



Intellectual Property,
Bilateral Agreements and
Sustainable Development:

THE CHALLENGES OF IMPLEMENTATION

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January 2007

Intellectual Property, Bilateral Agreements and
Sustainable Development Series: 1



The Center for International
Environmental Law

**ABOUT THE INTELLECTUAL PROPERTY, BILATERAL AGREEMENTS AND SUSTAINABLE
DEVELOPMENT SERIES**

This series was produced as part of a feasibility study generously funded by the John D. and Catherine T. MacArthur Foundation and the Rockefeller Foundation.

As part of the feasibility study, CIEL commissioned four papers to provide guidance on the landscape of procedural and substantive challenges posed by bilateral and regional intellectual property negotiations. The four papers are:

“Intellectual Property, Bilateral Agreements and Sustainable Development: The Challenges of Implementation,” by Pedro Roffe. This paper examines the development of strategies for developing country officials, civil society organizations, and other stakeholders with respect to the implementation of intellectual property provisions in bilateral and regional free trade agreements. In particular, the paper aims to raise awareness of the continuing pressure for higher intellectual property protection during the implementation and annual review of bilateral trade agreements, as well as to outline the opportunities created by the diverse options for implementation to “claw back” policy space.

“Intellectual Property, Bilateral Agreements and Sustainable Development: A Strategy Note,” by Ellen ‘t Hoen. This paper examines strategic considerations for developing country officials, civil society groups, and other stakeholders with respect to upcoming challenges and opportunities in the negotiation of intellectual property provisions in bilateral and regional free trade agreements. In particular, the paper uses the example of the access to medicines issue to provide tangible and realistic recommendations for the next steps that could be taken by civil society groups working on bilateral and regional intellectual property and sustainable development issues.

“Intellectual Property, Bilateral Agreements and Sustainable Development: Intellectual Property in the US-Peru Trade Promotion Agreement,” by Luis Alonso García. This paper was written under the auspices of the Sociedad Peruana de Derecho Ambiental (SPDA). It examines a specific free trade agreement, the US-Peru Trade Promotion Agreement, as an example of the challenges and opportunities presented by such negotiations. The paper aims to provide lessons for developing countries and civil society organizations to consider in their future work.

“Intellectual Property, Bilateral Agreements and Sustainable Development: US Trade Policy-making in Intellectual Property,” by Robert Weissman. This paper presents an analysis aimed at providing developing country officials, civil society groups, and other stakeholders with critical information as to challenges and opportunities in the U.S. trade policy-making process as it relates to intellectual property discussions in bilateral and regional free trade agreements. The paper provides a clear and comprehensive overview of this process, touching upon the key institutions and players and providing concrete possibilities and suggestions to increase the influence of developing countries, civil society groups, and other relevant stakeholders in bilateral intellectual property discussions.

The analyses and findings of the papers form the inputs to CIEL’s **Framework for Future Action in Bilateral and Regional Trade Agreements**, which recommends specific methodologies and priority areas for civil society work in the bilateral and regional arena.

ABOUT THE CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW (CIEL)

CIEL is a nonprofit organization that uses international law, institutions, and processes to protect the environment, promote human health, and create a just and sustainable world. Through our offices in Europe (Geneva) and North America (Washington D.C. and Berkeley, California), we provide advice and support to partners in civil society, government and intergovernmental organizations.

CIEL's Intellectual Property and Sustainable Development Project works with non-governmental organizations and developing country governments to include sustainable development concerns in current multilateral and bilateral rules on intellectual property.

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ACKNOWLEDGMENTS

The author wishes to acknowledge the valuable inputs and observations by Sergio Escudero, Preeti Ramdasi, Max Santa Cruz, Dalindybo Shabalala and Johanna von Braun.

CIEL provided guidance and direction in the production of this paper and wishes to thank the Rockefeller and John D. and Catherine T. MacArthur Foundations for their support of this project.

The images on the front cover are used courtesy of Lauren Baker.



