# Intellectual Property Rights in preferential trade agreements

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## *Introduction*

From a developing countries' perspective, the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)[1], constitutes a major event in the evolution of the international system. It has meant strengthening and expansion of intellectual property (IP) standards. Under the pre-existent system, countries were free to exclude from patent protection certain technological fields or to protect those excluded sectors only as processes and not provide product protection.[2] In this respect, at the time of the Uruguay Round negotiations leading to the adoption of TRIPS, a large number of countries exempted pharmaceutical products and food-related products from full patent protection.[3] TRIPS recognizes that Members shall not be obliged to implement in their law more extensive protection than is required by the Agreement (often referred to as "TRIPS-Plus"), and that such protection shall not contravene the provisions of TRIPS. This is the quintessence of the principle of minimum standards. Preferential trade agreements (PTAs), characterized in general as instruments that in their scope and obligations go beyond the TRIPS Agreement, are a legitimate consequence of TRIPS. They have meant in practice a major expansion of those minimum standards with important consequences in a number of areas such as access to medicines, genetic resources, copyright, settlement of disputes and enforcement issues.

Overall, the chapter shows the extent and breadth of the changes introduced by the PTAs and how they influence the balance between private rights holders and

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[1] The TRIPS Agreement constitutes Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization which was concluded on 15 April, 1994, and entered into force on January 1, 1995

[2] See Pedro Roffe and Gina Vea, *The WIPO Development Agenda in an Historical and Political Context*, THE DEVELOPMENT AGENDA: GLOBAL INTELLECTUAL PROPERTY AND DEVELOPING COUNTRIES, Edited by Neil W. Netanel, Oxford University Press, pp.79-109, 2009.

[3] See WIPO, document HL/CE/IV/INF/1, prepared for the consideration of the Committee of Experts on the harmonization of certain aspects of laws protecting inventions, fourth meeting, 14 October 1987. Countries not only excluded certain fields of technology from patent protection but also differed on the nature and duration of the respective rights.

consumers of IP. The chapter focuses its analysis on a number of PTAs subscribed principally by developing countries, respectively, with the USA, the European Union and EFTA. It traces the evolution that has taken place in recent years since the conclusion of the North American Free Trade Agreement (NAFTA),[4] the first of those agreements signed between the USA, Canada and Mexico.

The chapter examines extensively the issue of access to medicines because it provides the most striking case of the pervasive influence of PTAs and their role of anticipating new trends in the IP landscape. Suffice it to note at this point that because of the most favored nation (MFN) and national treatment principles, the conclusion of PTAs and their respective translation into national domestic legislation makes these new trends applicable to all parties operating in a particular country. These considerations apply not only to health related issues but also to all aspects covered by the IP chapters of the PTAs.

The chapter underlines that PTAs are a legitimate creature of TRIPS, taking full advantage of the ambiguities and gaps of the latter. At the same time we analyze how PTAs contribute to the expansion of the IP international architecture, not only in terms of adherence by new members to an important number of international treaties but also to a number of soft law recommendations made in the World Intellectual Property Organization (WIPO). The PTAs are also a clear manifestation of intrusion in international processes and impending negotiations. The paper gives a number of examples in this respect.

The paper thus focuses on the intellectual property rights (IPRs) chapters of PTAs,[5] which builds on the minimum standards of the TRIPS Agreement. We begin our analysis highlighting some of the main features of TRIPS and their link to PTAs.

## *I. The TRIPS Agreement*

Under the General Agreement on Tariffs and Trade (GATT) 1947[6], the adoption or enforcement by any contracting party of measures regarding "the protection of patents, trade marks and copyrights"[7] was an expression of exceptions to the general objective of "reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international commerce".[8] The TRIPS Agreement, among other important consequences, led to the formal incorporation of IPRs in the international trading system. One consequence of this incorporation is that the principles of national treatment and MFN apply to IPR relations between WTO Members. The incorporation of IPRs into the international trading system also means the application of the WTO's Dispute Settlement Understanding (DSU) justifying

[4] Available at http://www.nafta-sec-alena.org/en/view.aspx?x=343 (visited 21.05.2009)
[5] PTAs adopt different denominations: regional, bilateral trade agreements (FTAs) economic partnerships agreements (EPAs). These terms are indifferently used in the chapter. For the sake of convenience, we refer to them generally as PTAs.
[6] Text available at http://www.wto.org/english/docs_e/legal_e/gatt47_01_e.htm (visited 21.05.2009)
[7] See Article XX, GATT 1947
[8] Preamble to GATT 1947

measures of commercial retaliation, including cross-retaliation, in the event of non-compliance with TRIPS obligations.[9]

In the case of TRIPS, the strengthening and expansion of IP standards takes place through the establishment of minimum standards of protection and enforcement with respect to copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits and undisclosed information. As pointed out in the Introduction, countries need to adhere to the minimum standards but are free to apply more extensive protection –provided that such protection does not contravene the provisions of the Agreement.[10] The minimum standards concept is accompanied with the notion of "freedom of implementation" [11] in terms that "Members shall be free to determine the appropriate method of implementing … within their own legal system and practice".[12] As examined in this paper, the PTAs are instruments that expand in an upward direction the minimum standards of protection stipulated in TRIPS and do interfere with the principle of freedom of implementation.

The minimum standards also apply to the establishment of mechanisms to secure, through administrative, civil and criminal procedures, including border measures, the appropriate means for the domestic enforcement of IPRs. The incorporation of disciplines related to the enforcement of IPRs is one of the greatest innovations of TRIPS.[13] These TRIPS minimum standards dealing with enforcement are largely expanded by the PTAs as well.

Among the minimum standards addressed by the Agreement, probably the most important ones concern patents and undisclosed information. In all the other areas covered by the Agreement, TRIPS primarily imported and elaborated on the main standards covered already in pre-existing WIPO treaties, particularly the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations and the Treaty on Intellectual Property in Respect of Integrated Circuits.[14] However, the incorporation of pre-existing international instruments is subject to the minimum standards of protection and enforcement and the dispute settlement mechanisms of the WTO and the general principles of national treatment and MFN.

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[9] According to the WTO Dispute Settlement Understanding (DSU), retaliation may take place in the same sector as the one where the TRIPS violation has occurred (Article 22.3 (a)). A "sector" in this context is synonymous with a category of IP covered under the TRIPS Agreement; see Article 22.3 (f) (iii) of the DSU. If the complainant considers that retaliation within the same sector is not practicable, it may seek the suspension of concessions in a different sector of the same agreement, and eventually even suspend concessions under a different agreement ("cross retaliation"). See Article 22.3 (b), (c), DSU. For an exhaustive analysis of cross retaliation in the case of IPRs, see Abbott and Henning

[10] See Article 1.1, TRIPS. Cite Henning Ceilings

[11] See Resource Book, page

[12] Article 1.1, TRIPS

[13] See Part IV of the Agreement dealing with the ACQUISITION AND MAINTENANCE OF INTELLECTUAL PROPERTY RIGHTS AND RELATED INTER-PARTES PROCEDURES

[14] See Article 2, TRIPS.

While the TRIPS Agreement constitutes a major step in the upward strengthening of IPRs, it also provides important policy choices for the implementation of its provisions. Not many provisions are established in absolute mandatory terms and as discussed subsequently, "flexibilities" have many expressions. As pointed out, WTO Members enjoy also a freedom of implementation in determining the most appropriate method of incorporating the provisions of the Agreement into domestic law.[15] Thus, the Agreement recognizes flexibilities and discretion in the implementation of its minimum standards. How flexible the Agreement is and how free countries are to implement its provisions are important questions that have in many respects influenced the evolution of TRIPS and have dominated multilateral discussions not only under the Council for TRIPS but also deliberations in WIPO and the World Health Organization (WHO). In the context of the WTO, the matter reached a climax in the process and follow up to the adoption of the Doha Declaration on TRIPS and Public Health in 2001.[16]

Flexibilities have many expressions. For example, the use of technical terms without specific definitions provides a basis for implementation according to local circumstances. A case in point is the lack of definition, under TRIPS and most of the PTAs, of what constitutes a patentable invention. The way inventions are understood and how the parameters to determine the different criteria of patentability are set, may have a major impact on where countries draw the line between private exclusive rights and the public domain. From a public policy perspective, laxer criteria for patentability risks blocking follow-on innovation and competition through the possible monopolization of knowledge.[17]

Exceptions, limitations and exclusions also play a role in the design of a balanced system of IP protection. In general, the TRIPS Agreement limits the establishment of such exceptions to those that "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".[18] In this particular

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[15] Article 1.1, TRIPS

[16] 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 See also Box 1, infra.

[17] Finding an appropriate balance between private rights and the public domain and dissemination of knowledge is not only relevant for developing countries, but equally concerns developed countries' innovation policies. In the literature, concerns have been raised that further limitations in this direction, such as through multilateral harmonization efforts as in the case of substantive patent harmonization, may cause considerable harm to national innovation systems of those countries that are currently their main demandeurs (Reichman & Cooper Dreyfuss 2007).

[18] See Article 30, TRIPS, for the area of patent law. In an important case before the WTO DSU system (*Canada - Patent Protection of Pharmaceutical Products*, the Panel interpreted the three criteria in Article 30, TRIPS, that must be met in order to qualify for an exception (the so-called "Three-Step Test"): (1) the exception must be "limited"; (2) the exception must not "unreasonably conflict with normal exploitation of the patent"; (3) the exception must not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". The Panel concluded that the three conditions are cumulative, each being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in the Article 30 exception being disallowed. The three conditions, in the opinion of the Panel, must be interpreted in relation to each other. Each of the three must be presumed to mean something different from the other two, or else there would be redundancy. Normally, the order of listing can be read to suggest that an exception that complies with the first condition can nevertheless violate the second or third, and that one which complies with the first and second can still violate the third. Further, the

context, PTAs, in general, replicate the conditions of TRIPS for the establishment of further exceptions and limitations.

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.[19] These are commonly known as compulsory licenses, which are permitted under TRIPS, a subject to which we return below. Patent flexibilities also refer to national legal regimes for dealing with the exhaustion of rights[20] and in the case of pharmaceutical products the so called regulatory review or "Bolar" exception allowing for the submission for regulatory approval of generic copies of patented substances before the expiration of the patent, in order for these products to reach the market without delay upon expiration of the patent.[21]

Exceptions, limitations and exclusions can take a number of forms and they respond to different rationales.[22] For example, most patent laws provide that exclusive 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 experimental use).[23] In an interesting and innovative provision of the Swiss Patent Act, researchers may use a patented substance even for "commercial purposes", provided such use results in new knowledge on the patented product.[24]

## *II. Intellectual property rights in preferential trade agreements*

Adopting different modalities, major trading powers have signed PTAs with a number of countries with the view of intensifying and deepening their WTO trade commitments. Since the establishment of the WTO, Members have notified more

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syntax of Article 30 supports the conclusion that an exception may be "limited" and yet fail to satisfy one or both of the other two conditions. The ordering further suggests that an exception that does not "unreasonably conflict with normal exploitation" could nonetheless "unreasonably prejudice the legitimate interests of the patent owner". See, report of the Panel in WTO document WT/DS114/R of 17 March 2000. The TRIPS Agreement contains comparable exceptions in the areas of copyright (Article 13, TRIPS, with slightly modified language), trademarks (Article 17, TRIPS), and industrial designs (Article 26.2, TRIPS). Two other WTO panels basically confirmed the interpretation by the *Canada - Patent Protection of Pharmaceutical Products* Panel for Articles 13 and 17, TRIPS. See *United States – Section 110(5) of the US Copyright Act*, Report of the Panel of 15 June 2000, WTO document WT/DS160/R; *European Communities - Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS174/R of 15 March 2005 (US complaint) and WT/DS290/R of 15 March 2005 (Australian complaint).

[19] See Resource Book

[20] Such a regime is not limited to patents but also applies to other IPRs.

[21] The Hatch-Waxman Act of the US of 1986 was the first to legislate on this matter. EXPAND AND PROVIDE SOURCE

[22] (Scotchmer 2005: p. 114).

[23] See Christopher Garrison, (2006), *Exceptions to Patent Rights in Developing Countries*, UNCTAD-ICTSD ISSUE PAPER no.17, ICTSD, Geneva, www.iprsonline.org/unctadictsd/projectoutouts.htm.
See also recent study produced by WIPO to SCP.

[24] Article 9 of Swiss Law. See <http://www.admin.ch/ch/f/rs/232_14/> for a French version of the Swiss Patent Act.

than 250 of those agreements.[25] While the main aim of PTAs is precisely to deepen trade liberalization in goods and services and improved market access conditions between partners, these agreements contain a number of trade-related rules, including investment, intellectual property, government procurement following the concept of a single undertaking of the Marrakesh WTO Final Act.[26] With respect to IP, PTAs elaborate further on the TRIPS minimum standards and clearly constitute a further manifestation of the noted upward trend towards further expansion and strengthening of the protection and enforcement of IPRs.[27] PTAs cover countries at different level of development and do not target exclusively developing countries. Our analysis, however, will focus particularly on the implications of those agreements to the latter countries. We have concentrated on the most notorious and publicized PTAs, listed in Box 1. The listing is selective and does not cover the full range of PTAs signed in recent years,[28] nor the various agreements under negotiations at the time of writing. There are a number of other PTAs contemplating IP provisions such as those signed by Canada, Japan and even Taiwan.[29] In general, these latter agreements do not include full-fledged IP chapters as in the case of the USA -and the recent EPAs signed by the EC,- but do include provisions in line with the basic principles of the TRIPS Agreement.[30] Our paper deals mainly with the agreements where the USA and the EU are main counterparts as listed in Box 1.

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[25] See Henrik Horn, Petros Mavroidis and Andre Sapir, *Beyond the WTO? An Anatomy of EU and US preferential trade agreements*, BRUEGEL BLUEPRINT SERIES, 20 April 2009.

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[27] Some scholars have made valuable distinctions between WTO-Plus obligations compared to those that could be characterized as WTO-Extra. The former would consist of new commitments building on those already agreed at the multilateral level. WTO-Extra would be those commitments dealing with issues going beyond the current WTO mandate. See Horn et al, supra. The distinction is important from a system wide approach (i.e. application of the MFN principle to TRIPS-Plus obligations, as opposed to any TRIPS-Extra commitments).

but for purposes of the impact of those agreements, the consequences for the parties would be same: assuming more obligations than those contemplated in WTO and more precisely, in our case, going beyond the TRIPS Agreement.

[28] See Horn et al, supra.

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[30] See Pedro Roffe and Maximiliano Santa Cruz (2006), *Los derechos de propiedad intellectual en los acuerdos de libre comercio celebrados por paises de America Latina con paises desarrollados*, CEPAL, SERIE COMERCIAL INTERNACIONAL No.70. CITE SANYA, TWN

**Box 1**
**Selected PTAs with IP provisions negotiated by the USA, EU and EFTA[a]**

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| **U.S.A. with[b]** | Latin America | - Central America and Dominican Republic (CAFTA-DR, 2004)); Chile (2003); Colombia (2006); Mexico-Canada (NAFTA, 1993)); Panama (2007); Peru (2006) |
| | Asia | - Australia (2004); Singapore (2003); Republic of Korea (2007) |
| | Middle East | - Bahrain (2004); Israel (1985); Jordan (2000); Morocco (2004); Oman (2006) |
| | Others | - |
| **EU with[c]** | Latin America & Caribbean | - Chile (2000); Mexico (1999); Caribbean and Pacific States (CARIFORUM, 2008); |
| | Asia | - Kazakhstan (1999) |
| | Middle East and Africa | - Egypt (2004); Jordan (1997); Lebanon (2002); Palestinian Authority (1997); South Africa (1999) |
| | Others | - |
| **EFTA with[d]** | Latin America | - Chile (2003); Colombia (2008); Mexico (2000) |
| | Asia | - Republic of Korea (2005); Singapore (2002) |
| | Middle East and Africa | - Egypt (2007); Israel (2002); Jordan (2001); Lebanon (2004); Morocco (1997); Palestinian Authority (1998); Tunisia (2004); South African Custom Union (SACU) (2006); |
| | Others | - Croatia (2001); Macedonia (2000); Turkey (1991) |

[a] Parentheses indicate date of signature of the Agreement
[b] Agreements entered into by the USA are available at http://www.ustr.gov/trade-agreements/free-trade-agreements
[c] Agreements entered into by the EU are available http://ec.europa.eu/trade/issues/bilateral/index_en.htm
[d] Agreements entered into by the EFTA are available http://www.efta.int/content/about-efta/member-states/free-trade/fta-countries

The political economy of why governments, particularly of developing countries, enter into PTAs responds to a number of sovereign considerations that are beyond the scope of analysis of this chapter. Abundant literature exists on the subject.[31] In our understanding, developing countries tend to be the *demandeurs* of these mainly to gain better access for goods and services to more affluent markets, but developed country partners are those that push for the incorporation of strong IP in the conviction that this is the better way of strengthening their comparative advantages.[32] Similar to the acceptance of the TRIPS Agreement, as a quid pro quo for the benefits of WTO membership,[33] many government officials seem to acknowledge that the IP provisions respond to a trade off in exchange for trade concessions in areas more relevant to their national commercial interests.[34] Precisely in the case of developed countries, the driving forces behind the incorporation of comprehensive and robust IP provisions in PTAs have been those industrial sectors highly dependent on IP protection and interested in sustaining their technological edge.[35] In this respect the concept of the single undertaking is crucial to advance those interests.

