59/A59_R24-en.pdf.

98 See WHO document WHA 60.30 at www.who.int/gb/ebwha/pdf_files/WHA60/A60_R30-en.pdf.

99 See text of the ITPGRFA at ftp://ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf. In November 2001, the FAO Conference adopted the ITPGRFA, which came into force in 2004. Its "objectives are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits derived from their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security" (Article 1). The "Contracting Parties recognize [d] the sovereign rights of States over their own plant genetic resources for food and agriculture, including that the authority to determine access to those resources rests with national governments and is subject to national legislation (Article 10.1)" and "agree [d] to establish a multilateral system (MLS), which is efficient, effective, and transparent, both to facilitate access to plant genetic resources for food and agriculture, and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis (Article 10.2)". Parties must provide access expeditiously to other Contracting Parties through the MLS "for the purpose of utilization and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses" and "recipients shall not claim any intellectual property or other rights [over] the plant genetic resources […] in the form received from the Multilateral System (Article 12.3)". Among the ways of sharing benefits, the Treaty (Article 13) provides for exchange of information, access to and transfer of technology, capacity-building and Sharing of monetary and other benefits of commercialization. Source: FAO at http://www.fao.org/ag/cgrfa/itpgr.htm.

The paper has reviewed recent trends in the area of IP protection and their impact on sustainable development. We have focused on areas in which key developments have taken place, namely on access to knowledge, public health and genetic resources. These changes confirm the challenges ahead and the tasks developing countries will face in the coming years. Countries, particularly in the Latin American and Caribbean region, should be prepared to face these challenges. Among them, the implementation at the national level of new IP obligations constitutes a major challenge that offers, at the same time, opportunities for modernization and the establishment of more coherent approaches to policy making.

B. Is there space for a creative implementation?[100]

From the perspective of the demands of new commitments on the IP front that necessitate modernization of the national institutional base, policymakers could undertake the reform process in a dynamic way by not only recognizing and enforcing existing IPRs, namely from non-residents, but by developing structures and institutions that make it possible for the IP system to contribute to the promotion of sustainable development goals. Such a dynamic implementation should respond to certain policy objectives and specific strategies.

The implementation of IP obligations from a sustainable development perspective should consider the needs of the local environment. In undertaking these reforms the IP system should respond to objectives such as:

- Striking an appropriate balance between rewarding innovation, creativity and investments on one hand, and access to knowledge and transfer of technology on the other;
- Creating appropriate mechanisms to promote local innovation and creativity by instituting efficient and market-oriented incentives;
- Using flexibilities with economic and social goals in mind;
- Protecting the public interest in sectors of vital importance such as health, education and the sustainability of genetic resources;
- Promoting coherent interaction with other regulatory or economic systems, including technology development strategies, competition, trade and FDI policies.

In undertaking such reforms, countries should recall that they are not obliged to implement higher standards of protection and enforcement measures than those detailed in TRIPS and their respective FTAs (see for example, Article 15.1, CAFTA-DR).

With respect to strategies for implementing these objectives, two aspects appear relevant here. The first relates to the use of the flexibilities that exist in the international system to design IP regimes that respond to the particular policy objectives of the country in question; and secondly, the related policies that can mitigate the potential costs of implementing a highly harmonized IP system in line with the parameters of more technologically developed societies.

[100] See Roffe (2006).

a) Flexibilities within the IP system

As discussed in this paper, the international IP system was rather liberal and adaptable in the period prior to TRIPS. The Agreement introduced fundamental changes to the international IP architecture that have intensified with the new generation of FTAs. However, these agreements, building on the existing international architecture, still leave room for the design of IP regimes that can accommodate the particular needs of a country. It is crucial to ensure there is awareness of the existence of these spaces and their appropriate uses. They refer to questions such as the use of existing mechanisms and public policy instruments that are not normally affected by the current international IP architecture, including the FTAs. For instance, and as reiterated above, the FTAs negotiated by Latin American countries do not exclude, with respect to compulsory licensing, the use of a patent without the authorization of the right holder.

The Doha Declaration on the TRIPS Agreement and Public Health confirms the freedom of Members to establish their own regime for the exhaustion of IPRs, thus leaving countries with the possibility of choosing their domestic approach to parallel imports. Taking again the case of the FTAs negotiated by Latin American countries, the exhaustion of IPRs is not generally dealt with. This is not the case in the FTA between the USA and Morocco that allows the parties to limit parallel imports to cases where the patent owner has placed restrictions on importation by contract or other means. In brief, Latin American countries have in general retained the freedom in FTAs to design the most appropriate system of parallel importation.

Even if the FTAs adopt stricter standards of protection and in some cases reduce the space for defining the patentability criteria,[101] they still leave freedom for countries to define what constitutes an invention and to request a disclosure of origin in the case of inventions using genetic resources. This is also the case with respect to the use of exceptions and limitations, particularly in the case of patents and copyrights. However, in general, the exercise of exceptions in the case of patents (such as for teaching and research, commercial experimentation, prior use) (Garrison, 2003) needs to be explored further and used effectively by those countries modernizing their IP regimes. The same applies to exceptions and limitations in the case of copyright that are commonly used in developed countries (personal use, criticism, educational purposes) (Ruth Okediji, 2006).

Within the IP system there are a number of other instruments that could be used more effectively in the implementation process to promote innovative capacities at the local level. If, for example, foreign right holders are the main beneficiaries of a national patent system, innovations of an incremental nature, such as those produced by and large in the Latin American and Caribbean region, might be protected by simpler systems such as utility models (Suthersanen, 2006). Furthermore, other instruments of a non-proprietary nature could be explored, such as compensatory liability regimes and open source models.