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I. INTRODUCTION

The incorporation of trade-related intellectual property issues in the final outcome of the trade negotiations of the Uruguay Round (Marrakesh Final Act of 1994) signaled a major change in intellectual property (IP) law making. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) not only incorporates the subject matter in the international trading system by extending its two main pillars, namely national treatment¹ and most-favored-nation treatment, to IP relations and making the WTO dispute settlement mechanisms applicable to IP complaints. It also introduces the concept of minimum standards of protection in each of the IP categories dealt with by TRIPS: patents, industrial designs, layout-designs (topographies) of integrated circuits, trademarks, geographical indications, copyright and related rights, and undisclosed information. This included, for the first time ever in an international agreement, a systematic set of minimum standards on enforcement of intellectual property rights (IPRs). The enforcement requirements in TRIPS meant that it was not enough to recognize a certain level of minimum protection in each of the Members but a need to adopt measures to ensure that those rights are effectively applied and protected in each country.

The transformation brought about by TRIPS is particularly significant to developing countries. The bottom up approach of the pre-TRIPS system allowed each country to calibrate their IP regimes to their national interests. This permissive system allowed countries, not only developing but also most industrialized countries, to differentiate between industrial sectors and exclude certain subject matter from patent protection, for example, medicines or food products. This was the case at the time of the TRIPS negotiations where half of the patent laws around the world excluded pharmaceutical products from patentability.

This major innovation should be measured not only by the great changes made by the Agreement to the international IP architecture but by the fact that it provided legitimacy to new initiatives that would have broader and more profound consequences for the process of IP harmonization. Building on the minimum standards principle of TRIPS, a new generation of bilateral or regional trade agreements has been signed in recent years that include chapters on IP and deepen the process of harmonization initiated by TRIPS.² For the sake of convenience these agreements are referred to in this note as free trade agreements (FTAs) and are its main focus. For illustrative purposes, Table 1 lists selected FTAs already negotiated or under negotiation by major trading partners.

¹ It should be noted that several IP treaties administered by WIPO already recognized the national treatment principle, but the coverage in TRIPS is broader.

² See Correa, Fink.

Table 1: Selected recent trade-related agreements*

Country	Negotiated	Under Negotiation
USA with	<ul style="list-style-type: none"> - 1992: NAFTA - 2000: Jordan - 2001: Vietnam - 2003: Chile; Lao People's Democratic Republic; Singapore - 2004: Australia; Bahrain; Morocco - 2005: US-Central America and Dominican Republic (CAFTA-DR) - 2006: Oman; Peru; Colombia 	<ul style="list-style-type: none"> - Free Trade Agreement of the Americas (FTAA); Ecuador; Panama - Southern African Customs Union (SACU)** - Malaysia; Republic of Korea; Thailand - United Arab Emirates (UAE); Middle East Free Trade Area (MEFTA) Initiative
EU with	<ul style="list-style-type: none"> - 1994: Australia (Wine Agreement); Moldova; Russia; Ukraine - 1995: Belarus; Israel; Kazakhstan; Kyrgyzstan; Mongolia; Tunisia; Turkey (Customs Union) - 1996: Armenia; Azerbaijan; Georgia; Morocco; Turkmenistan; Uzbekistan - 1997: Jordan; Mexico; Palestinian Authority - 1999: South Africa - 2000: ACP Countries – Cotonou Agreement - 2001: Croatia (Stabilization and Ass. Agreement); Egypt; India (Science and Technology); Macedonia (Stabilization and Ass. Agreement) - 2002: Algeria; Chile; Lebanon; South Africa (Wines and Spirits) - 2003: Canada (Wines and Spirits) - 2005: India (Strategic Partnership) - 2006: Albania (Stabilization and Ass. Agreement) 	<ul style="list-style-type: none"> - Andean Community; Brazil; Canada (Trade and Investment Enhancement Agreement); Mercosur**** - Regional bilateral economic partnership negotiations, built on Cotonou Agreement: Countries of CARIFORUM (Caribbean) - CEDEAO (Western Africa + Mauritania); CEMAC and Sao Tome and Principe (Central Africa); Countries of SADC (Southern Africa); COMESA (Eastern and Southern Africa) - Turkey (as part of EU enlargement) - Iran; Syria; Gulf Cooperation Council***; Euro-Mediterranean Free Trade Area - Australia; New Zealand (Wines and Spirits)
EFTA***** with	<ul style="list-style-type: none"> - 1991: Turkey - 1992: Israel; Romania - 1993: Bulgaria - 1997: Morocco - 1998: Palestinian Authority - 2000: Macedonia; Mexico - 2001: Croatia; Jordan 	<ul style="list-style-type: none"> - Egypt - Canada - Thailand - Gulf Cooperation Council