[31] See for example Jean-Fredric Morin, Multilateralising TRIPS-Plus Agreements: Is the US Strategy a Failure; Sell 2003; Matthews, 2002; Drahos, Peter. & Braithwaite, John (2002) Information Feudalism - Who owns the knowledge economy? New York, New Press. Also von Braun
[32]
[33] See Bhagwati (1991), Stewart (1999) and Ryan (1998).
[34] Von Braun. See Roffe Chile
[35]

## A. Overview of European preferential trade agreements

Until very recently and unlike the US agreements, the IP chapters in the PTAs signed by the EU and also EFTA did not follow a particular model. By and large there was an emphasis in the agreements on reinforcing the existing international IP architecture by committing the parties to become party to a number of multilateral IP-related agreements.[36] For example, in the case of the Agreement between Chile and the EU, the Parties have "to accede to and ensure an adequate and effective implementation of the obligations arising from" a number of WIPO-administered treaties[37] and of making "every effort to ratify and ensure an adequate and effective implementation of the obligations arising from" multilateral conventions.[38] The adherence to these agreements is reinforced by the overarching obligation prescribed in the EU agreements of ensuring adequate and effective protection to IPRs in accordance with the highest international standards, including effective means of enforcing such rights.[39]

A major shift in the emphasis of the PTAs signed by the EU has taken place recently with the signature of the EPA with the countries of the CARIFORUM.[40] The latter agreement and the model being used in ongoing negotiations[41] show that the EU is now following a similar approach to that of the USA in the specificity and breadth of the commitments made with respect to IPRs. For example, in the recent European Partnership Agreement (EPA) with CARIFORUM, a very detailed treatment is given to the international treaties and related international IP instruments that parties need to adhere or comply with. Box 2 reproduces the commitments made to that effect.

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[36] Santa Cruz 2007

[37] For example: the World Intellectual Property Organization Copyright Treaty, WCT, 1996; the World Intellectual Property Organization Performances and Phonograms Treaty, WPPT, 1996; the Patent Cooperation Treaty of June 19, 1970, Washington Act amended in 1979 and modified in 1984;

[38] For example: the Protocol to the Madrid Agreement Concerning the International Registration of Marks; the Madrid Agreement concerning the International Registration of Marks, Stockholm Act 1967, as amended in 1979; and the Vienna Agreement establishing an International Classification of Figurative Elements of Marks, 1973, amended in 1985.

[39] (Roffe-Santa Cruz 2006).

[40] See ECONOMIC PARTNERSHIP AGREEMENT between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part, L 289/I/4 EN Official Journal of the European Union 30.10.2008

[41] Seuba. Ongoing negotiations regarding, *inter alia*, stronger and more detailed IP chapters than in past agreements, concern new Economic Partnership Agreements (EPAs) with six regional groupings of the African, Caribbean and Pacific (ACP) states (Santa Cruz, 2007) and with members of the Andean Community (Abdel Latif 2009) and Central American countries, which put greater emphasis on IP provisions particularly with respect to enforcement.

**Box 2**
**Multilateral treaties and related instruments that parties need to adhere to or comply with**
**(Example: EU – CARIFORUM)**

Copyright instruments

The Parties shall comply with:

- The World Intellectual Property Organization (WIPO) Copyright Treaty (Geneva, 1996); and
- The WIPO Performances and Phonograms Treaty (Geneva,1996).

The Signatory CARIFORUM States shall endeavour to accede to

- the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (1961).
- Trademarks

The Parties shall endeavour to apply

- the joint recommendations concerning trade mark licenses adopted by the Assembly of the Paris Union for the Protection of Industrial Property and the General Assembly of WIPO at the Thirty-Fifth Series of Meetings of the Assemblies of the Member States of WIPO, 25 September to 3 October 2000.

The Parties shall endeavour to accede to

- the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (1989) and the revised Trade mark Law Treaty (2006).

The Parties shall endeavour to apply

- the Joint Recommendation concerning the protection of marks, and other industrial property rights in signs, on the Internet, as adopted by WIPO at the Thirty-Sixth Series of Meetings of the Assemblies of the Member States of WIPO, 24 September to 3 October 2001.

Industrial designs

The Parties shall endeavour to accede to

- the Hague Agreement for the International Registration of Industrial Designs (1999).

Patents and public health

Parties recognize the importance of

- the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by the Ministerial Conference of the WTO
- Decision of the WTO General Council of 30 August 2003 on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and agree to take the necessary steps to accept the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005.
- Plant Varieties
- Parties shall consider acceding to the International Convention for the Protection of New Varieties of Plants — UPOV (Act of 1991).

Cooperation treaties

The EC Party shall comply with:

- The Patent Cooperation Treaty (Washington, 1970, last modified in 1984);
- The Patent Law Treaty (Geneva, 2000);
- The Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure (1977, amended in 1980).

The CARIFORUM States shall accede to:

- The Patent Cooperation Treaty (Washington, 1970, last modified in 1984);
- The Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure (1977, amended in 1980).

CARIFORUM States shall endeavour to accede to the Patent Law Treaty (Geneva, 2000).

Source: ECONOMIC PARTNERSHIP AGREEMENT between the CARIFORUM States and the European Community and its Members.

Traditionally, the most significant IP-related provisions in the EU agreements, prior to CARIFORUM, included specific arrangements on the trade in wines and spirits. These arrangements include provisions on the reciprocal protection of geographical indications (GIs) related to wines and spirits, and the protection of traditional

expressions (of both Parties). The special arrangements on wines include protection of "homonymous signs" as allowed in TRIPS.[42] In most recent agreements, the EPAs provide further strengthening of the provisions of GIs in a clear and determined way of aligning parties to those agreements to some extent to the position sustained by the EU countries in discussions and deliberations in the Council for TRIPS regarding the international registry for wines and spirits and the expansion of the protection given to the latter products to all other products.[43]

The EFTA model has followed, again, very closely the EU approach,[44] but expands the protection in the case of pharmaceutical products with respect to data provided to national authorities on the safety and efficacy of those products either by way of exclusive protection for an adequate number of years or by adequate compensation payable to the data originator by those making use of the data.[45] But again, the PTAs are not identical. For example, as noted, they all contain references to agreements that parties should adhere to, but follow different schemes to achieve the same objective.[46]

In broad terms, and compared to the PTAs sponsored by the USA, those with EFTA and the EU have so far been less comprehensive. However, as noted, the EU has recently launched a series of negotiations that include stronger IP chapters. These include the new Economic Partnership Agreements (EPAs) with six regional groupings of the African, Caribbean and Pacific (ACP) states[47] and Free Trade and Association Agreements with for instance members of the Andean Community[48] and Central American countries. All these agreements put greater emphasis on IP provisions particularly with respect to enforcement.

## B. Overview of the agreements negotiated with the United States of America

The agreements to which the USA is a Party have a more expansive and detailed coverage than those sponsored in the past by the EU. Since 2002 they have followed

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[42] "In the case of homonymous geographical indications for wines, protection shall be accorded to each indication, subject to the provisions of paragraph 4 of Article 22. Each Member shall determine the practical conditions under which the homonymous indications in question will be differentiated from each other, taking into account the need to ensure equitable treatment of the producers concerned and that consumers are not misled." Art. 23.3, TRIPS. For a detailed analysis of the EU's approach to GIs protection in FTAs, see Vivas-Eugui & Spennemann, 2007.

[43] See, for example, Article 145 A.2/3, 145 B.3(b) of the EU – CARIFORUM PTA.

[44] (Roffe & Santa Cruz 2006)

[45]

[46] For example, in the PTA between EFTA and Tunisia it is stipulated that the latter "will do its outmost to accede to the international conventions concerning IPRs to which EFTA States are Parties (Abdel Latif 2009). On the other hand, the PTA between EFTA and the states of the Southern African Customs Union (SACU) provides no particular obligation in respect to IPRs, but remains limited to a few general principles, such as national treatment and MFN. But, it states: "With the objective of progressively harmonizing their legal framework on intellectual property rights, the EFTA States and the SACU States affirm their commitment to review this Chapter not later than five years after the entry into force of this Agreement." (Article 26.5).

[47] (Santa Cruz, 2007)

[48] (Xavier Seuba 2008)

the general principles and objectives set in the Trade Promotion Authority Act of 2002 that guide the negotiations to the achievement of a number of objectives including the accelerated and full implementation of the TRIPS obligations and that the provisions of any trade agreement "reflect a standard of protection similar to that found in US law".[49] (Box 3 cites the relevant parts of the Trade Promotion Authority of 2002.)

**Box 3: The Trade Promotion Authority (Trade Act of 2002)**
**Section 2102**

(4) Intellectual property. …The principal negotiating objectives of the USA regarding trade-related intellectual property are…
(A) to further promote adequate and effective protection of intellectual property rights, including through—
(i)(I) ensuring accelerated and full implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)), particularly with respect to meeting enforcement obligations under that agreement; and
(II) ensuring that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the USA reflect a standard of protection similar to that found in US law;
(ii) providing strong protection for new and emerging technologies and new methods of transmitting and distributing products embodying intellectual property;
(iii) preventing or eliminating discrimination with respect to matters affecting the availability, acquisition, scope, maintenance, use, and enforcement of intellectual property rights;
(iv) ensuring that standards of protection and enforcement keep pace with technological developments, and in particular ensuring that rightholders have the legal and technological means to control the use of their works through the Internet and other global communication media, and to prevent the unauthorized use of their works; and
(v) providing strong enforcement of intellectual property rights, including through accessible, expeditious, and effective civil, administrative, and criminal enforcement mechanisms;
(B) to secure fair, equitable, and non-discriminatory market access opportunities for US persons that rely upon intellectual property protection; and
(C) to respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001.

Source: http://www.tpa.gov/pl107_210.pdf

At the bilateral and regional level, the USA has followed a consistent policy which complements its multilateral initiatives and the promotion of its domestic agenda. Even before the completion of the TRIPS Agreement, the USA concluded a bilateral agreement with Canada[50]in which IP features prominently. [51] Again, in NAFTA[52], the Chapter on IP is an important component of the treaty, which closely follows the contents of the TRIPS Agreement.

Following NAFTA a number of other bilateral agreements with comprehensive IP chapters were entered into by the USA.[53] In October 24, 2000, the USA reached an

[49] See, among others, Section 2102 of the Trade Promotion Authority, Trade Act of 2002
[50] The Canada – US Free Trade Agreement entered into force on January 1, 1989. See, http://wehner.tamu.edu/mgmt.www/nafta/fta/
[51] The USA had in that instance a particular concern regarding the liberal Canadian policies in allowing compulsory licensing in support of its pharmaceutical domestic generic industry. See Reichman, 2003
[52] See, http://www.nafta-sec-alena.org/DefaultSite/index_e.aspx?DetailID=78
[53] For the list of Agreements signed by the USA, see Box 1, supra.

agreement with the Hashemite Kingdom of Jordan on the establishment of a Free Trade Area, which entered into force in December 2001. [54] This agreement had significant political implications because it anticipated the policy which the USA later consolidated in the Trade Promotion Authority of 2002. The Bilateral Trade Agreements (BTAs) negotiated between the Lao People's Democratic Republic and the Socialist Republic of Vietnam[55] also have extensive TRIPS-plus provisions. The subsequent agreements that have followed this more expansive IP agenda were characterized by an upward trend in strengthen protection and enforcement of IPRs.

As in the case of TRIPS, the breadth and scope of the agreements sponsored by the USA relate to all major IP disciplines. The IP chapters, as in all PTAs, are an integral part of the general agreement that include, in a single undertaking, a number of trade disciplines and general chapters dealing with the settlement of disputes and the administration of the Agreement. While the structure and specific contents of the agreements vary in the choice of words, they follow a common pattern comprising: all-purpose provisions,[56] and transparency of laws and administrative regulations; trademarks; GIs; Internet domain names; obligations pertaining to copyright and related rights; protection of encrypted program-carrying satellite signals; patents; measures related to certain regulated products (pharmaceutical and chemical products); and enforcement of IPRs.

An important development in the evolution of US policies with respect to PTAs relates to the changes introduced in May 2007, after the expiration of the Trade Promotion Authority of 2002 and as a result of a bipartisan understanding with respect to the ratification of outstanding free trade agreements.[57] As a result of this understanding, changes were introduced in the PTAs with respect to provisions dealing with pharmaceutical products, reflecting concerns expressed in many quarters on the impact of the free trade agreements on public health policies.[58] The changes relate to issues such as extensions of the patent term, data exclusivity, the patent-data protection linkage and the appropriate treatment of the Doha Declaration on Health.[59] Subsequently the texts of the agreements negotiated with Colombia, Panama and Peru[60] were respectively amended and soon thereafter the Peruvian

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[54] The agreement was signed on October 24, 2000. http://www.sice.oas.org/Trade/us-jrd/usjrd.asp

[55] The US–Laos Bilateral Trade Agreement (BTA) was concluded in 1997 and signed in 2003. See, http://www.ustr.gov/regions/asia-pacific/2003-04-bta-laos.pdf. The US-Vietnam BTA was signed in July 2000. See, http://www.ustr.gov/regions/asia-pacific/text.pdf

[56] For example, the entry into force of the agreements, a general reference to the international IP architecture and the ratification of a number of WIPO-administered conventions. The coverage of agreements and instruments for ratification or adherence, with differences in the timing of the ratification or compliance, follows in general the EU scheme. See Box 2, supra.

[57] Four bilateral trade agreements negotiated and signed by the Executive, respectively, with the Republic of Korea, Panama, Peru and Colombia were still subject to ratification by Congress at the time of the 2006 Congressional elections. In early May 2007, Congressional leaders reached a compromise with the Administration on issues related to IP, labor standards and the environment with respect to three of the PTAs pending for ratification by Congress (Peru, Colombia, Panama).

[58] See for example GAO

[59] Roffe & Vivas 2007).

[60] The original IP chapters of the PTAs with Colombia, Panama and Peru included similar provisions as those contained in the agreements already in force, such as the CAFTA-DR and the US-Chile.

Trade Promotion Agreement was approved by Congress and signed by the President.[61]

***Some legal peculiarities of the US law***

TRIPS, as pointed out, recognizes a certain degree of autonomy in implementation in the sense that Members are free to determine the appropriate method of implementation, "within their own legal system and practice".[62] In the case of the PTAs signed with the USA, because of the peculiarities of the US legislative process, this freedom of implementation appears to have been narrowed down in a serious manner for the US bilateral and regional trading partners.

For example, in the United States-Central American-Dominican Republic Free Trade Agreement (US-CAFTA-DR), the implementation bill passed by Congress[63] sets the entry into force of the Agreement "at such time as the President determines that countries … have taken measures necessary to comply with the provisions of the Agreement…"[64] This determination conditions the entry into force upon the satisfaction expressed by the President of the USA that the other Party has taken the necessary measures to implement effectively the provisions of the agreement. This aspect of the implementation process, known in some quarters as the "certification" act, commits the other Party -in this case the countries of Central America and the Dominican Republic- to adopt the necessary (IP) implementation legislation that meets the expectations of the USA. This process adds major hurdles to the implementation in good faith of these agreements. In practical terms it means that once the negotiations of the formal PTA has been concluded and signed by the parties, a new negotiating process begins with respect to the implementation legislation, which demands a major redesign of the legal and institutional base.[65] This important aspect of the implementation process has been highlighted by industry as one major feature of PTAs implementation that needs to be strengthened further.[66]

Another important feature of the US legal system is that, domestically, the agreements are not self-executing.[67] This again is made explicit in the case of

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[61] The FTA with Peru entered into force in February 2009.
[62] See Article 1.1, TRIPS Agreement and UNCTAD-ICTSD, Resource Book, pages 25-27.
[63] Dominican Republic-Central American-United States Free Trade Agreement Implementation Act, Pub.L. 109-53, 109th Cong., 1st sess. (2005).
[64] Ibid, section 101.
[65] In the recent case of the PTA between the USA and Peru, this process meant the enactment of several legislative acts that had to be revised a few weeks before President G.W. Bush put his signature to the Agreement, just days before he concluded his mandate. See Roca
[66] In its Report of February 2006, the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15), stated with respect to Peru: "ITAC 15 urges the US not only to monitor very closely the implementation by Peru (and other FTA partners) of their FTA obligations but also to ensure that Peru and other FTA partners have in place, before the entry into force of the FTAs, national legislation that faithfully reflects their FTAs obligations. …IFAC-15 commends the US for working with FTA partners to secure fully-compliant national legislation before each agreement enters into force. ITAC-15 considers it essential that, if need be, entry into force be postponed until full compliance is achieved."
[67] See Frederick M. Abbott, (2006), Intellectual Property Provisions of Bilateral and Regional Trade Agreements of the United States in Light of U.S. Federal Law, UNCTAD-ICTSD Issue Paper no.12,

CAFTA-DR where it is stated that nothing in the PTA shall be construed to amend or modify any law of the United States, or to limit any authority conferred under any law of the United States.[68]

Provisions equivalent to the implementation bill of the CAFTA-DR PTA, are found in all implementation bills passed by Congress when action is taken with respect to any PTA signed by the USA.[69]

In brief, these peculiarities of the US legal system put partner countries under the obligation to take measures to adjust their internal IP regimes to the new PTA standards, prior to the entry into force of the Agreement, initiating a complex process of certification of the implementing legislation that questions the relevance of the principle of freedom of implementation sanctioned by TRIPS. By contrast, according to the US implementation bills, the agreements are non self-executing, and explicitly do not affect domestic legislation. The USTR has advised Congress that accordingly it may adopt subsequent legislation inconsistent with the terms of a PTA.[70]

## *III. The impact of preferential trade agreements: main issues*

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Geneva, available at: http://www.iprsonline.org/resources/docs/Abbott%20-%20US%20bilateral%20and%20regional%20trade%20agreements%20-%20Blue%2012.pdf.