One of the most sensitive areas for the countries that have committed to FTAs that go beyond their TRIPS obligations is that related to pharmaceutical products. Specifically, these agreements introduce new standards for the marketing approval of new pharmaceutical products relating to the submission of undisclosed data concerning safety and efficacy. The FTAs contain detailed provisions on issues such as the prohibition of the use of such data without the consent or acquiescence of the first applicant for marketing approval, for at least five years from the date of approval. The FTAs also provide for a "linkage" between the marketing approval and the patent in the sense that a country is not permitted to provide marketing approval to any third party prior to the expiration of the patent term, unless by "consent or acquiescence" of the patent owner.

[101] See, for example, the FTA between the US and Peru that provides that each Party shall provide that a claimed invention is industrially applicable if is has a specific, substantial, and credible utility.

These provisions that tend to expand the protection of pharmaceutical products are enhanced by parallel obligations dealing with compensatory extensions of the duration of the patent in cases of undue delays in the administrative granting of the patent, or as a result of delays in the marketing approval of the products. The FTAs generally do not contain parameters for defining these compensatory extensions. This is a matter to be regulated domestically. For example, in the case of the US, from whom these provisions gain their inspiration, the restoration period is limited to five years in the case of administrative delays in the granting of the patent. With respect to "unreasonable curtailment of the patent term as a result of the marketing approval process", there is a close relation in the USA between both extension terms: "the effective patent term including the restoration period may not exceed 14 years" (Roffe, 2004).

These FTA provisions have attracted attention and have been the subject of criticism not only because of their TRIPS-plus nature, but because they make the exercise of flexibilities more problematic and run the risk of impairing access to medicines. They might also reinforce the dominant position of strong firms and make the entry of new competitors more difficult. Thus, there is a need to implement these provisions in a pro-competitive manner, in order to preserve a competitive environment and sanction possible abuses of dominant positions. In this area there is room for creative implementation.[102]

A dynamic and pro-competitive implementation of new commitments should apply not only to health-related matters. Among the issues discussed in this paper, such as access to knowledge and genetic resources, the creativity in designing IP systems that would preserve flexibilities such as exceptions and limitations should be explored to the maximum. It should also be remembered that in the areas discussed throughout, as shown by recent developments in the US Congress with respect to health, the international system continues to evolve. This suggests the importance of permanently observing and understanding trends in this dynamic sphere of economic law.

b) Modernizing IP-related regulatory regimes and institutions

The implementation of new commitments should be undertaken in a coherent interaction with other regulatory regimes. We are dealing with broad and critical issues that could only be touched upon here. One of the main arguments advanced by advocates of changes in IP relations, particularly in the case of FTAs, is that they provide an opportunity for reform and modernization. One of the challenges faced by countries in the Latin American and Caribbean region is that in the area of IP these countries import systems of protection that have been tried and experienced in more advanced and legally sophisticated countries, which, among other features, have evolved systems of "checks and balances". These systems are codified in legislation and regulations, and often in court interpretations (Abbott, 2006).

The implementation process should be used as an opportunity for reform and modernization that would involve investment to ensure appropriate institutions and human resources. One area calling for reform relates to competition laws and policies that, in the case of developed countries, have taken years to mature and evolve into more sophisticated systems that ensure the market operates under competitive conditions. Competition and IPRs should not be seen as contradictory but rather as interdependent elements. This should mean that the efficiency of the IP system is at stake whenever competition is distorted or artificially restrained. Only a

[102] An interesting example of dynamic implementation is the case of Chile. In order to safeguard the public interest, the law provides that undisclosed information will not be protected in the events of: anticompetitive behavior; public health, national security, non-commercial public use, national emergency; when the pharmaceutical product is subject to a compulsory license; the product has not been commercialized in Chile within 12 months from the date of registration or sanitary approval in the country; the product has a registration or authorization in a foreign country of more than 12 months.

fully competitive market is likely to minimize the social costs resulting from the fact that IP protection cannot be adjusted to individual needs (UNCTAD, 1997).

Probably more importantly, a well-structured IP system should interact coherently with the national innovation system and with the structures and institutions that support such a system. The implementation of high IP standards should be matched with a major effort to reinforce institutions and human resources related to science and technology, and creativity in general. This should be undertaken with the view that the weaker parties in FTAs should benefit from the IP system in ways that match the benefits received by their stronger trading partners.

C. Final observations

Until very recently, IP matters were perceived to be the domain reserved for legal experts and technocrats related to specific industrial sectors. The emergence of TRIPS and the inclusion of IP matters in FTAs have altered this perception. Civil society actors are active in assessing the implications of IPRs, particularly with respect to access to knowledge, medicines, nutrition and the appropriation of genetic resources.

Considering the important socio-economic implications of the IP system, the reform and implementation of new IP obligations should constitute a participatory and coherent process where producers, competitors, and consumers all have a voice. At the government level, an inter-ministerial approach should facilitate a wider consideration of the public interest and its different sensitivities and forms, particularly with respect to the impacts of IP policies on sustainable development priorities.

A key challenge faced by countries in the Latin American and Caribbean region is in coping with the rapid evolution of ideas and concepts around IP and the understanding of their impact on development in general. This facet of the globalization process demands both a more coherent and holistic approach to international negotiations and the establishment of dynamic structures and competencies in economic diplomacy. Here there is an important role for regional organizations, such as the Economic Commission for Latin American and the Caribbean (ECLAC), to assist countries in pursuing coherent and informed policies in these interrelated areas of economic law.

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