	<ul style="list-style-type: none"> - 2002: Singapore - 2003: Chile - 2004: Lebanon; Tunisia - 2005: Republic of Korea - 2006: SACU 	
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*Dates refer in general to the year of signing of the respective agreement

** Botswana, Lesotho, Namibia and Swaziland

***Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE

****Argentina, Brazil, Paraguay, Uruguay, Venezuela

***** Norway, Lichtenstein, Iceland, Switzerland

Sources: www.ustr.gov, http://ec.europa.eu/comm/trade/issues/bilateral/index_en.htm,
<http://secretariat.efta.int>, www.bilaterals.org

II. THE FTAs: MAIN FEATURES

Developed countries, particularly the EU, EFTA and the USA have, with different degrees and depth, pursued in recent years selected free trade initiatives with a number of countries, including developing countries, with a view to intensifying and deepening the WTO agreements. These free trade initiatives adopt different names. For simplicity we encompass all these arrangements under the broad label of FTAs. In the case of IP, these agreements have been characterized as TRIPS-Plus arrangements. These agreements correspond to a number of criteria and in many respects follow the concept of a single undertaking as the case of the Marrakesh Final Act. Governments entering into these agreements do so for a number of considerations that are beyond the scope of analysis in this note.³ It is generally accepted that the IP chapters in the FTAs are one of the most controversial issues and that the *demandeurs* are the developed country partners. For many scholars, the IP provisions in the FTAs are the price paid by the developing countries in exchange for trade concessions in areas more sensitive to their national commercial interests and where they are in fact *demandeurs*.

II.1 The FTAs Signed with the EU and EFTA

The FTAs with IP chapters do not follow a single model. In the case of agreements signed with the EU and also with EFTA there is a major emphasis on reinforcing the existing international architecture by committing the parties to become party to a number of multilateral IP related agreements. For example, in the case of the Agreement between Chile and the EU, as illustrated in Box 1, there is the requirement of ratifying a number of WIPO administered treaties. EFTA follows a similar approach. The ratification of these agreements is reinforced by the overarching obligation prescribed in the EU agreements of ensuring “adequate and effective protection to intellectual property rights in accordance with the highest international standards, including effective means of enforcing such rights provided for in international treaties.”

³ See Roffe (2004).

Box 1: Chile-EU Association Agreement

The Parties agreed, by 1 January 2007, to accede to and ensure an adequate and effective implementation of the obligations arising from the following multilateral conventions:

- 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;
- The Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks of 15 June, 1957, Geneva Act 1977, amended in 1979; and
- The Strasbourg Agreement Concerning the International Patent Classification of 1971, amended in 1979.

In addition, the Parties agree to apply the following conventions by January 1, 2009:

- The Convention for the Protection of Producers of Phonograms against the Unauthorized Reproduction of their Phonograms, Geneva, 1971;
- The Locarno Agreement establishing the International Classification for Industrial Designs, 1968, amended in 1979;
- The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, of April 28, 1977, amended in 1980; and
- The Trademark Law Treaty, 1994.

A best endeavour obligation^a was also included with respect to ratifying 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.

^a Article 170(d) of the Agreement between Chile and the European Communities and its Members States provides that the Parties shall “make every effort to ratify and ensure an adequate and effective implementation of the obligations arising from the following multilateral conventions at the earliest possible opportunity...”