[68] See Section 102 of the Congressional Implementation Bill of the CAFTA-RD agreement: "(a) RELATIONSHIP OF AGREEMENT TO UNITED STATES LAW-
(1) UNITED STATES LAW TO PREVAIL IN CONFLICT- No provision of the Agreement, nor the application of any such provision to any person or circumstance, which is inconsistent with any law of the United States shall have effect.
(2) CONSTRUCTION- Nothing in this Act shall be construed--
(A) to amend or modify any law of the United States, or (B) to limit any authority conferred under any law of the United States, unless specifically provided for in this Act.
(b) RELATIONSHIP OF AGREEMENT TO STATE LAW-
(1) LEGAL CHALLENGE- No State law, or the application thereof, may be declared invalid as to any person or circumstance on the ground that the provision or application is inconsistent with the Agreement, except in an action brought by the United States for the purpose of declaring such law or application invalid.
(2) DEFINITION OF STATE LAW- For purposes of this subsection, the term `State law' includes--
(A) any law of a political subdivision of a State; and (B) any State law regulating or taxing the business of insurance.
(c) EFFECT OF AGREEMENT WITH RESPECT TO PRIVATE REMEDIES- No person other than the United States--
(1) shall have any cause of action or defense under the Agreement or by virtue of congressional approval thereof; or (2) may challenge, in any action brought under any provision of law, any action or inaction by any department, agency, or other instrumentality of the United States, any State, or any political subdivision of a State, on the ground that such action or inaction is inconsistent with the Agreement.
(SEC. 102. RELATIONSHIP OF THE AGREEMENT TO UNITED STATES AND STATE LAW of the Dominican Republic-Central American-United States Free Trade Agreement Implementation Act (2005).

[69] See, for example, Text of H.R. 3688 [110th]: United States-Peru Trade Promotion Agreement Implementation Act, Section 102, identical to text quoted in footnote 68. Available at http://www.govtrack.us/congress/billtext.xpd?bill=h110-3688 (visited 16 may 2009)

[70] USTR has also advised Congress that decisions of dispute settlement panels under the FTAs do not affect US Federal law unless those decisions are expressly given effect by Congress. Abbott (2006), op.cit., at page 5.

While developing countries have often been the demandeurs of PTAs, they have been more hesitant to deal with IP provisions. For example, Chile sought to avoid the inclusion of IP provisions in the PTA with the United States.[71] Concerns expressed by developing countries in this regard relate to the fact that the new IP obligations proposed by partners go beyond the TRIPS minimum standards ("TRIPS-plus") or include obligations not even contemplated in TRIPS ("TRIPS-extra").[72] Such obligations constitute a challenge for developing countries for at least three main reasons.

First, many of these new obligations decrease developing countries' opportunities to use the flexibilities in implementation provided under TRIPS. Second, their implementation arguably adds another layer of complexities and expenses with regard to the administration and enforcement of IP obligations, in addition to the many challenges that most developing countries already face in implementing the minimum standards of the TRIPS Agreement. Third, TRIPS-plus and TRIPS-extra commitments may pre-empt or affect positions that countries might pursue or sustain in multilateral negotiation fora. In other words, the bilateral track –legitimatized by the TRIPS Agreement- might be detrimental to advances that could be made through the multilateral system.

Advocates of PTAs argue that the IP provisions are a mere elaboration of the TRIPS minimum standards. A case in point would be, for example, the elaborated provisions on the protection of pharmaceutical products found in PTAs. The argument is also made that PTAs are the only possible path to advance positions that otherwise are not achievable through a multilateral system that has become cumbersome and time-consuming.[73]

However, few could dispute that the IP provisions have been one of the most contentious aspects of the negotiations of the PTAs. The general critique is that while the agreements build on the TRIPS minimum standards, they tend to affect the general balance of the Agreement by overemphasizing the protection aspects of IP while reducing policy spaces otherwise available for the protection of the broader public interest.[74] The rest of the paper elaborates further on this general observation with respect to developing countries' public policy objectives in areas such as access to medicines, genetic resources, access to knowledge and settlement of disputes and enforcement issues. In dealing with these questions, the paper will also consider the implications of PTAs for the international IP system.

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[71] Roffe 2004, p. 9.
[72] Mavroides
[73] For an overview of the push for TRIPS-plus, see Carolyn Deere, "The Implementation Game. The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries", Oxford University Press, 2009, pp. 114-118.
[74] See, for example, James Boyle, "The Public Domain: Enclosing the Commons of the Mind", Yale University Press, New Haven, London, 2008 (hereinafter Boyle).

## *A. The access to medicines issue and the preferential trade agreements*

In dealing extensively with the impact of PTAs on access to medicines, we begin by examining pertinent TRIPS flexibilities, with particular reference to the Doha Declaration of 2001. Subsequently, we consider the most controversial related questions covered by the PTAs, namely: the extension of the duration of patents beyond the TRIPS minimum standard of 20 years; the patentability criteria; the extent to which recent trade agreements might impact the use of policy instruments such as compulsory licensing and exhaustion of IPRs; the treatment of undisclosed information in the case of clinical test data submitted for the marketing approval of pharmaceutical products and finally the linkage between the marketing approval and the status of the related patent.

### 1. TRIPS flexibilities in the area of pharmaceuticals and the Doha Declaration on the TRIPS Agreement and Public Health

The implementation of the TRIPS Agreement and the use of some of its flexibilities became particularly controversial with respect to the protection of pharmaceutical products which obliged a number of developing countries to introduce full patent protection in sectors that were generally off-patent. As pointed out supra, the TRIPS Agreement leaves, in general, WTO Members with some discretion in the design of their national patent laws. The full use of these flexibilities was challenged in national jurisdictions (e.g. case of the South Africa Medicines and Related Substances Control Amendment Act of 1997)[75] and at the WTO (e.g. case of Brazil's 1996 industrial property law).[76]

The flexibilities in the case of pharmaceutical products have a number of expressions. For example, WTO Members have the freedom to apply, within the boundaries of the Agreement, laxer or stricter criteria of patentability (details on patentability criteria will be provided in the following section). Also, the TRIPS Agreement does not affect the authority for curbing prices of patented products nor the control of abuses, in general, resulting from the use of the exclusive rights granted by patents through competition laws and policies, in particular in IP licensing agreements.[77]

The Agreement also allows for exceptions to the exclusive rights conferred by a patent.[78] One relevant exception in the sphere of public health is the early working or regulatory review exception. The regulatory review exception was one of the main issues before the WTO Panel in the *Canada - Patent Protection of Pharmaceutical Products* case.[79] The Panel concluded that in the case of the Canadian law, the regulatory review exception of Section 55.2(1) is a "limited exception" within the meaning of Article 30 of the TRIPS Agreement.

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[75] See Resource Book, op.cit., p. 111.
[76] See Resource Book, op.cit., pp. 481-482.
[77] See Articles 8.2, 40, TRIPS Agreement.
[78] See Article 30, TRIPS Agreement.
[79] See note 18, supra

TRIPS also allows Members to freely determine the substantive grounds for the issuance of compulsory licenses[80] and authorizes them to determine their own system of IPR exhaustion that could be a means of facilitating parallel imports of low-priced drugs.[81] Finally, the Agreement in dealing with test data submitted to regulatory authorities for marketing approval purposes leaves each Member with the appropriate determination of their method of protection.[82] This relative freedom of implementation has been drastically affected by the PTAs.

These flexibilities, -which are in many respects a result of the challenges made to the form of implementation initiated by some governments- were reaffirmed in the Doha Declaration on Public Health of 2001 which reiterates the right of WTO Members "to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."[83] (See Box 4 that reproduces the text of the Declaration.)

[80] See Article 31, TRIPS Agreement.
[81] See Article 6, TRIPS Agreement.
[82] This flexible interpretation of Article 39.3 of the TRIPS Agreement is not unanimous. For a different view see Kampf (2002), p.120.
83 See paragraph 4 in fine of the Declaration on the TRIPS Agreement and Public Health

**Box 4**

**DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH**

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree 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.

In this 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.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

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[84] extended the TRIPS flexibilities with regards to compulsory licensing. It facilitates the exportation of generic drugs produced under compulsory license to countries without sufficient domestic pharmaceutical manufacturing capacities. The 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.[85] 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.[86] Finally, the Decision provides incentives to pharmaceutical producers located within a regional trade agreement, at least half of the membership of which is made up of least developed countries (LDCs).[87] In essence, these producers are not subject to the generally applicable limitation that the compulsory license in the exporting country will only authorize production of the amount necessary to meet the needs of the eligible importing Member.[88]

As reiterated in this chapter, the relationship of IPRs, particularly patents, with public health policies and access to medicines, in general, has been one of the most controversial multilateral trade-related topics of recent years. With the adoption of the Doha Declaration, the WTO General Council Decision for the implementation of Paragraph 6 of that Declaration and the subsequent amendment of the TRIPS Agreement, the focus of the debate has shifted away from the multilateral level to the regional and bilateral front and the impact of public health-related TRIPS-plus provisions in recent PTAs.[89] At the multilateral level, the World Health Organization (WHO) [90] has been increasingly engaged in questions related to IP and health with particular emphasis in its relationship with trade issues.[91]

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84 WTO document WT/L/540 of 2 September 2003.
[85] See paragraph 2 of the Decision.
[86] See paragraph 3, second sentence of the Decision.
[87] See paragraph 6(i) of the Decision.
[88] In spite of its existence for over five years, the mechanisms has only most recently for the first time been successfully implemented. In a process that took over four years to put together, Canada's generic producer Apotex started to export Apo-TriAvir, a triple-combination HIV/AIDS drug, to Rwanda in 2008. Public health advocates blame above all the complex nature of making use of the mechanisms for its scarce use (Bridges 2008).
[89] (Roffe & Spennemann 2006; Abbott & Reichman 2007)
[90] See: http://www.who.int/intellectualproperty/en/
[91] See report of the Commission on Intellectual Property Rights, Innovation and Public Health, and the follow-up work of its Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) and the final adoption in 2008 of the Global Strategy and Plan of Action public health, innovation and intellectual property. 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]; the "Global strategy and plan of action on public health, innovation and intellectual property" was subsequently adopted by the 61st World Health Assembly in May 2008. The document can be found at: http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

## 2. Analysis of the controversial public health-related provisions in preferential trade agreements

### a. General concerns

The TRIPS-plus nature of provisions found in PTAs has been characterized as having a major undermining effect on the use of internationally agreed flexibilities[92] and making accessibility to medicines a major hardship to developing countries.[93] Concerns raised by the expansive exclusive rights on pharmaceutical products are not limited to access issues, but extend to the building of technological capacities in developing countries. Overly broad exclusive rights may threaten the ability of local innovators, especially in developing countries, to engage in research and development (R&D) through reverse engineering and the creation of functional generic equivalents and improvements.[94] Extended exclusive rights might discourage potential generic investors from investing in existing local production plants in developing countries, thus denying important opportunities for technology transfer to local producers of pharmaceuticals.[95] Thus, PTA provisions, where implemented without due regard to their potential impact on innovation, may seriously hamper developing countries' efforts of technological catching-up.[96]

As noted, some of these concerns were reflected in the changes introduced in recent PTAs signed by the USA to echo more accurately the need to conform the trade agreements to the spirit and letter of the Doha Declaration on Public Health (See Box 4).[97] The subsequent sections focus on the following pharmaceutical related provisions of the free trade agreements: patent extensions, the patentability criteria, compulsory licensing, parallel imports, test data protection and the patent-marketing approval linkage.

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[92] "…In the 2002 Trade Promotion Authority Act, Congress directed the Administrative branch to adhere to the Doha Declaration as a 'principal negotiating objective' in U.S. trade negotiations. Regrettably, recent … FTAs appear to undermine this commitment with provisions that strip away flexibilities to which countries are entitled under TRIPS. The FTAs provisions also appear to upset an important balance between innovation and access by elevating intellectual property at the expense of public health. The end result is that they threaten to restrict access to life-saving medicines and create conditions where poor countries could wait even longer than the Unites States for affordable generic medicines." Public letter dated 12 March 2007 addressed to the USA Trade Representative, signed by 12 members of the USA Congress

[93] Nobel Prize laureate Joseph Stiglitz has observed with respect to the agreement with Morocco that "The new agreement, many Moroccans fear, will make generic drugs needed in the fight against AIDS even less accessible in their country than they are in the United States." Stiglitz 2004).

[94] (Jaszi 2004: p.8).

[95] In February 2009, a joint venture between the Indian producer *Cipla* and the domestic Ugandan producer *Quality Chemicals* began producing anti-retroviral drugs at a modern production site near Kampala. One of the factors attracting the Indian investor was reportedly the implementation by Uganda of the LDC transition period on pharmaceutical product patents accorded by the WTO Council for TRIPS. See David Rocks, "Cheap AIDS Drugs Bring Uganda Hope", Business Week of 14 July 2008, available at <http://www.businessweek.com/globalbiz/content/jul2008/gb20080714_399079.htm>.

[96] (UNCTAD 2009

[97] Details of these amendments are discussed, respectively, in the analysis of the PTAs provisions dealing with pharmaceutical products.

## b. The 20 years Plus

Under Article 33 of the TRIPS Agreement, the minimum term of patent protection is 20 years from the filing date. However, particularly in the case of regulated products such as medicines, the period during which the patentee may actually take advantage of his exclusive rights may be affected by administrative delays in the actual grant of the patent and finally in the marketing approval process of the medicine. This is the apparent rationale behind the PTA provisions that require an extension of the patent term in cases where 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. For example, the PTA between the USA and Morocco provides:

> Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than four years from the date of filing of the application in the territory of the Party, or two years after a request for examination of the application, whichever is later. Periods attributable to actions of the patent applicant need not be included in the determination of such delays.[98]

Such extensions of the patent term correspond to the interests of the R&D-based industry, but, from a public health policy standpoint, they further postpone, beyond the original patent term, the entry of competing medicines into the market.

While patent extensions of this type had been an obligation since the NAFTA negotiations[99], this approach has been modified in recent agreements following the 2007 bipartisan understanding in the US Congress, reported above. In the revised version of the PTAs each party "may" extend ("restore") the term of a patent for a pharmaceutical product to compensate for unreasonable delays in the patent- or marketing-approval process.[100] According to the agreement between the USA and Peru (Article 16.9.6(b), (c)):

> Each Party shall provide the means to and shall, at the request of the patent owner, compensate for unreasonable delays in the issuance of a patent, other than a patent for a pharmaceutical product, by restoring patent term or patent rights. Each Party may provide the means to and may, at the request of the patent owner, compensate for unreasonable delays in the issuance of a patent for a pharmaceutical product by restoring patent term or patent rights. […]
>
> With respect to any pharmaceutical product that is covered by a patent, each Party may make available a restoration of the patent term or patent rights to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party. Any restoration under this subparagraph shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions applicable to the original patent.

In other words, the obligation to compensate for those delays laid out in the original negotiated version of the PTA, as in the case of already concluded free trade

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[98] Article 15.9.7, US-Morocco
[99] (Roffe 2004)
[100] See, for example, Article 16.9.6(b) of the US – Peru PTA; and Article 15.9.6(b) of the US – Panama PTA.

agreements (e.g. USA-Morocco), is transformed into an option for the parties. It is important to note that this flexibility applies only to the case of pharmaceutical products. In the event of patents not related to pharmaceutical products, the patent extensions, as in the case of PTAs in force, remain mandatory. In the cases of pharmaceutical and agro-chemical products, the parties need to make a best effort to process patent and marketing approval applications expeditiously with a view to avoiding unreasonable delays.[101] In the case of Peru, the country has taken advantage of the option to exclude pharmaceutical product patents and related processes from patent term restoration.[102]

The change in US policies in this area is an interesting case that confirms the argument that non-discrimination, as recognized in TRIPS,[103] does not exclude differentiation among sectors as also illustrated in the WTO case concerning the Canadian legislation on patent pharmaceutical products.[104]

## c. Patentability criteria and their potential impact on access to affordable medicines

As opposed to the TRIPS Agreement, a number of US PTAs includes a definition of what constitutes "industrial application", referring to the US legal concept of "utility" in the sense that the invention operates according to its intended purpose.[105] This is the case, among others, of the agreements with CAFTA-DR, Morocco, Peru, Colombia, and Panama.[106] This type of provision implies the intrusive nature of PTAs that in this particular case might preclude countries from adopting narrower definitions, like the concept of "industrial applicability" as defined, for example, in European countries.[107]

Contrary to the concept of "industrial applicability", the "utility" approach could open the opportunity for the patentability of business models. As opposed to copyright, patents would protect the right holder against independent creators of comparable business models. This may prove to be a considerable disincentive for generic competitors with regard to the development of efficient business methods.[108] With respect to the patenting of pharmaceutical research tools, it should be noted that

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[101] See Article 16.9.6(a) of the US – Peru PTA.
[102] See Peru, Decreto Legislativo 1075, Articles 32 of 28 June 2008.
[103] Article 27.1, TRIPS: "patent protection shall be available and patents rights enjoyable without discrimination… as to the field of technology".
[104] In the Canada Pharmaceutical Patent Protection case, the Panel held that WTO members can adopt different rules for particular product areas, provided that the differences are adopted for bona fide purposes. See Resource Book, op.cit., pp. 370-371
[105] (Jean F. Morin 2004)
[106] For example, Article 16.9.11 of the US – Peru PTA states: "Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility." See also Article 15.9.11 of the Morocco PTA.
[107] See 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.
[108] See Reichman & Cooper Dreyfuss (2007), p.22, in the context of the information technology sector.

changes in US law[109] have toughened the utility standard by requiring credible, specific and substantial utility, particularly with respect to biotechnological inventions.[110] Research tools that may be used for a variety of different undefined purposes, such as expressed sequence tags (ESTs)[111] and single nucleotide polymorphisms (SNPs),[112] do not meet these tighter utility requirements.[113] This being said, the concern remains that provisions in PTAs referring to "utility" may be interpreted in a less restrictive manner, especially in jurisdictions less familiar with the specific treatment of the utility test in US domestic patent practice.[114] The broad patenting of research tools would create considerable obstacles for the development of competing products and domestic technological capacity as such.[115]

In addition to the potential misapplication of unknown patentability standards, developing countries subscribers of free trade agreements face additional challenges to domestic innovation and access to medicines as a result of requirements to patent new uses of known products (sometimes referred to as "ever-greening" of existing patents). The TRIPS Agreement contains no obligation to make patents available for new (or second) uses of known patented products.[116] In this respect, PTAs play an influential role in guiding countries to adopt a particular model of protection. For example, the US – Oman agreement, makes the protection of new uses mandatory, by confirming that the Parties:

> "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".117

Comparable obligations to patent new uses are also included in the US PTAs with Australia, Bahrain and Morocco, where there is the obligation to make patents

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[109] See revised Patent and Trademark Office (PTO) Utility Examination Guidelines (2001)

[110] Thomas 2005: p.68-70).

[111] An EST is a tiny portion of an entire gene that can be used to help identify unknown genes and to map their positions within a genome, in a quick and inexpensive fashion. See http://www.ncbi.nlm.nih.gov/About/primer/est.html.

[112] SNPs are variations of a DNA sequence. Variations in the DNA sequences of humans can affect how humans develop diseases, respond to pathogens, chemicals, drugs, etc. As a consequence SNPs are of great value to biomedical research and in developing pharmacy products.

[113] See *In re Fisher*, 421 F.3d 1365, 1373 (Fed. Cir. 2005), where the USA Federal Circuit rejected the patentability of ESTs if disclosure of their use is not more specific than broadly referring to the isolation of protein-encoded genes for the purpose of performing further research.

[114] Jaszi 2004: footnote 19; Abbott 2006).

[115] For further reading on the importance of patentability criteria for maintaining public health standards in the examination of pharmaceutical patents, see: Correa (2006b).

[116] 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%20Patent.pdf and http://mb.rxlist.com/rxboard/viagra.pl?noframes;read=183.

[117] Article 15.8.1(b), http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Oman_FTA/Final_Text/asset_upload_file715_8809.pdf. Identical provision is to be found in the FTA between the USA and Morocco (see Article 15.9.2, http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Morocco_FTA/FInal_Text/asset_upload_file797_3849.pdf

available for "any new uses or methods of using a known product".[118] This type of provision does not expressly state whether new use patents should cover only the new process or even the known product as such. To the extent a government intends to promote generic competition, it would appear to be free to follow the domestic US model, which limits the patentability of new uses to process patents ("method-of-use" claims).[119] New use patents could arguably provide developing country innovators with incentives to engage in incremental innovation. On the other hand, the owner of the original patent (often OECD-based) would seem to have the greatest opportunities to discover a new use of the patented product, due to his exclusivity position.

Provisions regarding the obligation to patent new uses are not found in similar PTAs signed by the USA with Latin American countries.

## d. Compulsory licenses

As noted, the TRIPS Agreement leaves Members free to determine the substantive ground for the issuance of a compulsory license. However, PTAs signed between the USA, respectively, 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.[120] This excludes the grant of compulsory licenses on other essential grounds, such as the promotion of innovation and research in case of one patent blocking the exploitation of another one ("dependent patents", TRIPS Article 31 (l)), or in case of the unavailability, due to a patent, of an essential research tool for the development of new products. In the literature, concern has been expressed regarding the impact of such limitations on countries' technological development prospects.[121]

However, the type of provisions found in the above-mentioned agreements concerning the limited use of compulsory licensing are not found in PTAs signed with Latin American countries or in more recent agreements subscribed by the USA, for example with Bahrain and Morocco, respectively, that do not contain express limitations on the use of compulsory licenses. These agreements include side letters[122] referring to the "WTO health solution". The PTA with Chile, for its part,

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[118] See, e.g., Article 15.9.2 of the PTA USA - Morocco (http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Morocco_PTA/FInal_Text/asset_upload_file797_3849.pdf).

[119] Thomas, p. 37/38.

[120] "Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances:(a) to remedy a practice determined after judicial or administrative process to be anti-competitive; (b) in cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or (c) on the ground of failure to meet working requirements, provided that importation shall constitute working. Where the law of a Party allows for such use pursuant to sub-paragraphs (a), (b) or (c), the Party shall respect the provisions of Article 31 of TRIPS and Article 5A(4) of the Paris Convention. (Article 4. 20 of the USA - Jordan PTA)

[121] (Jaszi 2004: p.10).

[122] 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

expressly refers to the terms of the Doha Declaration on TRIPS and Public Health in a Preamble to its IP Chapter, a practice that afterward was not followed in subsequent US PTA negotiations. It was only most recently reintroduced when the reference to the Doha Declaration made its way back into the main text of the US PTA with Peru as a result of the congressional bipartisan agreements to introduce amendments to more recent free trade agreements such as the treaty with Peru that entered into force in February 2009.[123]

With respect to European agreements with third parties there has been a consistent policy to include a reference to the Doha Declaration. For example, in the Agreement with the CARIFORUM countries it is acknowledged:

> The EC Party and the Signatory CARIFORUM States recognize the importance of the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001by the Ministerial Conference of the WTO and the Decision of the WTO General Council of 30 August 2003 on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and agree to take the necessary steps to accept the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005.[124]

## e. Exhaustion of rights

The doctrine of exhaustion addresses the issue of when the IPR holder's control over the distribution of a specific good ceases. This cessation of control is critical to the functioning of any market economy because it facilitates the circulation of goods.[125] The basic idea is that once the right holder has been able to obtain an economic return from the first sale or placing of a good on the market under conditions of exclusivity, 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 continue exercising control over the sale, transfer or use of a good or service after the first sale. This doctrine has a particular impact on pharmaceutical products, where prices for the same products vary substantially among different countries. From the standpoint of the international trading system, the issue is whether the exhaustion operates on a national, regional or international basis.[126]

Exhaustion was one of the most difficult issues that arose during the negotiation of the TRIPS Agreement.[127] The compromise at that time was that each WTO Member

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text. See a USTR document from July 2007 clarifying several aspects of an 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. However, their status has never been tested in case of conflict and some scholars expressed doubt of their legal statute. See for example: Roffe, von Braun and Vivas (2007).

[123] See Article 16.13 of the US – Peru PTA (Understandings regarding certain public health measures).

[124] Article 147 B

[125] See Resource Book, op.cit., pp.92-117.

[126] 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 by a competitor of a good for which exhaustion of an IPR has occurred abroad is commonly referred to as "parallel importation".

[127] (Gervais 1998, p.61). Rochele

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 each WTO Member is free to establish its own regime on exhaustion of IPRs. (See Box 4, supra)

Some PTAs signed by the USA (Australia, Morocco and Singapore) expressly acknowledge the patent holder's right to prevent parallel imports through the use of contracts or other means.[128] This approach was openly criticized, as contrary to the national interests, in a US House of Representatives report (2005) prepared for Rep. Henry Waxman. [129]

This apparent impact on the freedom of countries to import goods, which IPRs have been exhausted, has not found a place in the PTAs signed with Latin American countries and in more recent PTAs signed with Bahrain, Oman and the Republic of Korea.[130]

## *e. Protection of clinical test data under preferential trade agreements*

### *i. TRIPS requirements: different views and perceptions*

The treatment of clinical test data under TRIPS is one manifestation of the negotiating ambiguities of the Agreement.[131] The original intention of the main advocates of the TRIPS Agreement was a more unambiguous system of protection than what finally became embraced in Article 39.3 of TRIPS.[132] However, as no

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[128] See e.g. Chapter 15, Article 15.9.4 of the USA - Morocco PTA, and Chapter 17, Article 17.9.4 of the USA - Australia PTA.

[129] "…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."

[130] (GAO 2007: 32).

[131] This could be explained at the time of the negotiations by the controversial nature of the subject matter and particularly in view of the fact that the protection of clinical test data was practically not a topic of legal special treatment particularly in the developing world." (See Resource Book, op. cit., p. 522). The Agreement limited to set general principles under the somewhat vague provision dealing with undisclosed information:

> Members, 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. (See Article 39.3, TRIPS).

[132] For example, in a submission made by the USA during the Uruguay Round negotiations in 1990, which was joined by the EC and Switzerland, it was proposed that:

agreement could be reached among the negotiating parties, the final version of the TRIPS Agreement was deliberately less precise and in many respects vague. It established that undisclosed information should be protected against unfair competition, leaving the appropriate implementation of this provision strategically vague.[133]

Exclusive protection of test data for at least five years from the date of approval of the pharmaceutical product was first introduced in NAFTA and has been further elaborated and included in PTAs concluded by the USA with a number of developing countries, as discussed below. As briefly explained below, a similar but more expanded model is being proposed by the EC in its negotiations of new bilateral free trade agreements[134] which is again a clear case of exporting to developing countries regimes established under more sophisticated legal and health environments.

The main controversy regarding the interpretation of Article 39.3, TRIPS, has focused on the question of how to define the terms "unfair commercial use", in the absence of any definition under the TRIPS Agreement. This has wide reaching implications for the pharmaceutical industry and potentially also for access to medicines. The question is to what extent a generic competitor when requesting regulatory approval for a copy of an original drug may rely (or have the drug regulatory authority rely) on clinical test data previously generated and submitted by a brand name producer to show the safety and efficacy of the original drug. Such "reliance" would limit the generic producer's obligations to a demonstration of bioequivalence,[135] as opposed to the submission of a full clinical trials dossier showing the safety and efficacy of the generic copy.[136]

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> 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: p.198).

[133] While an express provision for data exclusivity was included in earlier consolidated version of the future Article 39.3, it was later removed from the final text of the Agreement (see the Brussels Draft of the TRIPS Agreement, as quoted in UNCTAD-ICTSD (2005), p. 525; see also accompanying text on p. 526, ibid.

[134] Seuba

[135] Generic producers obligated to demonstrate bioequivalence may do so by measuring "the time it takes the generic drug to reach the bloodstream in 24 to 36 healthy volunteers. This gives them the rate of absorption, or bioavailability, of the generic drug, which they can then compare to that of the innovator drug. The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug." See Meir P. Pugatch, "Intellectual Property, Data Exclusivity, Innovation and Market Access", in *Negotiating Health. Intellectual Property and Access to Medicines* (eds. Roffe, Tansey, Vivas-Eugui, Earthscan, London, 2006; hereinafter Pugatch, 2006), p. 102, referring to Food and Drug Authority (FDA) sources.

[136] In the literature, it has been argued that Article 39.3 of the TRIPS Agreement enables reliance, limiting the obligation to provide protection against "unfair commercial use" to making available remedies under the law of unfair competition (see Carlos Correa, "Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements", in *Negotiating Health. Intellectual Property and Access to Medicines* (eds. Roffe, Tansey, Vivas-Eugui, Earthscan, London, 2006; hereinafter Correa, 2006) pp. 81-96 (84). This means that competitors of the data originator pharmaceutical producer must be prevented from obtaining the latter's data through unfair commercial means ("misappropriation"), and of using it for unfair commercial advantage, such as to shorten the time and reduce the cost for reverse engineering. But, competitors would not be required to undertake the same clinical trials that have already been undertaken and submitted by the data originator.

In many jurisdictions, including the USA or the EU, reliance by the regulatory authority is only possible after the expiry of a certain period.[137] During this period, the originator of the data is provided with exclusive rights in the clinical trials data, which makes reliance by the regulatory authority dependent on his consent (which will normally not be granted). It is important to note that data exclusivity applies to both on-patent and off-patent substances. As far as the latter are concerned, data exclusivity thus creates a new exclusive right. As to on-patent substances, the patent term usually lasts longer than the term of data exclusivity.[138] But data exclusivity in on-patent substances may have an impact on the efficient operation of a compulsory license. The latter being a public policy instrument related to patent law, without a clear link to exclusive rights in test data. Despite the existence of a compulsory license, a generic producer, in order to receive regulatory approval, still depends on the consent of the holder of the exclusive data rights. Under EU law, for instance, there is no possibility to grant regulatory approval without the data originator's consent, despite the existence of a compulsory license on a patented medicinal product.[139] The only exception applies to cases of compulsory licensing for the purpose of facilitating exports to countries with insufficient pharmaceutical manufacturing capacities.[140]

The research-based pharmaceutical industry argues that the protection of data submitted for the registration of medicines is of fundamental importance, and that data exclusivity regimes are mandatory under Article 39.3 of the TRIPS Agreement.[141],

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Reliance does not require the disclosure of the originator data to the generic competitor; it suffices for the regulatory authority to examine the bioequivalence of the generic drug and the originator drug and approve the generic product on this basis. For examples for "misappropriation" see J. H. Reichman, "The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Good?", in *Negotiating Health. Intellectual Property and Access to Medicines* (eds. Roffe, Tansey, Vivas-Eugui, Earthscan, London, 2006, p. 142 (hereinafter Reichman, 2005), referring to cases where the DRA discloses the originator's data to a local competing firm or facilitates that firm's access to the data in order to provide the local producer with a competitive advantage; or where the government itself or one of its former staff exploit the commercial advantage of having access to clinical trials data.

[137] For the United Sates, see Section 355 of the 1997 Federal Food, Drug and Cosmetic Act (providing a lapse of five years between approvals of original substances and approvals of generic copies based on bioequivalence, plus an additional three years for new indications of existing drugs). For EU countries, see Article 10 of Directive 2004/27/EC ("8 + 2 + 1 formula", providing an eight-year period plus a two-year-period during which generic companies may submit bioequivalence tests but not yet market their product, plus an additional year of protection for new indications of existing drugs). See Pugatch, 2006, pp. 102-108.

[138] Pugatch, pp. 119/120, referring to some cases where the data exclusivity term lasted longer than the patent term.

[139] See Karin Timmermans, "Monopolizing Clinical Trial Data: Implications and Trends", PLoS Medicine Journal, 13 February 2007, p. 3 (hereinafter Timmermans); available at http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0040002#journal-pmed-0040002-b011.

[140] See European Parliament (2006) Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacturing of pharmaceutical products for export to countries with public health problems, Official Journal of the European Union.

[141] See International Federation of Pharmaceutical Manufacturers Associations (IFPMA), "The Pharmaceutical Innovation Platform - Sustaining Better Health for Patients Worldwide", Geneva, 2004, p. 40; J. Gorlin, "Encouragement of New Clinical Drug Development: The Role of Data Exclusivity",

From a systemic point of view, however, voices in the literature have criticized the protection of clinical test data through patent-like exclusive rights, for the fact that a clinical data file is not the result of human ingenuity and inventiveness, but of time and money consuming, repetitive actions, which should be encouraged through other legal regimes such as non-exclusive compensatory liability systems.[142] In the case of developing countries, it may also be argued that data exclusivity is not essential, as the data originator would have already recouped the R&D costs in affluent OECD markets.[143] Against this background, it does not seem appropriate to limit the possibilities of the regulatory authority to rely on previous test data to promote reduced drugs prices through generic competition as a major public health policy objective.[144]

### ii. Preferential trade agreements as the channel to transpose clinical test data protection to developing countries

As observed, the US PTAs have introduced a new regime of data exclusivity, providing that once a firm 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).[145] For example, the PTA with Bahrain provides:

> If a Party requires or permits, as a condition of granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of information concerning safety or efficacy of the product, the Party shall not, without the consent of a person that previously submitted such safety or efficacy information to obtain marketing approval in the Party, authorize another to market a same or a similar product based on:
>
> (i) the safety or efficacy information submitted in support of the marketing

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IFPMA, Geneva, 2000. The rationale is that the manufacturer has invested, often heavily, in the research necessary to develop the relevant data (it is argued that the estimated clinical costs per approved new drug exceed 50% of its total development costs. See Meitinger (2005), p.123) and where patent law fails to provide protection of such data it constitutes the only barrier against a generic competitor rapidly producing and registering an exact copy of the drug. (Failing patent protection could apply in cases where the active component was shortly to be off-patent, or because the tested drug was based on a combination of known substances used in a novel manner, which may not satisfy domestic patentability requirements).

[142] Jerome H. Reichman, "Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach", 13 Marquette Intell. Prop. L. Rev 3 (forthcoming, 2009; hereinafter Reichman, 2009). In addition, it has been argued that data exclusivity regimes risk over-compensating the data originator at the expense of early generic market entry and a reduction in pharmaceutical prices. This view is based on the important benefits generated through patent protection alone, and on the important amounts of public funding made available for upstream research drug development (Reichman, 2009, referring to almost USD 30 billion per year made available by the US National Institute of Health (NIH). Figure from "Health Issues and Opportunities at NIH: Hearing Before the S. Subcomm. Labor, Health and Human Services, Education Appropriations", (2008) (testimony of Elias A. Zerhouni, M.D., Director, NIH), available at http://appropriations.senate.gov/Hearings/2008_07_16Labor-_Testimony_of_Dr_Elias_A_Zerhouni_at_the_July_16_NIH_Hearing.pdf).

[143] Reichman, 2009.

[144] UNCTAD-ICTSD 2005: p.538; Correa 2007: p.373-392).

[145] See, e.g., Chapter 15, Article 15.10.1(a) of CAFTA

> approval; or
>
> (ii) evidence of the marketing approval;
>
> for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval in the Party.[146]

This type of provision effectively requires generic producers to come up with their own test data, which very often is not economically feasible and/or may be considered unethical.[147] It thus provides the data originator with a further period of exclusivity, especially in respect of non-patented pharmaceutical or agrochemical products, thus creating a new form of monopoly not required by TRIPS.[148]

The amended texts of the PTAs negotiated with Colombia, Panama and Peru have introduced a number of important flexibilities with regard to data exclusivity rights.