Source: http://www.europa.eu.int/comm/external_relations/Chile/assoc_agr/text.htm, cited in Roffe (2004), p.8

Probably, the most significant IP-related provisions in the EU agreements relate to specific arrangements on 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 (Articles 23.3).

The EFTA model follows again very closely the EU approach⁴ but expands the protection in the case of pharmaceutical products to data provided to national authorities on the safety and efficacy of those products.⁵

As seen in the subsequent section, the agreements signed with the USA are more ambitious in nature compared to those with EFTA and the EU. However, it is difficult to predict at this stage the nature of the new generation of agreements that these two groups of countries might promote in the future particularly in light of the present crisis in the WTO Doha Round. There are clear indications, at least in the case of the EU, that greater emphasis will be given by those countries in the future to IPR enforcement measures.

II.2 The FTAs Signed with the USA

As suggested, the FTAs signed with the USA have a more expansive and detailed coverage. They are guided, among others, by the following principles:

- Promoting adequate and effective protection of IPRs by ensuring accelerated and full implementation of TRIPS, particularly with respect to meeting enforcement obligations and ensuring that the provisions of any trade agreement reflect a standard of protection similar to that found in US law;
- Providing strong protection for new and emerging technologies and new methods of transmitting and distributing products embodying intellectual property;
- Preventing or eliminating discrimination with respect to matters affecting the availability, acquisition, scope, maintenance, use, and enforcement of intellectual property rights;
- Ensuring that standards of protection and enforcement keep pace with technological developments, and in particular ensuring that right holders 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;
- Providing strong enforcement of IPRs, including through accessible, expeditious, and effective civil, administrative, and criminal enforcement mechanisms and provisional measures and requirements related to border measures; and
- Creating an additional WTO-based dispute settlement mechanism applicable also to IP related matters including non-violation complaints.⁶

The comprehensiveness of the agreements signed with the USA relate to all major IP disciplines. The structure and precise contents vary but in general they comprise matters such as:

⁴ See Roffe & Santa Cruz.

⁵ For example, the recent agreement with the Republic of Korea provides: “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.”

⁶ See Resource Book, p.668.

- general provisions (entry into force, the international IP architecture, the ratification of WIPO administered conventions,⁷ and the transparency principle);
- trademarks;
- geographical indications;
- domain names on the Internet;
- obligations pertaining to copyright and related rights;
- protection of encrypted program-carrying satellite signals;
- patents;
- measures related to certain regulated products; and
- enforcement of IPRs.

It is pertinent to reiterate that the IP chapters are an integral part of the FTAs that include, in a single undertaking, a number of trade disciplines and general chapters dealing with settlement of disputes and the administration of the Agreement, including the supervision of its implementation.

III. THE IMPLEMENTATION CHALLENGES AND THE DILEMMA FACING DEVELOPING COUNTRIES

The FTAs that in general deepen the harmonization process already accelerated by TRIPS pose a number of challenges to developing countries. This part of the note addresses those challenges and suggests strategies and models for their implementation.

Developing countries that have negotiated FTAs face a similar dilemma to the one faced at the time of the conclusion of the Uruguay Round. As highlighted in this note, developing countries negotiating FTAs do it because of the perceived benefits they see in entering an agreement of this nature, particularly with a strong and major trading partner. These countries, as in the case of TRIPS, are not the *demandeurs* in the area of IP where their general attitude has been rather defensive and of a damage limitation nature. As in the case of TRIPS, besides regretting the acceptance of further IP obligations, countries might decide to limit domestic reforms only to those that would provide a safe margin for avoiding future conflicts over IP. A different approach, which this note advocates, would be to assume the challenges posed by the FTAs by adopting less limited reforms and accepting some risks, in a more creative and dynamic way.