In the case of Peru, for example, the changes introduced include the notion that the protection of undisclosed test or other data should not exceed "a reasonable period of time." The relevant provision clarifies that for this purpose, such a timeframe shall normally mean five years, taking into account the nature of the data and the degree of effort and expenditure required to produce the data. The provision further clarifies that parties shall be allowed to implement abbreviated approval procedures for such products on the basis of bioequivalence or bioavailability studies, subject to the requirement to implement the data exclusivity obligation.[149] The revised text of the Peru PTA is indeed more flexible than its original negotiated version, which did not condition the five-year protection rule on the quality of the data and the economic investments made in producing them. Contrary to, for example, the CAFTA-DR or the Bahrain PTA, the revised text leaves room for a balanced domestic implementation of the norms including, for example, a protection for less than five years when the origination of such data has not involved considerable efforts and expenditures.[150]

In another important departure also related to data exclusivity, the text of the revised Peru PTA provides that the reasonable period of exclusive use shall begin when the drug was first approved in the USA (a so-called "concurrent period"), provided that Peru grants the approval of the compound within six months of an application:

> Where a Party relies on a marketing approval granted by the other Party, and grants approval within six months of the filing of a complete application for marketing approval filed in the Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.[151]

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[146] Article 14.9.1 (a), Bahrain-USA
[147] See: World Medical Association Declaration of Helsinki: http://www.wma.net/e/policy/b3.htm
[148] Abbott 2004: p.7. F. Abbott observes that such exclusivity renders illegal the actual marketing of generic drugs produced under a compulsory or public non-commercial use license (p.8). This is so because the exclusive nature of the test data makes the validity of marketing approvals dependent on the authorization by the data originator.
[149] See Article 16.10.2 (b), PTA Peru-USA and the implementing legislation (Decreto Legislativo 1072, Article 5).
[150] Ibid.
[151] Peru PTA, Article 16.10.2(c)

This new mechanism provides an incentive for rapid marketing approval in exchange for a period of protection that starts in the country where the drug was first approved, generating a shorter period of effective protection in the country where the drug was approved subsequently. This important change responds to criticisms addressed to the original version of the PTA, which allowed for a priority period of five years from obtaining the first approval abroad, within which the innovator could claim exclusivity in the other country. Such a priority right could generate, as in the case of CAFTA-DR, Bahrain and others, a *de facto* extension of the period of protection up to 10 years in the countries of subsequent approvals.[152]

A much more liberal approach to the concurrent period has been adopted by Chile in its implementation of the PTA with the United States. Chilean domestic law *inter alia* provides that data exclusivity will not be granted in Chile if the data originator has not applied for regulatory approval in Chile within 12 months from receiving approval for the same substance abroad.[153]

Departing from the earlier US PTAs, the amended texts of the Colombia, Panama and Peru agreements also call on the parties, in the main text and not in side letters, to affirm their commitments to the Doha Declaration, particularly emphasizing that the provisions on data exclusivity should be subordinated to the right of a party to take measures to protect public health. The revised texts further oblige the parties to respect existing waivers granted by WTO Members regarding provisions of the TRIPS Agreement.[154] These changes put both the Doha Declaration and existing waivers on the same level as other provisions in the PTAs, thus facilitating pro-public health interpretations of the provisions on regulated products, as well as other sections of the PTA.

Finally, it should be noted that the EFTA countries, in their free trade agreements, have not followed a uniform approach to the protection of undisclosed pharmaceutical test data. While the EFTA – Chile PTA obligates Parties to provide a data exclusivity regime for at least five years,[155] the EFTA – Egypt PTA broadly refers to Article 39, TRIPS Agreement, without further specification.[156] Yet another option is provided under EFTA's PTAs with the Republic of Korea and Colombia, where protection of undisclosed information may be provided either through exclusivity or through a regime of compensatory liability. In this respect, the EFTA – Korea PTA provides:

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[152] See Article 15.10.1(b) of the US – CAFTA PTA, and its interpretation by Correa 2006 a: p. 89; Abbott 2004: p.7.

[153] Decree 153 (2005) of the Health Ministry, Mechanisms for the Protection of Undisclosed Data; see discussion by Pedro Roffe, INTELLECTUAL PROPERTY PROVISIONS IN BILATERAL AND REGIONAL TRADE AGREEMENTS: THE CHALLENGES OF IMPLEMENTATION, CIEL, Geneva, 2006. It should be noted that the text of the PTA with Chile is not identical to other PTAs (Roffe 2004). The USA and the EFTA countries have challenged the treatment of this and other matters in the Chilean law. In the case of the USA it has prompted the USTR to place Chile in the Priority Watch List of its 2006 annual report (see Pedro Roffe & David Vivas *A Shift in Intellectual Property Policy in US PTAs?,* BRIDGES MONTHLY, Volume 11, Number 5, August 2007, ICTSD, Geneva (hereinafter Roffe/Vivas).

[154] In the case of the PTA with Peru, see Article 16.13.

[155] Annex XII, Article 4.2 of the EFTA – Chile PTA.

[156] Annex V, Article 3(e) of the EFTA – Egypt PTA.

> The Parties shall protect undisclosed information in accordance with Article 39 of the TRIPS Agreement. The Parties shall prevent applicants for marketing approval for pharmaceutical and agricultural chemical products from relying on undisclosed test or other undisclosed data, the origination of which involves a considerable effort, submitted by the first applicant to the competent authority for marketing approval for pharmaceutical and agricultural chemical products, utilizing new chemical entities, for an adequate number of years from the date of approval, except where approval is sought for original products. Any Party may instead allow in their national legislation applicants to rely on such data if the first applicant is adequately compensated."[157]

This option seems to be based on suggestions made in the literature[158] and deserves further discussion at both the international and the domestic levels. The above-mentioned EFTA – Colombia PTA also provides for the compensatory liability option, but with an important qualification: this option applies only to agricultural chemical products involving vertebrate animals.[159] In the case of test data related to pharmaceuticals, the PTA insists on protection through a regime of exclusivity, "which in the case of pharmaceutical products means normally five years".[160] In a way comparable to the most recent US PTAs, the agreement in this context refers to Parties' rights to "take measures to protect public health" in accordance with the implementation of the Doha Declaration, any related waiver of any TRIPS obligation, and any related amendment to the TRIPS Agreement.[161]

This section has focused mainly on PTAs signed by the USA with a brief reference to EFTA. In the case of the EC no actual agreement with a developing country has included provisions on data protection as the case of the recent CARIFORUM agreement shows. However, in current negotiations with other countries such as Ecuador, Colombia and Peru, the EC has put forward stricter rules on data protection that in some cases go beyond the model used by the USA.[162]

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[157] See Annex XIII (Article 3) to the EFTA-Korea FTA (http://secretariat.efta.int/Web/ExternalRelations/PartnerCountries/KR/KR_RUAP/annexes/KR_Annex_XIII_-_IPR.pdf).

[158] See Reichman 2005 and 2009 and Robert Weissman, *Data Protection: Options for Implementation*, NEGOTIATING HEALTH. INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES (eds. Roffe, Tansey, Vivas-Eugui, Earthscan, London, 2006), pp. 151-178.

[159] Article 6.11.3(b) of the EFTA – Colombia PTA.

[160] Article 6.11.2 of the EFTA – Colombia PTA. Footnote 15 to this provision states that

> "Normally" means that the protection shall extend to five years, unless there is an exceptional case, where the public health interests would need to take precedence over the rights provided for in this paragraph.

[161] Article 6.11.4 of the EFTA – Colombia PTA.

[162] According to information made available to the authors, the proposals put forward by the EC include the following elements: a) Parties to implement a comprehensive system to guarantee the confidentiality, non-disclosure and non-reliance of data submitted for the purpose of obtaining an authorization to put a pharmaceutical product on the market; b) Parties to implement legislation ensuring that any information submitted to obtain an authorization to put a pharmaceutical product on the market will remain undisclosed to third parties and benefit from a period of at least ten years of protection against unfair commercial use starting from the date of grant of marketing approval in either of the Parties; c) The ten-year period to be extended to a maximum of eleven years if, during the first eight years after obtaining the authorization, the holder of the basic authorization obtains an

## iii.The linkage between marketing approval and patent status

While the above observations may relate to non-patented pharmaceutical and agrochemical products, most of the PTAs do contain an additional provision that can have an important impact in the area of patented pharmaceutical and agrochemical products. For instance, in the USA-CAFTA-DR agreement it is stated that:

> 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 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.[163]

The obligation is made more direct in the case of the USA-Chile free trade agreement:

> With respect to pharmaceutical products that are subject to a patent, each Party shall: not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner.[164]

In a related provision -not in all the agreements under consideration- the period of protection allowed for the undisclosed information submitted for marketing approval is not affected by the respective duration of the relevant patent:

> When a product is subject to a system of marketing approval … and is also covered by a patent in the territory of that Party, the Party shall not alter the term of protection that it provides … in the event that the patent protection terminates on a date earlier than the end of the term of protection …[165]

In other words, the decision by regulatory authorities to grant marketing approval to third parties is subject to the acquiescence of the patent holder, thereby linking the separate realms of drug regulation and patent law. Such a requirement effectively

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authorization for one or more new therapeutic indications which are considered of significant clinical benefit in comparison with existing therapies.

[163] See Article 15.10.3(a), CAFTA-DR. See almost identical provision in USA-Bahrain, Article 14.9.4.

[164] Article 17.10.2 (c), Chile-USA.

[165] Article 14.9.3, USA-Bahrain. See equivalent provision in USA-Peru (Article 16.10.5).

transforms the regulatory agencies into patent enforcement authorities. Besides the difficulties created for regulatory authorities to determine the validity of patents, and besides the fact that according to the preamble of TRIPS, IPRs are private rights (and the private parties owning them thus bear the primary responsibility of enforcing them), this provision has been interpreted as potentially precluding governments' options for using compulsory licenses to increase the availability of low-priced pharmaceutical products.[166] As observed in the context of data exclusivity rules, regulatory approval is independent of patent law, and 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.[167]

The new US PTAs with Peru, Colombia and Panama make such linkage optional and in particular do not require that sanitary authorities withhold approval of a generic until they can certify that no patent would be violated if the generic were marketed.[168] Peru has taken advantage of this option in its implementing legislation.[169]

Instead, the revised PTAs require parties to provide procedures and remedies (judicial or administrative proceedings, including injunctions or equivalent effective provisional measures) for adjudicating expeditiously any patent infringement of validity or dispute that arises with respect to a product for which marketing approval is sought.[170] The revised texts also require greater transparency in these procedures, calling on parties to the PTA to make available: a) an expeditious procedure to challenge the validity or applicability of the patent (so as to break the 'link', where applicable) and b) effective rewards for a successful challenge to the validity or applicability of the patent.[171] In other words, the revised PTAs seek to balance the rights of patent holders with opportunities for generic producers to challenge patented products that might prevent competing products from entering the market. They shift the primary responsibility for patent enforcement back to the patent owner.

The above-mentioned developments in US PTAs suggest an interesting shift in policies towards IP in the USA. The revised PTAs provide clarifications on a number of ambiguous aspects of the earlier free trade agreements still in force in a number of countries. The revised model leaves space for innovative implementation of the agreements as they emphasize public health related flexibilities much more clearly than did the original texts negotiated by the same countries with the USA.

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[166] Abbott 2004: p.8.
[167] See Resource Bok, op.cit., p.537.
[168] See Article 16.10.2(d) and 16.10.4 of the United States – Peru PTA..
[169] See Article 4, *Decreto Legislativo* 1074 of 28 June 2008.
[170] "Each Party shall provide: (a) procedures, such as judicial or administrative proceedings, and remedies, such as preliminary injunctions or equivalent provisional measures, for the expeditious adjudication of disputes concerning the validity or infringement of a patent with respect to patent claims that cover an approved pharmaceutical product or its approved method of use; (b) a transparent system to provide notice to a patent holder that another person is seeking to market an approved pharmaceutical product during the term of a patent covering the product or its approved method of use; and (c) sufficient time and opportunity for a patent holder to seek, prior the marketing of an allegedly infringing product, available remedies for an infringing product." (Peru, Article 16.10.3)
[171] According to the revised version of the PTA with Peru, a Party may comply with this clause by providing a period of marketing exclusivity for the first applicant to successfully challenge the validity or applicability of the patent (footnote 18 of chapter 16 of the PTA).

## *3. Beyond medicines: the other controversial issues*

As pointed out, the issues related to access to medicines has been the focus of most of the attention regarding the impact and pervasiveness of PTAs. A number of scholars and civil society groups have singled out several other issues as being controversial for unnecessarily expanding TRIPS minimum standards, thereby upsetting the structural balance reached in the Agreement. Among these issues we highlight the following: the treatment of genetic resources, protection of life forms and other related questions; the circumvention of technological measures in the digital environment; the settlement of IP related disputes and finally, the enforcement of intellectual property rights.

### a. Genetic resources, protection of life forms and related questions

One general observation that could be made is that the PTA provisions on these matters tend to anticipate outcomes in current multilateral negotiations. First, they go beyond TRIPS in some instances by imposing the obligation to patent plants and animals and by suggesting forms of treatment of genetic resources and traditional knowledge that are still under review. Second, the PTAs appear to put countries in contradiction with positions they sustain in international forums. The latter shows some mismatch between regional and multilateral processes. This apparent gap on these very issues between multilateral diplomacy and bilateral and regional negotiations seems to have been a particular concern by the EU in its recent EPA negotiations with CARIFORM.[172]

### i. The broad TRIPS standards

In one controversial aspect under constant review at the WTO, TRIPS contemplates, -under the general principle that patents shall be available for any inventions-, that Members may exclude from patentability:

> plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement .[173]

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[172] See Article 150 EC-CARIFORUM on genetic resources, traditional knowledge and folklore: "5.The EC Party and the Signatory CARIFORUM States agree to regularly exchange views and information on relevant multilateral discussions: (a) In WIPO, on the issues dealt with in the framework of the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore; and, (b) In the WTO, on the issues related to the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore. 6. Following the conclusion of the relevant multilateral discussions referred to in paragraph 5, the EC Party and the Signatory CARIFORUM States, at the request of the EC Party or a Signatory CARIFORUM State, agree to review this Article within the Joint CARIFORUM-EC Council in the light of the results of such multilateral discussions."

[173] Article 27.3 (b), TRIPS.

TRIPS, thus, allows 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. TRIPS suggests that Members need to afford patent protection for the following: microorganisms, non-biological processes and microbiological processes. Furthermore, Members need to provide protection to plant varieties either by patents, an effective sui-generis system or by any combination of the two. At the same time, TRIPS suggests that Members may exclude from patent protection: plants, animals, essentially biological processes for the production of plants or animals and plant varieties. The reference to an 'effective sui generis system' is rather vague. It might suggest the breeder's rights regime, as established in the UPOV Convention, but the text very deliberately does not refer to UPOV. The possibility is open to combine the patent system with a breeders' rights regime, or to develop other 'effective sui-generis' forms of protection.[174]

The patentability of microorganisms and microbiological processes may raise similar concerns to those raised by the patenting of research tools in the pharmaceutical area. Access to patented or otherwise protected biological material may be rendered more difficult, especially for stakeholders from developing countries who lack the financial means to pay licensing fees. In addition, products developed on the basis of biotechnology are often subject to various exclusive rights held by a multitude of IP owners. A good example is the development of "Golden Rice", which utilized a variety of about 70 intellectual property rights and/or inventions belonging to 32 different companies and universities.[175]

In the context of the review process referred to by TRIPS, a number of developing countries have reiterated their discomfort with the implications of Article 27.3(b), TRIPS, particularly emphasizing the need to reconcile TRIPS with the relevant provisions of the Convention on Biological Diversity (CBD) of 1994 especially with respect to the principles of prior informed consent and access and benefit sharing.[176]

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[174] For a non-exclusive rights approach to the implementation of Article 27.3 (b), TRIPS Agreement, see Reichman & Lewis (2005), suggesting the protection of traditional knowledge and its use to promote small-scale innovation through a compensatory liability regime. For national examples of implementation, see Dhar (2002), referring to Indian and Namibian legislation.

[175] "To enable those who will acquire Golden Rice and/or its technology 'freedom to operate' (being a humanitarian product), the developers needed to obtain free licenses. Whilst one acknowledges that Golden Rice would possibly have not been developed that quickly if the patented inventions were not publicly available or kept secret, negotiating through this maze or "thicket" of patents was tasking. In the case of Golden Rice, public pressure and the use of a private partner proved to be vital." UNCTAD-WIPO-CBD Secretariat (2007), para 139.

[176] The African Group, particularly, has consistently raised concerns about the implications of this provision of the Agreement on life forms. In their view, patents should not be granted on micro-organisms, on non-biological and microbiological processes for the production of plants and animals because this "is contrary to the fabric of their society and culture, and would want to invoke these exceptions in this regard." (Se Note by the WTO Secretariat. The relationship between the TRIPS Agreement and the Convention on Biological Diversity: Summary of issues raised and points made', IP/C/W/369/Rev.1, 9 March 2006, paragraphs 28–29.

## ii. The issue of UPOV

The PTAs under consideration in a number of ways preclude parties from taking advantage of the general principles and exclusions acknowledged in TRIPS. These agreements do not provide options in this respect. In all agreements under consideration, the 1991 Act of the UPOV Convention is listed as one of the international treaties that Parties should subscribe or endeavor to adhere to (e.g., see Box, 2 supra) as the modality of protection for plant varieties. The TRIPS Agreement, as suggested, obliges countries to prescribe protection of plant varieties but offers various options including an effective sui generis system of protection.

UPOV provides a framework for the protection of plant varieties.[177] 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") are covered in both versions of the Convention. The PTAs oblige countries to opt for the 1991 version of UPOV, which is seen as less flexible and more stringent than its previous incarnations.[178]

UPOV's plant breeders' rights regimes have been challenged on the grounds that they better respond to conditions prevailing in industrialized countries and thereby

[177] 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.

[178] For example, the 1991 version states that the original breeder's right also extends to varieties that are essentially derived from the protected one. The intention is that follow-on 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. Another important difference between the two acts is that in the 1978 version species eligible for plant breeder's rights cannot be patented whereas in the 1991 version the possibility of double protection is tacitly permitted. Further, 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. It was accepted practice under UPOV 1978 to consider the farmers' privilege as authorizing farmers to use and exchange seeds from protected varieties for free. While under UPOV 1991, governments can also use their discretion to decide whether to uphold farmers' rights the 1991 version of the Convention is more specific (and restrictive) on the scope of these farmers' rights. It 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 a[n essentially derived] variety" (see Article 15.2 UPOV 1991). This means that the farmers' privilege no longer includes the right to use seeds for free. The reference to the "safeguarding of the legitimate interests of the breeder" means that those acts that are still expressly permitted may only be exercised against the payment of remuneration to the owner of the breeder's rights. The optional nature of the exception 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 has been observed to presumably mean there is no such privilege and that farmers cannot re-sow harvested seed even on their own farms (UNCTAD-ICTSD 2003: p. 53/54).

risk undermining the food security of communities in developing countries.[179] According to activists in the NGO community, this 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; 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.[180]

### iii. Protection of life forms via patents

Countries party to PTAs with the USA undertake further commitments to make efforts to introduce legislation concerning the patenting of plants which is not, as we have seen, mandatory under TRIPS. For example, the agreement between Chile and the USA provides for a "best endeavor" clause for both parties –meaning in practice for Chile- 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.[181]

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.[182] In addition, according to the same PTA, 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.[183] This means a practical derogation from the TRIPS flexibility to determine the appropriate method of implementation by "locking-in" countries to maintain such protection without alteration. This is no doubt a clear indication of the pervasive nature of these agreements that as a matter of principle would not be in a position of amending their national legislation if conditions and circumstances changed.[184] The same approach is followed in the most recently concluded PTAs with Colombia, Panama and Peru.[185]

Contrary to this best endeavor clause, in the case of the agreement between the USA and Morocco, the Parties assume the obligation to grant patents to inventions on animals and plants.[186] An intermediary approach is followed in the agreement with

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[179] See UNCTAD-ICTSD 2003: p 105
[180] (Oxfam 2007: p12-13).
[181] Chile–USA, Article 17.9.2.
[182] CAFTA-DR, Article 15.9.2.
[183] Ibid.
[184] This apparently would not be the case with the USA that according to its respective implementation bills makes these PTAs subordinate to US law. See discussion supra on this matter.
[185] Peru-USA, Article 16.9.2.
[186] Morocco-USA, Article 15.9.2.

Bahrain that makes mandatory the patenting of "plant inventions" and not of animals.[187]

Contrary to the US trend on these matters, the EC PTAs appear not to interfere with the issue of dealing with life forms.

### iv. Revocation of patents, oppositions, disclosure requirements

In US free trade agreements, a common provision not found in 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. The DR-CAFTA and Peru PTAs add other considerations for revocation, such as fraud, inequitable conduct or misrepresentation.[188] The agreement with Bahrain recognizes a similar principle but is more restrictive than, for example, the US-PTA with Peru, by stating that

> Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available prior to the grant of the patent.[189]

In the latter situation, the PTA goes into pure administrative issues by foreclosing the possibility of establishing, at the domestic level, a pre-grant opposition system. Thus in this case opposition could only take place after the grant of the patent.

A related question might arise as to whether parties may incorporate substantial requirements at the domestic level on the disclosure of origin of genetic resources and associated traditional knowledge (TK). The TRIPS Agreement is silent in this respect, providing only that applicants

> 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.[190]

As a matter of principle, TRIPS does not limit Members to place further conditions to the disclosure of inventions. As such, the disclosure of origin at the domestic level is, in principle, TRIPS compliant.[191] Those opposed to the disclosure of origin have argued in the Council for TRIPS that such requirement would add a further obligation to applicants and would not be TRIPS compliant.[192]

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[187] Bahrain-USA, Article 14.8.2.

[188] "Without prejudice to Article 5.A (3) of the Paris Convention, each Party shall provide that a patent may be revoked or nullified only on grounds that would have justified a refusal to grant the patent according to its laws. However, a Party may also provide that fraud, misrepresentation, or inequitable conduct may be the basis for revoking, nullifying, or holding a patent unenforceable." (Peru, Article 16.9.4).

[189] US-Bahrain, Article 14.8.4.

[190] Article 29,1, TRIPS

[191] For example, Swiss government has amended its patent law precisely to include such a requirement. (See Article 49 a II of the Swiss Patent Act as entered into force on 1 July 2008 (French language version available at http://www.admin.ch/ch/f/rs/232_14/).

[192]

Some have argued that in some PTAs -for example the agreements of the USA, respectively, with 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".[193] This assertion finds its basis in two provisions of the PTAs. The respective provisions in the agreement with Peru[194] state:

> 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.
>
> 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 provisions would inhibit the possibility of introducing disclosure requirements at the domestic level remains a matter of interpretation. But if this were their effect, as argued by some,[195] there would be large political ramifications, especially for a country like Peru that has been one of the main proponents of amending TRIPS to accommodate a disclosure requirement of origin to combat biopiracy and the misappropriation of TK and finally make TRIPS fully consistent with CBD.[196]

This consistency with CBD appears to have found its place in the recent agreement between the EC and the CARIFORUM countries. The Agreement recognizes that the patent provisions of the PTA and the Convention on Biological Diversity shall be implemented in a mutually supportive way. With respect to disclosure requirements the agreement provides

> The EC Party and the Signatory CARIFORUM States may require as part of the administrative requirements for a patent application concerning an invention which uses biological material as a necessary aspect of the invention, that the applicant identifies the sources of the biological material used by the applicant and described as part of the invention.[197]

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[193] Oxfam 2007: p.14).
[194] See Articles 16.9.9 and 16.9.19, USA-Peru. Similar provisions are found in USA-Morocco, see Articles 15.21.10 and 15.21.11.
[195] Footnote 197, supra.
[196] See Bridges Weekly, (2008), Where does TRIPS go from here?, Volume 12, Number 27, 7th August.
[197] EC-CARIFORUM, Article 150.4

## v. Side letters on the protection of traditional knowledge and biodiversity

Side letters have been included in agreements negotiated by the USA with Colombia[198] and Peru[199], respectively, recognizing "the potential contribution of traditional knowledge and biodiversity to cultural, economic, and social development". The side letters reaffirm the importance of obtaining prior informed consent and the equitable sharing of benefits as provided in the CBD even if the USA is not a Party to the latter Convention. The Parties also recognize the importance of promoting quality patent examination to ensure the conditions of patentability are satisfied. Furthermore, the side letters acknowledge the need for "best endeavors" with respect to seeking 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."

The side letters on biodiversity were at a point in time highlighted by the Andean negotiators as constituting a major success in the negotiating process because they received from the USA, for the first time, a formal recognition of the importance of preserving biodiversity and respecting TK. This apparent success responded to many criticisms made by civil society groups to the negotiations and the official stance held by Colombia and Peru that if concessions were to be made on IP, positive commitments would be made in exchange on biodiversity and TK.[200] In the case of Peru this was particularly important, because, as outlined above, the country has been an active advocate of the reform of TRIPS by incorporating a new provision into the Agreement (i.e. a proposed Article 29*bis*).

A critical point in the cited side letters appears to reaffirm the position taken by the USA in multilateral fora on this issue, namely a contract based approach should be favored for the protection of TK and genetic resources:

> 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.[201]

The EU appears to take an opposing approach on this matter.[202] This may be seen in the context of the EU's current efforts to secure developing countries' support for

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[198] See USTR at http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Colombia_FTA/Final_Text/asset_upload_file953_10182.pdf.

[199] See: http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Peru_TPA/Final_Texts/asset_upload_file719_9535.pdf.

[200] See *IP Standards in the US-Peru FTA: Health and Environment* and Manuel Ruiz, *The Not-So-Bad US–Peru Side Letter on Biodiversity*, both notes in BRIDGES, January-February 2006, pp. 17-19.

[201] In this sense, critics have questioned the merits of this kind of side agreement (von Braun 2008). See also Manuel Ruiz, op.cit, reflecting different views on this matter.

[202] In its EPA with CARIFORUM countries it is acknowledged: "Subject to their domestic legislation the EC Party and the Signatory CARIFORUM States respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles

increased protection of geographical indications at multilateral level, accompanied by corresponding concessions in the area of biodiversity.[203]

## *b. The PTAs and the issue of circumvention of technological measures in the digital environment*

### i. Copyright and the TRIPS and WIPO-Plus provisions

As alluded to, the PTAs have deepened the process of upward harmonization starting with TRIPS and impacting the evolution of the IP architecture in many respects. PTAs provisions on the protection and enforcement of copyright and related rights are quite rigorous and precise. One manifestation of this is the expansion of the duration of copyright and related rights by 20 years in addition to the 50 years, as generally established in TRIPS. Provisions like the following (USA – Bahrain) are common to the US PTAs:

> Each Party shall provide that, where the term of protection of a work (including a photographic work), performance, or phonogram is to be calculated:
>
> (a) on the basis of the life of a natural person, the term shall be not less than the life of the author and 70 years after the author's death; and
>
> (b) on a basis other than the life of a natural person, the term shall be
>
> (i) not less than 70 years from the end of the calendar year of the first authorized publication of the work, performance, or phonogram, or
>
> (ii) failing such authorized publication within 50 years from the creation of the work, performance or phonogram, not less than 70 years from the end of the calendar year of the creation of the work, performance, or phonogram.[204]

As far as the EU is concerned, its PTAs with developing countries contain no specific provision on the term of copyright protection, such as, for example, the latest agreement with CARIFORUM countries. However, the EU's stance in recent negotiations appears to favor an approach closer to the one put forward by the USA.[205]

The provisions on effective technological protection measures (TPMs) in US PTAs go beyond the WIPO "Internet treaties" of 1996 (the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty),[206] which state that Parties "shall provide adequate legal protection and effective legal remedies" against the circumvention of TPMs,[207] leaving it to each Party to decide the way in which it will

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relevant for the conservation and sustainable use of biological diversity and promote their wider application with the involvement and approval of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices." Article 150.1, EPA EC-CARIFORUM.

[203] See proposal TN/C/W/52 at the WTO Council for TRIPS by the EU and 110 other WTO Members.

[204] USA-Bahrein, Article 14.4.4.

[205] In negotiations with Andean countries, the EC has put forward the proposal that rights shall run for 70 years and calculated differently under various circumstances detailed in the text.

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[207] WCT, Article 11; WPPT, Article 18.

implement the provisions and whether it will apply civil and/or criminal sanctions to infringers. The WIPO Internet treaties are not incorporated in the TRIPS system and by themselves they are already a manifestation of a multilateral effort to go beyond the minimum requirements of TRIPS.

The US PTAs, in general, contain detailed rules aimed at providing adequate legal protection and effective legal remedies to fight against the circumvention of effective TPMs used by authors, performers and the producers of phonograms to protect their works, performances and phonograms protected by copyright and related rights.[208] In a common provision that can be found with minor variations in all PTAs signed with the USA, Parties are committed to provide for a detailed system of protection from circumvention that practically exports the US domestic law into the domestic legislation of US partners. Box 5 reproduces, for illustrative purposes, a provision commonly found in US PTAs. In addition, the PTAs provide for the obligation to make available adequate and effective legal remedies to protect rights management information.[209]

[208] "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), PTA US-Chile.

[209] According to the PTA with Peru, -almost identical in all respective provisions of PTAs- rights management information means: (i) information that identifies a work, performance, or phonogram; the author of the work, the performer of the performance, or the producer of the phonogram; or the owner of any right in the work, performance, or phonogram; (ii) information about the terms and conditions of the use of the work, performance, or phonogram; or (iii) any numbers or codes that represent such information, when any of these items is attached to a copy of the work, performance, or phonogram or appears in connection with the communication or making available of a work, performance, or phonogram, to the public. (Article 16.7.5 (c))

**Box 5: Antcircumvention provisions**

15.7. (a) In order to provide adequate legal protection and effective legal remedies against the circumvention of effective technological measures that authors, performers, and producers of phonograms use in connection with the exercise of their rights and that restrict unauthorized acts in respect of their works, performances, and phonograms, each Party shall 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; or

(ii) manufactures, imports, distributes, offers to the public, provides, or otherwise traffics 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 and subject to the remedies provided for in Article 15.11.14. Each Party shall provide for criminal procedures and penalties to be applied when any person, other than a nonprofit library, archive, educational institution, or public non-commercial broadcasting entity, is found to have engaged willfully and for purposes of commercial advantage or private financial gain in any of the foregoing activities.

(b) […]

(c) Each Party shall provide that a violation of a measure implementing this paragraph is a separate civil cause of action or criminal offense, independent of any infringement that might occur under the Party's law on copyright and related rights.

(d) Each Party shall confine exceptions to any measures implementing the prohibition in subparagraph (a)(ii) on technology, products, services, or devices that circumvent effective technological measures that control access to, and, in the case of clause (i), that protect any of the exclusive rights of copyright or related rights in, a protected work, performance, or phonogram referred to in subparagraph (a)(ii), to the following activities, provided that they do not impair the adequacy of legal protection or the effectiveness of legal remedies against the circumvention of effective technological measures:

(i) noninfringing reverse engineering activities with regard to a lawfully obtained copy of a computer program, carried out in good faith with respect to particular elements of that computer program that have not been readily available to the person engaged in those activities, for the sole purpose of achieving interoperability of an independently created computer program with other programs;

(ii) noninfringing good faith activities, carried out by an appropriately qualified researcher who has lawfully obtained a copy, unfixed performance or display of a work, performance, or phonogram, and who has made a good faith effort

to obtain authorization for such activities, to the extent necessary for the sole purpose of identifying and analyzing flaws and vulnerabilities of technologies for scrambling and descrambling of information;

(iii) the inclusion of a component or part for the sole purpose of preventing the access of minors to inappropriate on-line content in a technology, product, service, or device that itself is not prohibited under the measures implementing subparagraph (a)(ii); and

(iv) noninfringing good faith activities that are authorized by the owner of a computer, computer system, or computer network for the sole purpose of testing, investigating, or correcting the security of that computer, computer system, or computer network.

(e) Each Party shall confine exceptions to any measures implementing the prohibition referred to in subparagraph (a)(i) to the activities listed in subparagraph (d) and the following activities, provided that they do not impair the adequacy of legal protection or the effectiveness of legal remedies against the circumvention of effective technological measures:

(i) access by a nonprofit library, archive, or educational institution to a work, performance, or phonogram, not otherwise available to it, for the sole purpose of making acquisition decisions;

(ii) noninfringing activities for the sole purpose of identifying and disabling a capability to carry out undisclosed collection or dissemination of personally identifying information reflecting the on-line activities of a natural person in a way that has no other effect on the ability of any person to gain access to any work; and

(iii) noninfringing uses of a work, performance, or phonogram, in a particular class of works, performances, or phonograms, when an actual or likely adverse impact on those noninfringing uses is demonstrated in a legislative or administrative proceeding by substantial evidence; provided that in order for any such exception to remain in effect for more than four years, a Party must conduct a review before the expiration of the four-year period and at intervals of at least every four years thereafter, pursuant to which it is demonstrated in such a proceeding by substantial evidence that there is a continuing actual or likely adverse impact on the particular noninfringing use.

(f) Each Party may provide exceptions to any measures implementing the prohibitions referred to in subparagraph (a) for lawfully authorized activities carried out by government employees, agents, or contractors for law enforcement, intelligence, essential security, or similar governmental purposes.

(g) **Effective technological measure** means any technology, device, or component that, in the normal course of its operation, controls access to a protected work, performance, phonogram, or other protected subject matter, or protects any copyright or any rights related to copyright.[210]

The terminology of the TPM provisions found in the PTAs draws from the controversial US Digital Millennium Copyright Act (DMCA),[211] which was "nominally

[210] Article 15.7 of the United States – CAFTA/DR PTA. Similar provisions are included in other US PTAs see, for example, Article 16.7 of the United States – Peru PTA and Article 14.4.7, USA-Bahrein.
[211] USC. Title 17 § 1201.

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."[212] 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 and offering to the public of devices, products or components that serve the purpose of circumventing TPMs that control access and the exclusive rights in a work or phonogram.[213]

Both the prohibition to circumvent TPMs and the prohibition to produce and distribute circumvention tools do not apply to a number of public interest institutions (nonprofit libraries, archives, educational institutions, or public non-commercial broadcasting entities) and are subject to some exceptions. Despite these exceptions, it has been observed that the DMCA, while providing protection to digital content, has gone far beyond what is necessary in this regard and is causing avoidable "collateral harm" by imposing, *inter alia*: undue restrictions of fair and other legitimate uses of digital content; unnecessary obstacles to competition within the content industry; and inappropriate obstacles to competition in the market for TPMs.[214]

Provisions like the one in the United States–CAFTA/DR free trade agreement (see Box 5) exempt certain stakeholders from copyright infringement liability, but do not include private parties making copies for their private use only. To the contrary, liability is provided for those engaged in TPM circumvention or the trafficking in circumvention tools *inter alia* for "private financial gain". This could arguably encompass private copies, which in the non-digital area are in many countries' laws considered as falling under a private use or fair use exception.[215]

In addition, paragraphs (d)(i), (ii) of the provision reproduced in Box 5 limit the legality of reverse engineering of software in the TPM context to activities related to the achievement of computer program-to-program interoperability and identifying software bugs.[216] Comparable provisions in the DMCA have been criticized in the literature for not covering all legitimate purposes of reverse engineering of software.[217]

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[212] (Lemley et al. 2000: p.89)

[213] "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).

[214] See Pamela Samuelson/Susan Scotchmer, « The Law & Economics of Reverse Engineering », version of 4 December 2001, p. 57 (hereinafter Samuelson/Scotchmer; available at http://www.dklevine.com/archive/scotchmer-reverse.pdf).

[215] See, e.g., § 53(1) of the German Copyright Act (Urheberrechtsgesetz).

[216] Note that TPMs consist of software, the reverse engineering of which is necessary to circumvent it and to understand its functioning.

[217] For instance, reverse-engineering activities carried out to develop interoperability between computer programs and certain hardware or data would not benefit from the exemption under paragraph (d)(i) of the cited provision (Samuelson/Scotchmer with respect to the DMCA (p. 55, footnote 288). This could have anti-competitive effects in the entertainment industry by blocking competitors' efforts to break up "locked in" systems of content (on a DVD or CD) and certain players. "Lock in" effects occur in information and communication technologies (ICTs), to the extent the copyright owner exercises *de facto* control over certain technological standards. ICTs are often

Furthermore, the quoted model provision limits reverse engineering to issues of interoperability; reverse engineering may, however, also be required to understand the idea behind the software with a view to designing a better software product, outside the context of interoperability.