What appears to be the experience of countries that have negotiated FTAs is that the process of negotiations does not conclude with the signing of the agreement. The implementation process is a complex and tedious one.⁸ In addition, once this implementation phase has been concluded, a subsequent and difficult phase begins with the monitoring of this implementation as it actually takes place not only with the annual reviews of the USTR but also with regular monitoring by industry interested groups (e.g., the International Intellectual Property Alliance

⁷ The coverage of agreements, with differences in the timing of the ratification, closely follows the EU scheme (see Box 1).

⁸ See Vivas & von Braun.

(IIPA), Business Software Association (BSA), and the Pharmaceutical Research and Manufacturers of America (PhRMA)).

Before considering the implementation issues and their challenges we will briefly review the controversial questions raised by the FTAs in the implementation phase.

III.1 Controversial Issues

The most controversial questions raised by the FTAs relate to obligations assumed by countries that go beyond those of the TRIPS Agreement, characterized as TRIPS-Plus provisions. There could be controversies around this characterization particularly by those that advocate that the FTAs provisions are the mere elaboration of the TRIPS minimum standards. For the sake of simplicity, Table 2 summarizes the issues that according to the author could be considered controversial and of a TRIPS-Plus character.

Table 2
TRIPS-Plus controversial issues

<i>Patents and regulated products</i>	<i>Copyright</i>	<i>Biotech/ traditional knowledge</i>	<i>Geographical Indications</i>	<i>Enforcement & dispute settlement</i>	<i>Development impacts</i>
1.Compensatory extensions of the patent term (administrative delays, marketing approvals) 2.Protection of undisclosed data 3.Linkage between patent protection and marketing approval 4.Use of compulsory licenses 5. Exhaustion of IPRs 6.Use of exceptions and limitations 7.Patentability criteria (e.g. protection of business models, software)	1.Extension of duration of rights 2.Expansion of protection to the digital environment 3.Application of effective technological measures 4.Use of exceptions and limitations	1.Protection of life forms 2.Protection of biodiversity and traditional knowledge - compatibility with CBD: disclosure of source, benefit sharing, PIC, positive protection	1.Expansion of protection particularly on wines and spirits 2. Protection of GIs vs. the protection of trademarks. The “first to come first in right” 3.Protection of homonymous signs	1.Expansion of enforcement measures 2.Human and financial resources to cope with enforcement requirements 3.Treatment of non-violation complaints	1.Access to medicines in light of the Doha Declaration 2.Transfer of technology 3.Access to knowledge 4.Technical assistance 5.Interface between competition and IPRs

III.2 Implementation Issues

TRIPS recognizes some flexibility in implementing the Agreement in that individual Members are free to determine the appropriate method of doing this, within their own legal system and practice (See Article 1.1).⁹ In the case of the FTAs, particularly those signed with the USA, this flexibility has been narrowed. For example, in the case of the United States-Central American-Dominican Republic Free Trade Agreement (US-CAFTA-DR), the implementation bill passed by Congress¹⁰ establishes the conditions for entry into force of the Agreement (Sec. 101): “At such time as the President determines that countries ... have taken measures necessary to comply with the provisions of the Agreement that are to take effect on the date on which the Agreement enters into force with respect to those countries that provide for the Agreement to enter into force for them.” This determination conditions the entry into force of the Agreement to the decision of the President of the USA in terms that the other Party has taken the necessary measures to implement effectively the provisions of the FTA. This aspect of the implementation process, known in some quarters as the “certification” act, commits the other Party to adopt, in the case of IP, the necessary implementation legislation that meets the expectations of the USA. This important aspect has been highlighted by industry as one major feature of the implementation of the FTAs that needs to be strengthened.¹¹

Another important aspect of the FTAs is that, in the case of the USA, these agreements are not self-executing.¹² This again is made explicit in the case of CAFTA (Section 102 of the US implementation Act) where it is stated that nothing in the FTA 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. Box 2 reproduces the pertinent provisions of the Bill.

⁹ See UNCTAD-ICTSD, Resource Book, pages 25-27.

¹⁰ Dominican Republic-Central American-United States Free Trade Agreement Implementation Act, Pub.L. 109-53, 109th Cong., 1st sess. (2005).

¹¹ In a Report (February 2006) of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15), with respect to the FTA recently signed with Peru it is stated: “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.”

¹² See Abbott.

Box 2
**SEC. 102. RELATIONSHIP OF THE AGREEMENT TO
UNITED STATES AND STATE LAW**

(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.

Dominican Republic-Central American-United States Free Trade Agreement Implementation Act (2005)

In brief, partner countries are under the obligation to take measures to adjust their internal IP regimes to the new FTA standards, prior to the entry into force of the Agreement. With respect to the USA these agreements are first, non self-executing, and explicitly do not affect domestic legislation. The USTR has expressly advised Congress that it may adopt subsequent legislation inconsistent with the terms of an FTA. 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.¹³

¹³ Abbott, page 5.

III.3 Is There Space for a Creative and Forward Looking Implementation?

Countries that have negotiated FTAs have undertaken obligations for their concrete implementation. As we have seen earlier and in accordance with US law, the implementation needs to be in place before the entry into force of the Agreement. As already suggested, this implementation could adopt a defensive approach to avoid possible conflicts in the monitoring phase. However, it could also assume the challenges posed by the FTA particularly in terms of modernization of the national institutional base. Policymakers could use the IP system in a dynamic way in terms of not only a system that legitimately recognizes and enforces existing IPRs, but develops structures and institutions that makes it possible for the IP system to contribute to the promotion of technological innovation, and transfer and dissemination of technology, that are the core objectives of such a system, according to the TRIPS Agreement. Such dynamic implementation should respond to some general objectives and specific principles that will be developed in the following sections.

III.3.1 General Objectives

The implementation of the IP chapter and the subsequent reform of the domestic regimes should be placed in a broader perspective going not only beyond trade but also taking into account the provisions of other chapters of the FTA that might have an impact on IP matters. In this respect, the reform process should be undertaken bearing in mind the needs of the local economy. In undertaking these reforms the IP system should respond to the following objectives:¹⁴

- Strike an appropriate balance between creation and dissemination;
- Create appropriate mechanisms to promote local innovation and creativity by instituting efficient and market-oriented incentives;
- Minimize the costs of innovative activity;
- Provide timely disclosure of innovation or creation;
- Encourage fair use with economic and social goals in mind;
- Pursue coherent interaction with other regulatory or economic systems, including competition policies, trade and FDI policies, and general technology development strategies.

In undertaking reforms, Parties should also bear in mind that they are not obliged to implement higher protection and enforcement measures than those provided in the FTA (see for example, 15.1, CAFTA) and that the objectives and principles of TRIPS (Articles 7 and 8) should guide the implementation and reform process.

¹⁴ See UNCTAD, 1997.

III.3.2 Specific Principles

Concerning the more specific principles that should guide the implementation and reform process, two aspects appear relevant in this respect. One relates to the use of the flexibilities - in addition to the built-in flexibilities of the FTA itself - that exist in the current architecture in designing an IP system that responds to the particular objectives of the country in question. The second is the related policies that would permit a country to limit the possible costs of implementing a highly harmonized IP system in line with the parameters of more technologically developed societies.

III.4 Exploring the Spaces of Flexibilities within the IP system

As mentioned above, the IP system was rather liberal and adaptable in the period prior to TRIPS. The latter introduced fundamental changes to the international IP architecture that have intensified with the FTAs. However, these agreements that build on the existent international architecture still leave room for the design of IP regimes that could accommodate the particular needs of a country. What is important is to raise awareness of the existence of these spaces and their appropriate use. These spaces for flexibilities are related to the controversial issues highlighted in Table 2 and they refer to questions such as the use of existing mechanisms and public policy instruments that are normally not affected by the FTAs already negotiated. For example, with respect to compulsory licensing, the FTAs do not exclude, in general, the use of the subject matter of a patent without the authorization of the right holder. This is not the case of all FTAs. For example, the Agreement between the USA and Jordan does restrict the use of this instrument to particular circumstances.¹⁵ The use of compulsory licensing - quite common in countries such as the USA and Canada¹⁶ - and the right of WTO Members to define the grounds for their use has been reaffirmed in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health (2001).¹⁷