Finally, the anti-circumvention rules contained in PTAs and the DMCA are stricter than under the WIPO, WCT and WPPT. Free trade agreements prohibit the circumvention of TPMs in case of acts that are not authorized by the rights holders. By contrast, the WCT and the WPPT provide Parties the freedom to allow circumvention of TPMs in cases where the act in question is permitted under a Party's domestic law.[218] This may include cases where use of copyrighted material is authorized under fair/private use provisions and cases of reverse engineering exceptions for software that go much further than the model provision used in this analysis.

In addition to these effects generated by the anti-circumvention rule (paragraph 15. 7(a)(i), as quoted in Box 5), the rule against production and dissemination of circumvention tools (paragraph 15.7(a)(ii)) has been criticized in the DMCA context for generating anti-competitive effects in the market for TPMs.[219]

In the literature, it has therefore been suggested that the prohibition of disseminating anti-circumvention tools to the public should be maintained (in order to prevent mass copying of content), but that the ban on the manufacture of circumvention tools should be lifted in a purely private context.[220] This approach would arguably enable interested experts and researchers to reverse engineer existing TPMs and develop more performing ones, while barring the general public from the use of circumvention tools. Due to the use of improved TPM technology, the threat of criminal sanctions would no longer be required. On the other hand, researchers would be able to

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characterized by their interdependence with other ICTs, and a corresponding disincentive for consumers to change from the ICT initially chosen to an alternative product, which would require additional investment in alternative compatible parts. See Gustavo Ghidini, INTELLECTUAL PROPERTY AND COMPETITION LAW: THE INNOVATION NEXUS, Edward Elgar Publishing, 2006, p. 105). An example is the development of interlocked systems between copyrighted content on DVDs or CDs and their players. Content and players are combined through the use of TPMs, such as digital watermarks on CDs, which must be detected by corresponding software in the player before it can be listened to, and which will only respond to players made by the producer of copyrighted sound recordings (Samuelson/Scotchmer, p. 63). To the extent that DVDs are considered as consisting of data (rather than constituting a computer program), the above provision would not justify the decompilation of the TPM software protecting the DVD with a view to achieving interoperability with an alternative player (Samuelson/Scotchmer in footnote 325 (p. 63) refer to the decision by a US court not to apply the DMCA reverse engineering exception to DVDs, based on the argument that DVDs are not programs, but data: *Universal City Studios, Inc. v. Reimerdes*, 82 F. Supp.2d 211, 217-18 (S.D.N.Y. 2000)).

[218] See Article 11 of the WCT and Article 18 of the WPPT.

[219] Samuelson/Scotchmer, p. 64. TPMs in general consist of software, and the development of competing and more performing TPMs may potentially constitute an important market. However, this market to some extent depends on researchers' possibilities to understand the original TPMs through reverse engineering. The prohibition to manufacture any circumvention tools, however, makes such reverse engineering very difficult. In addition, the obligation to introduce criminal sanctions for the manufacture of circumvention tools adds another barrier to effective competition in the TPM market.

[220] Ibid., p. 57.

exchange ideas about the quality of certain technical measures and would be rewarded for promoting competition in a thriving technology market, rather than being punished.[221]

The incidence of these anti-circumvention and anti-tool making provisions in PTAs 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. [222]

In order to overcome some of the difficulties posed by the PTAs to the legitimate use of traditional copyright exceptions and fair use norms, a number of proposals have been advanced in the literature, such as the development of "smart DRM" (digital rights management) technologies with the inbuilt capacity to recognize and accommodate traditional copyright exceptions, and the negotiation of an international agreement restricting the use of DRMs in cases where digital objects carry a high proportion of public interest-relevant information.[223] Another proposal focuses on remedial action to be taken by domestic courts when dealing with anti-circumvention provisions.[224]

### ii. The unintended consequences

Historically, IP systems have been constructed around the need for public policies in terms of exclusive rights to secure and reward innovators and creators for their contributions to society. Society prospers, culturally and economically, through innovation and the creation of new ideas.[225] Implicit in this conception is that the exclusive rights granted to authors and innovators should be premised on the encouragement of future authors and innovators to use those contributions to further technological and cultural progress.[226] Thus, the dissemination of knowledge has

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[221] Ibid., p. 64.
[222] (Okediji 2004: p.24).
[223] (Jaszi 2004).
[224] Depending on the domestic design of anti-circumvention regimes, courts should, according to this suggestion, enable information users to notify copyright owners of their intent to make public good uses of technologically protected copyrighted works, triggering the rights owners' responsibility to take down the TPMs or otherwise make lawful uses possible (Reichman, Dinwoodie & Samuelson 2007).
[225] 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”. US Constitution, Article 1, Section 8, Clause 8.
[226] (Jaszi 2004: p. 2,3).

been at the heart of the IP system. This was well captured in the TRIPS Agreement as part of its objectives and principles:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[227]

Accordingly, the IP system should contribute to the dissemination of knowledge and to improved forms of transfer of technology. Access and dissemination of knowledge could thus be considered as the quid pro quo in exchange of the exclusive rights accorded to authors and innovators in general. However, one could question whether the bargain between society at large -benefiting from the knowledge produced and disseminated by IP- and the right holders -extracting rents from their time-limited monopoly- is indeed being promoted by PTAs initiatives such as the ones analyzed under this section; considerations that might probably apply to other parts of the IP chapters under analysis.

Society is highly dependent on the dissemination of knowledge goods. For example, the activities of researchers, follow-on entrepreneurs, software developers, libraries, educational institutions, publishers and media rely heavily on a robust public domain and on the delimitation of the boundaries of exclusive property rights through the establishment of exceptions to and limitations of those rights. In this respect, overprotection as implied in the PTAs may reduce the scope of the public domain. For example, limiting the use of exceptions and limitations, restricting possibilities for reverse engineering of software, and the extensive use of digital TPMs combined with criminal sanctions for their circumvention, although useful to protect works, may also have unintended consequences.[228]

One important assumption of the IP system is that once the exclusive temporal rights of authors and inventors expire, they fall into the public domain. The process of expanding these rights and the continuing extension of their duration, either by unilateral action of States or under the influence of the PTAs, beyond the minimum required by TRIPS, could have adverse effects on the public domain and follow-on innovation.

Additionally, the system is constructed on the premise that certain things are not protected because the burden on society would be too heavy and general access to the respective subject matter should be provided at all times. The boundaries of protection are defined by the scope of protection, protected subject matter and rights granted. For example, according to TRIPS in the case of copyright, the scope “shall extend to expressions and not to ideas, procedures, methods of operation or

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[227] Article 7.

[228] It has been thus argued that the proliferation of exclusive rights could raise fundamental roadblocks for the national and global provision of public goods, including scientific research, education, health care, biodiversity and environmental protection (Maskus & Reichman, 2004: p. 7).

mathematical concepts as such".[229] For example, the restriction of reverse engineering of software arguably interferes with this fundamental principle.[230]

## *c. Preferential trade agreements: the settlement of IP-related disputes and enforcement issues*

### i. Settlement of disputes

PTAs - both of the EC and the USA- contain specific dispute settlement chapters. They provide for consultations and mediation as first steps of dispute avoidance.[231] In case the Parties fail to resolve the dispute by such means, all PTAs provide for the establishment of an arbitration panel to render a binding decision, including on the compliance with the arbitration ruling.[232]

Apart from this general framework, there are a number of differences between the US and EC-sponsored PTAs. The EC – CARIFORUM agreement expressly states that arbitration bodies set up under that agreement shall not adjudicate on rights and obligations under the WTO Agreement.[233] By contrast, the US-sponsored PTAs allow the Parties to choose the forum in which a dispute should be settled when a matter arises under the PTAs or under another trade agreement (i.e., the WTO) to which they are parties. The complaining Party has the right to choose the forum. In that case, the selected forum shall be used to the exclusion of the others.[234]

Another important difference relates to the scope of application of the dispute settlement mechanism. While the EC – CARIFORUM PTA limits the reasons for invoking binding arbitration to alleged breaches of the agreements,[235] the US-

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[229] TRIPS, Article 9.2.

[230] Anybody has the right to read a copyrighted book to find out more about the idea behind that work and then express the same idea differently. In the same way, reverse engineering of software serves the purpose of finding out about the (non-copyrightable) idea behind a computer program, thus enabling the independent expression of that idea through new software. Excluding reverse engineering for the purpose of creating competing software, for example, may thus be considered as preventing legitimate uses of non-copyrightable ideas. In the case of patents, scientific theories or discoveries are ineligible for protection in many countries, unless they are used in the context of a concrete technical application. Even then, certain requirements of novelty, inventive step, and industrial applicability must be fulfilled in order to benefit from the minimum statutory 20 years of protection. In the case of trademarks, certain words may never be protected (generic terms), while descriptive terms may not be protected, unless a secondary meaning can be proven. In the case of the protection of undisclosed information, TRIPS provides for the protection against unfair commercial use of investments made on test data required for approving the marketing of pharmaceutical and agricultural chemical products, but only if a "considerable effort" has been made (Roffe & Santa Cruz 2007).

[231] See, e.g., Articles 204, 205 of the EC – CARIFORUM PTA; and Articles 21.4, 21.5 of the US – Peru PTA.

[232] See Articles 206-214 of the EC – CARIFORUM PTA; and Articles 21.6-21.18 of the US – Peru PTA.

[233] See Article 222.1, EC- CARIFORUM. Paragraph 2 specifies that recourse to the dispute settlement system under the PTA does not affect Parties' rights to invoke the WTO dispute settlement system. While a case is pending under either the PTA or the WTO dispute settlement system, the other system may not be invoked at the same time.

[234] See, for example, Article 21.3 of the USA – Peru.

[235] Article 206.2, EC – CARIFORUM.

sponsored PTAs are much wider in scope. They allow for the possibility that the Parties may bring cases related to: a) the alleged inconsistency of an actual or proposed measure by the other Party with the obligations arising under the PTA; b) other situations of alleged failures by the other Party to carry out its obligations under the PTA; and c) cases when a Party believes that a PTA-consistent measure of the other Party causes nullification or impairment of its (i.e. the claimant's) reasonable expectations, inter alia in the area of IPRs.[236] Thus, the US PTAs allow the Parties to bring not only cases that address inconsistencies with the obligations of the Parties, but also cases described in the WTO system as non-violation and situation complaints.[237]

Affected parties bringing non-violation cases might eventually argue, in the case of IP, that certain public policies restricting market access of protected products deprive rights holders of certain expectations arising from the substantive rules in the PTAs. For example, the recourse of price controls, particularly in the area of pharmaceutical products, could be considered as impairing marketing expectations on the part of foreign patent holders. Also, the use by governments of flexibilities, such as the grant of a compulsory license or the narrow design of patentability criteria, might trigger the recourse to non-violation complaints. This could be extended, in theory, to public policy choices pursued through internal taxes, packaging and labeling requirements, consumer protection rules and environmental standards that might be perceived as causing nullification or impairment.

In the case of TRIPS and in the current state of play in WTO, non-violation complaints enjoy a factual moratorium in the sense that they are not fully operational.[238] The PTAs, as suggested, in a clear manifestation of their intrusion in multilateral processes make operational this type of situations in the context of their settlement of disputes mechanisms.

Finally, with regards to remedies in cases of non-compliance with the arbitration panel's decision, both the US and the EC in the case of CARIFORUM authorize the suspension of trade concessions.[239] The EC makes an exception in cases of disputes with respect to the environment and on social aspects, and is generally obliged to exercise "due restraint in asking for compensation" or suspending trade concessions.[240]

### ii. Enforcement measures

One important feature of US agreements as compared to European ones, has been their strong articulation of enforcement measures. The European approach has drastically changed in recent years and their new model, as discussed here, resembles in many respects the approach taken by the USA. However, recent

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[236] See, for example, Article 21.2.1 of the US – Peru PTA. For a more detailed discussion of non-violation complaints under the Chile-USA PTA, see Roffe (2004), pages 47/48.
[237] See RESOURCE BOOK, op.cit., p. 680.
[238] Ibid., pp. 673-676, with an overview of various interpretations. In the February 2009 meeting of the Council for TRIPS, Members agreed on further consultations in this regard.
[239] See, e.g., Article 21.16 of the US – Peru PTA; Article 213.2 of the EC – CARIFORUM PTA.
[240] Ibid., Article 213.1 and 2.

developments in the EU suggest an even more ambitious and drastic approach to enforcement issues.[241] These trends, in general, reflect the new enforcement agenda[242] led at the international level by these same countries with a clear expression of the efforts being made to adopt an Anti Counterfeiting Agreement (ACTA).[243]

In general, the enforcement provisions of the PTAs negotiated with the USA follow the same structure as the TRIPS Agreement. Accordingly, they contain provisions dealing with General Obligations; Civil and Administrative Procedures; Provisional Measures; Border Measures; and Criminal Procedures. For the USA, probably the most important achievement in this area has been to make mandatory many of the discretionary remedies included under TRIPS.[244] An important novelty of the PTAs, as far as TRIPS and the WIPO Internet Treaties are concerned, is that they provide for "Limitations on Liability of Internet Service Providers".

Inspired by TRIPS, the PTAs provide that there is no need to create a special enforcement system for IPRs, distinct from the one that exists for law enforcement in general. There is neither an obligation to assign special resources for the enforcement of IPRs, different from that for the law in general, but this shall not excuse a Party from compliance with the provisions on enforcement of the PTA. This principle is reflected in a common provision found in all recent PTAs stating:

> This Article does not create for the Parties any obligation:
>
> (a) to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general; or
>
> (b) with respect to the distribution of resources for enforcement of intellectual property rights and the enforcement of law in general.
>
> The Parties understand that a decision that a Party makes on the distribution of enforcement resources shall not be a reason for not complying with the provisions of this Chapter. [245]

Among the general provisions on enforcement, PTAs provide for one important legal copyright presumption:

> In civil, administrative, and criminal proceedings involving copyright or related rights, each Party shall provide for a presumption that, in the absence of proof to the contrary, the person whose name is indicated in the usual manner is the right holder in the work, performance, or phonogram as designated. Each Party shall also provide for a presumption that, in the absence of proof to the contrary, the copyright or related right subsists in

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[241] Seuba

[242] See ICTSD, Correa et

[243] See Susan Sell, THE GLOBAL IP UPWARD RATCHET, ANTI-COUNTERFEITINGAND PIRACY ENFORCEMENT EFFORTS: THE STATE OF PLAY, 2008, available at http://www.iqsensato.org/wp-content/uploads/Sell_IP_Enforcement_State_of_Play-OPs_1_June_2008.pdf

[244] Note for example the IFAC-3 Chile Report (2003) stating (p.17) that the agreement makes some "significant advances" towards deterring further infringements, and clarifies and builds upon existing TRIPS standards. Cited in Roffe (2004)

[245] See Article 17.11.2 (b) PTA with Chile and Article 16.11.4, PTA with Peru.

such subject matter.[246]

Under this provision, all works bearing a name in a usual manner should be considered protected (copyrighted), except for subject matter that evidently has fallen into the public domain. In other words, the burden of proof of demonstrating that a work is not protected falls on the general public that uses original works and not on the author. Thus, under this provision the burden of proof regarding infringement or lack of infringement is reversed, falling on the defendant.[247]
The PTAs further provide that damages should be paid by the infringer to compensate for the injuries suffered by the right holder,[248] without qualifying the nature of the infringement. The equivalent provision in the TRIPS Agreement[249] limits damages to a contravention of the rights by an infringer who "knowingly, or with reasonable grounds to know, engaged in infringing activity". Therefore, innocent infringement according to TRIPS may be excluded; however, it is not apparent whether that possibility is open in the PTAs.

As far as border measures are concerned, the PTAs once again go beyond TRIPS, particularly in one aspect. The latter Agreement provides for border measures, including ex officio actions, -under some conditions-[250] only for the importation of counterfeit trademarks or pirated goods. The application of border measures to goods being exported and to goods in transit[251] is optional. The PTAs are again TRIPS-plus in the sense that they provide for ex officio measures for goods being imported, as well as for those destined for export or moving in transit.[252] Border measures also appear to be an important feature of recent PTAs signed by the EC. But, as suggested earlier, the recent EPA signed with CARIFORUM appears to go even beyond the agreements sponsored by the USA. The latter PTAs stick to the minimum standard of TRIPS in the sense that border measures apply to counterfeit trademark or pirated copyright goods. In the case of CARIFORUM, border measures apply in general to 'goods infringing an intellectual property right', a concept that embraces a wide range of IPRs including designs and geographical indications and patents. CARIFORUM States agree also "to collaborate to expand the scope of this definition to cover goods infringing all intellectual property rights." The idea of expanding IPRs covered by border measures appears to be a recent feature of the proposals made in the negotiations initiated by the EC with Andean countries and India.[253]

Box 6 compares the border measure provisions found in a typical US PTA with the recent EC-CARIFORUM partnership agreement. As noted in the Box, the US PTAs

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[246] USA-Peru, Article 16.11.5. Identical provision to be found in CAFTA-DR, Article 15.11.5
[247] Chile-USA, Article 17.11.6(b).
[248] In a similar provision in the PTA with Chile, Parties, however, are free to provide that the presumption will only be valid on two conditions: that the work appears on its face to be original and that it bears a publication date not more than 70 years prior to the date of the alleged infringement. The 70 years from publication term is the equivalent to the term of protection granted to legal persons. See, USA-Chile, Article 17.11.8(a)
[249] Article 45.1, TRIPS.
[250] See Article 58, TRIPS.
[251] Footnote 13,TRIPS.
[252] See Article 16.11.23, USA-Peru.
[253] Seuba

provide for a clear authority to exercise legal action, ex officio, without the need for a formal complaint to initiate border measures with respect to imported, exported, or in transit merchandise.[254]

[254] See, for example USA-Peru, Article 16.11.11.

**Box 6: Comparing USA and EC approaches to border measures**

| *USA-Bahrain: Article 14.10*<br>*Special Requirements Related to Border Measures* | EC-CARIFORUM: Article 163<br>Border Measures |
|---|---|
| 20. Each Party shall provide that any right holder initiating procedures for suspension by its competent authorities of the release of suspected counterfeit or confusingly similar trademark goods, or pirated copyright goods* into free circulation is required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is *prima facie* an infringement of the right holder's intellectual property right and to supply sufficient information that may reasonably be expected to be within the right holder's knowledge to make the suspected goods reasonably recognizable by its competent authorities. The requirement to provide sufficient information shall not unreasonably deter recourse to these procedures. Each Party shall provide that the application to suspend the release of goods shall remain in force for a period of not less than one year from the date of application, or the period that the good is protected by copyright or the relevant trademark registration is valid, whichever is shorter.<br>21. Each Party shall provide that its competent authorities have the authority to require an applicant to provide a reasonable security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Each Party shall provide that such security or equivalent assurance shall not unreasonably deter recourse to these procedures. Each Party may provide that such security may be in the form of a bond conditioned to hold the importer or owner of the imported merchandise harmless from any loss or damage resulting from any suspension of the release of goods in the event the competent authorities determine that the article is not an infringing copy.<br>22. Where its competent authorities have made a determination that goods are counterfeit or pirated, each Party shall grant its competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer, and the consignee, and of the quantity of the goods in question.<br>23. Each Party shall provide that its competent authorities may initiate border measures *ex officio*, with respect to imported, exported, or in transit merchandise, without the need for a formal complaint from a private party or right holder. | 1. The EC Party and the Signatory CARIFORUM States shall, unless otherwise provided for in this Section, adopt procedures** to enable a right holder, who has valid grounds for suspecting that the importation, exportation, re-exportation, entry or exit of the customs territory, placement under a suspensive procedure or placement under a customs free zone or a customs free warehouse of goods infringing an intellectual property right*** may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation or the retention of such goods.<br>2. The provisions of Articles 52 to 60 of the TRIPS Agreement shall be applicable. Any rights or duties established under such provisions concerning the importer shall be also applicable to the exporter or to the holder of the goods. |

| | |
|---|---|
| 24. Each Party shall provide that goods that have been determined to be pirated or counterfeit by the competent authorities shall be destroyed, except in exceptional cases. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of the goods into the channels of commerce. In no event shall the competent authorities be authorized to permit the exportation of counterfeit or pirated goods, nor shall they be authorized to permit such goods to be subject to other customs procedures, except in exceptional circumstances.<br>25. Where an application fee or merchandise storage fee is assessed, each Party shall provide that such fee shall not be set at an amount that unreasonably deters recourse to these procedures | |

Furthermore, the PTAs expand the provisions in TRIPS on criminal measures. According to the latter, for example, criminal measures apply to cases of willful trademark counterfeiting or copyright piracy on a commercial scale. The PTAs go beyond TRIPS in that they broaden the scope of what is considered a willful infringement on a commercial scale:

> Each Party shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale. Willful copyright or related rights piracy on a commercial scale includes:
>
> significant willful copyright or related rights infringements that have no direct or indirect motivation of financial gain;
>
> willful infringements for purposes of commercial advantage or private financial gain.
>
> Each Party shall treat willful importation or exportation of counterfeit or pirated goods as unlawful activities subject to criminal penalties to the same extent as the trafficking or distribution of such goods in domestic commerce.[255]

This obligation disregards the quantitative "commercial scale" requirement in TRIPS and replaces it with the notion of a "commercial advantage or financial gain" element, which focuses more on the purpose of the infringement, even if it is not made at a commercial scale. Other examples of provisions that go beyond TRIPS deal with criminal procedure, specifically the detailed rules on seizure, forfeiture and destruction of infringing goods and elements used in the infringements.[256]

As noted, the PTAs include specific rules on liability of and limitation of the liability of services providers (ISPs) for infringing content that is transmitted or stored in their

[255] USA-Peru, Article 16.11.26
[256] See for example, USA-Peru, Article 16.11.17

networks when they perform certain functions, such as hosting, caching or linking. The rules include legal incentives for service providers to cooperate with copyright owners in deterring the unauthorized storage and transmission of copyrighted materials; and with respect to limitations in domestic law regarding the scope of remedies available against service providers for copyright infringements that they do not control, initiate or direct, and that take place through systems or networks controlled or operated by them or on their behalf.[257]

Finally, it should be noted that while the above considerations apply mostly to PTAs signed with the USA, the EC, as shown in the case of CARIFORUM, has recently stepped up bilateral efforts to strengthen IP enforcement in third country trading partners. In the context of its negotiations with the ACP states on follow-up agreements ("European Partnership Agreements", EPAs) to the Cotonou Agreement, the EU has made a number of proposals related to new provisions on IPRs in the ACP region. The CARIFORUM agreement is the first in a series of agreements under negotiations with ACP countries. Overall, concern has been voiced regarding a "one-size-fits-all" approach by the proposals related to enforcement, without due regard to different levels of development of partner countries.[258] Negotiating proposals in the cases of free trade agreements with Colombia, India and Peru are also characterized by their expansive nature, as they go even beyond the US model outlined here.

## *III. Conclusions*

### A. General trends

The chapter has reviewed recent developments since the adoption of the TRIPS Agreement that by itself represented a major shift in the evolution of the international IP architecture. TRIPS recognized that Members shall not be obliged to implement in their law more extensive protection than is required by the Agreement, and that such protection shall not contravene the provisions of TRIPS. This is, in essence, the embodiment of the principle of minimum standards. PTAs, characterized in general as instruments that go beyond the TRIPS Agreement, are a legitimate consequence of TRIPS. They have meant in practice a major expansion of those minimum standards with important consequences in a number of areas such as those reviewed here, mainly access to medicines, genetic resources, copyright issues regarding the shrinking of the public domain and settlement of disputes and enforcement issues.

Overall, this chapter has shown that with respect to the policy areas reviewed, the PTAs have shifted the balance in favor of private rights holders. The impact generated through PTAs in reducing access to essential products, such as medicines or educational material, narrowing down the public domain of essential information needed for the development of technological capacities, creative works, and further reducing a pro-competitive environment should be a source of concern and a major challenge to policy makers, especially, but not only, in developing countries. To

[257] See, for example, Article 17.11.29 (US-Australia FTA), Article 16.9.22 (US-Singapore FTA) and Article 15.11.27, CAFTA.
[258] See Musungu 2008

restore the necessary balance between producers and consumers of IPRs, policy makers need to become aware of and make use of the flexibilities that have remained in place, for example through the application of strict patentability criteria or the innovative and constructive implementation of PTAs into national laws. Proposals in the literature illustrate the potential to accommodate public interest concerns even within the most delicate legislative framework. Policy makers universally, not just in developing countries, should seek to identify common interest denominators, based on the understanding that for the promotion of innovation, there is an optimal level of IP protection, beyond which ever-increasing exclusive rights will prove counterproductive to society at large.[259]

In brief, despite its importance for technological innovation and cultural progress, the public domain has been seriously affected by an expansion of private rights, both under the TRIPS Agreement and even more so under the new generation of PTAs. It has been observed in the literature that a fundamental tension is emerging "between the public purposes of intellectual property and the tendency toward the commodification (and attendant rationing) of more and more forms of basic information."[260] This tendency has been supported by the belief in many countries that stronger exclusive rights will necessarily yield higher levels of creativity and innovation, despite the lack of concrete empirical evidence in this regard.[261] Taken together, these trends have upset the balance between private rights and the free dissemination of knowledge.

## B. Comparing US PTAs and European ones

The chapter has focused its analysis on a number of PTAs subscribed principally by developing countries with both the USA and the European Union (See Table 1). The USA has shown since the adoption of the TRIPS Agreement a consistent policy of expanding the minimum standards of TRIPS via a number of free trade agreements. NAFTA was the first of those agreements building on the notion of the minimum standards of TRIPS. This expansion, as reviewed in this paper, has a number of manifestations in almost all areas covered by TRIPS but more significantly on three aspects: the protection of pharmaceutical products, copyright issues in the digital environment and a very strong enforcement agenda. The European agreements in their first expressions (e.g. the agreements with South Africa, Chile and Mexico) show a less incremental nature of commitments compared to the US PTAs. They were limited to some general principles reinstating the importance of TRIPS, the adherence to a number of international treaties administered by WIPO (see Box 2) and especial regulations regarding geographical indications for wines and spirits. More recently, the European agreements have become more intrusive and similar in approach to the ones negotiated by the USA. A major shift in European EPAs is manifested in the agreement finalized with the CARIFORUM countries in 2008 and in negotiations taking place at the time of writing with countries with former colonial association with European countries and with Colombia, Peru and India. The most

[259] See, for example, the Swiss Patent Office's new approach to the innovation - protection interface, as illustrated by Thumm (2006).
[260] (Jaszi 2004: p.2).
[261] Boyle.

notable feature of the new generation of agreements is their more aggressive agenda in the same area covered by the US PTAs.

The chapter has also highlighted that in the case of the USA, recent agreements also represent an interesting shift in emphasis with respect to pharmaceutical products. The latest PTAs provide clarifications on a number of ambiguous aspects of the earlier free trade agreements still in force in a number of countries. The revised model leaves space for innovative implementation as they emphasize public health related flexibilities much more clearly than did the original texts negotiated by the same countries with the USA. From a political economy point of view, it is interesting to note that these changes were the result of an agreement in the US Congress and not the consequence of the bargaining process with the interested countries. Notwithstanding the relevance of this recent shift, important questions remain open regarding the actual implementation of the model at the domestic level and the effects of those changes in third countries that have already signed PTAs with the USA.

In any case, both of the approaches -followed by the USA and the EC, respectively- pursue the same main objective of affecting major changes in the laws of developing countries that as consequence of the MFN principle would result in benefits to right holders from any third WTO Member operating in a country signatory of a PTA.

## C. PTAs and the international IP architecture

The PTAs take advantage not only of the minimum standard principle but of the gaps and ambiguities of the TRIPS Agreement. One important premise of the TRIPS Agreement is the desire "to reduce distortions and impediments to international trade, and … the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."[262] But, also the "underlying public policy objectives of national systems… including developmental and technological objectives".[263] TRIPS emphasizes that IPRs are private rights[264] buttressed by a strong system of enforcement where public authorities are called to play a major role. In a major disjunction with its trade character, the Agreement does not take a position on parallel trade leaving it to each Member to decide on its own system of exhaustion of IPRs.[265]

With respect to ambiguous compromises or simply gaps in TRIPS, such as in the cases of undisclosed information particularly on test data, protection of plants and animals, non-violation complaints, technological protection measures and management rights and enforcement issues, the PTAs expand and elaborate further on all these questions.

To fully grasp the significance of PTAs and their impact on the international system, it might be useful to have a glance at those developing countries that have signed PTAs respectively with the USA and European countries (See Table 1). In general,

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[262] See Preambular paragraph, TRIPS Agreement.
[263] See Preamble, TRIPS and its objectives (Article 7) and principles (Articles 8).
[264] Ditto
[265] See Rochelle

they are countries with small markets, unlike the fully-fledged participants in the IP international law making process. For example, countries such as Argentina, Brazil, and India have not signed PTAs with strong IP chapters at the time of writing, with the notable exception of the ongoing EU – India PTA negotiations. The question to be raised is that under those circumstances what is the impact of PTAs in the international system?[266]

As noted, the PTAs are a legitimate creature of TRIPS, taking full advantage of the ambiguities and gaps of the latter. They constitute a major contribution to the expansion of the IP international architecture, not only in terms of adherence by new members of an important number of international treaties such as the PCT, the Budapest treaty, UPOV (1991); but, also by rendering mandatory a number of simple recommendations made in WIPO on issues such as well-know marks that become binding instruments in the context of the PTAs (see Box 2, supra). On questions such as non-violation complaints, stricter enforcement measures, expansion of copyright protection particularly in the digital environment (duration, technological protection measures, rights management information) and undisclosed information, the PTAs reflect a new set of norms and standards that build on the TRIPS Agreement, enlarge its scope and set precedents on its future evolution. One of the most notable cases is the "importation" of foreign schemes of protection in the case, examined at length here, of the protection of clinical test data. The PTAs have been the channel to export clinical test data exclusivity regimes from developed to developing countries.[267]

The PTAs are also a clear manifestation of intrusion of bilateral efforts into international processes and pending negotiations. The paper gives a number of examples in this respect. A clear case relates to the inclusion in PTAs, in the context of dispute settlement, of non-violation and situation complaints which, in the case of TRIPS, is still an unsettled issue. As a matter of recapitulation one could refer to three additional cases where PTAs take positions on ongoing international processes.

First, the case of biodiversity and deliberations going on in WTO and WIPO, particularly, in the latter case, in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore. Open questions in those deliberations are, among other questions, whether there is a need for new international instruments or amendments to existing ones. The latter is the view generally sustained by developing countries in these forums. As noted supra, in the US-PTAs agreed with Colombia and Peru in side letters signed respectively by the two countries, 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 users and providers."[268]

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[266] See on this question the interesting article by Morin
[267] See Reichman, 2009, op.cit.
[268]

Second, the issue of plant protection is an outstanding issue in TRIPS and in the regular reviews of Article 27(3) b, under the Council for TRIPS, no clear direction has emerged on these issues. By contrast, as discussed here, the PTAs take positions on these matters by favoring an approach leading to the patenting of plants. Agreements such as the one between the USA and Morocco go even further.[269]

In the same vein, other PTAs take the approach that a 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". However, these PTAs further provide that once a country has legislated for patent protection for plants or animals on or after the date of entry into force of the PTA it shall maintain such protection.[270]

The third example of PTA intrusion in international processes relates to the question of further upward processes of patent harmonization and IP in general. In the case of the PTA between USA and Australia the parties commit

> "to reduce differences in law and practice between their respective systems, including in respect of differences in determining the rights to an invention, the prior art effect of applications for patents, and the division of an application containing multiple inventions. In addition, each Party shall endeavour to participate in international patent harmonization efforts, including the WIPO fora addressing reform and development of the international patent system."[271]

In recent negotiations undertaken by the European Union with the Andean countries, the former has proposed "to adopt further steps towards deeper regional integration in the field of IP rights. This process shall cover further harmonization…, further progress towards regional management and enforcement of national IP rights, as well as the creation and management of regional IP rights, as appropriate. The Parties undertake to move towards a harmonized level of IP protection between their respective regions."[272]

Finally, on this particular point, and emphasizing the pervasiveness of the PTAs, one could mention that the controversial initiative for an ACTA includes as main partners the USA, EU, Japan, together with New Zealand, and Switzerland, which are joined by six other countries signatories of PTAs respectively with the US and the EU, namely: Australia, Canada, Mexico, Morocco, Singapore and South Korea.[273]

## D. The role and weaknesses of developing countries

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[269] "Each Party shall make patents available for … (a) plants, and (b) animals. In addition, the Parties confirm that patents shall be available for any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals."
[270] (Peru, Cafta-US)
[271] Australia-US)
[272] (EU and Andean countries: negotiating text)
[273] See IPWatch

Leaving aside the systemic issues discussed here, a question arises regarding what conclusions one could reach on the involvement of developing countries in PTAs with strong chapters on IPRs. As pointed out, it is not the purpose of the paper to consider why countries decide to enter into PTAs, particularly when via these agreements, developed countries export legal regimes with conditions that normally are substantially different from those of the "exporting" developed countries. This intention is more than obvious in the case of the USA, where its main negotiating objective is to ensure "that the provisions of any bilateral trade agreement governing intellectual property rights that is entered into by the USA reflect a standard of protection similar to that found in US law."[274]

There is no doubt, in the view of the authors, that PTAs are freely entered agreements where developing countries seek a number of aggressive trade and political objectives.[275] However, this is not the case when referring to the obligations assumed with respect to IPRs where developing countries' position has been self-defensive. The difficulties in these processes, as discussed in the paper, relate to the complex phases of the negotiation and renegotiation of commitments. As pointed out, the negotiations do not end with the subscription of the agreement but become more burdensome in the so called "certification" process in the case of US PTAs. Under that process, the US authorities need to be satisfied that the other Party has fully met the US expectations regarding the translation into national law of the obligations undertaken in the respective PTA. Otherwise, the agreement is not ready to enter into force. This critical and objectionable process nullifies the TRIPS principle of freedom of implementation.

Developing countries need to be aware of these complexities and the consequences of reaching agreements that will be the subject of stringent monitoring processes by private parties and in the case of the USA by the USTR through its 301 Annual reviews. An interesting exercise would be to examine how many countries party to PTAs with the USA are subject to the different characterizations made by the USTR on performing countries in the area of IPRs. For instance, how many PTAs partners are in the priority watch list?[276] Being listed there may produce a deterrent effect on national reforms and the adoption of more innovative forms of implementation of the PTAs.

The serious challenge for developing countries is the fact that, when importing foreign systems of IPRs including sophisticated pieces of legislation such as, for example the Digital Millennium Copyright Act, they do it without the necessary checks and balances[277] that do exist in the "exporting" countries. Less developed countries have major shortcomings in terms of weak judiciary and administrative systems, and an almost non-existent critical academic and professional bar community. This implies a lack of critical capacity and boldness to implement, for example, legitimate exclusions, exceptions and limitations; there is practically no use of the Appendix of the Berne Convention on Special Provisions regarding Developing

[274] (US TPA)
[275] Roffe 2004
[276] Roffe, Chile watch list
[277] See Abbott

Countries; scarce resort to public policy instruments such as compulsory licensing and finally, there is limited experience on the use of competition instruments.

Is there a way forward? Some countries have understood that PTAs present major challenges, among them a challenge of modernization that demands major investments in various fronts. To face those challenges, IP alone would not be the answer. IP reform should be part of a major design anchored in wide-ranging sustainable development objectives, where protection and enforcement goes par to par with access to knowledge, transfer and dissemination of technologies, the promotion of innovation and competition policies, and, overall, the recognition of the important role the public domain plays for innovation and creativity.