The latter Declaration also confirms the freedom of Members to establish their own regime for the exhaustion of IPRs, thus leaving countries with the possibility of choosing their domestic approach to parallel imports. The FTAs in existence do not generally deal with exhaustion of IPRs, with the exception of the FTA between the USA and Morocco that allows the Parties to limit parallel imports to cases where the patent owner has placed restrictions on importation by contract or other means. A similar approach is followed in the FTAs between the USA, respectively with Australia and Singapore. In brief, there is in general the freedom in the FTAs for the design of the most appropriate system of parallel imports.

Even if the FTAs adopt stricter standards of protection and, in some cases, reduce the space for defining patentability criteria,¹⁸ they leave each country free, in general, to define what an invention is and to request a declaration of origin in the case of inventions using national

¹⁵ The FTA with Jordan only allows the use of compulsory licensing in cases such as to remedy a practice considered to be anticompetitive, in cases of non-commercial use or national emergencies and on the ground of failure to meet working requirements. (Article 4.20 of the FTA)

¹⁶ See Reichman.

¹⁷ See UNCTAD-ICTSD, *Negotiating Health*.

¹⁸ See for example the FTA between USA and Peru that provides that each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.

genetic resources. This is also the case with respect of the use of exceptions and limitations in the particular case of patents. Copyright exceptions to the protection of digital expressions are treated in some FTAs in more restrictive terms. However, in general, the exercise of exceptions in the case of patents (such as for teaching and research, commercial experimentation, prior use)¹⁹ needs to be explored further and used effectively by those countries implementing FTAs. The same applies to exceptions and limitations in the case of copyright that are commonly used in developed countries (e.g. personal use, criticism, educational purposes).²⁰

Within the IP system there are a number of other instruments that could be given better use in the implementation process with a view to promoting innovative capacities at the local level. For example, in those cases where, foreign right holders are the majority users of patents, innovations of an incremental character, which are the major mode of innovation in developing countries, could be better protected by simpler systems such as utility models.²¹ This is one example of opportunities that exist for exploring, without prejudice to other obligations, other instruments of a non-proprietary nature such as compensatory liability regimes and open source models.

One of the most sensitive areas of the new generation of FTAs refers to measures related to “regulated products”. This fundamentally relates to the new standards introduced in these agreements on the marketing approval of new pharmaceutical or chemical-agricultural products relating to the submission of undisclosed data concerning safety and efficacy. The FTAs contain detailed provisions on issues such as the prohibition on the use of such data without the consent or acquiescence of the first applicant for a marketing approval, for at least five years from the date of approval in the case of pharmaceuticals. The FTAs also provide for a kind of linkage between the marketing approval and the patent. A Party may not provide marketing approval to any third party prior to the expiration of the patent term, unless by “consent or acquiescence” of the patent owner.

These provisions that tend to expand the protection of pharmaceutical products are enhanced by parallel obligations dealing with compensatory extensions of the duration of the patent in cases of undue delays in the administrative granting of the patent or as a result of delays in the marketing approval of the products. The FTAs generally do not contain parameters for defining these compensatory extensions. This is a matter to be regulated domestically. For example, in the case of the USA where these provisions find their inspiration, the restoration period is limited to five years in the case of administrative delays in the granting of the patent. With respect to “unreasonable curtailment of the patent term as a result of the marketing approval process, in the USA there is a close relation between both extension terms: “the effective patent term including the restoration period may not exceed fourteen years”.²²

As stated, these provisions are the most controversial ones in the FTAs and have been the subject of criticisms not only because of their TRIPS-Plus nature, but principally because they make more problematic the exercise of flexibilities and run the risk of making access to

¹⁹ See Garrison.

²⁰ See Ruth Okediji (2006).

²¹ See Suthersanen.

²² Roffe (2004).

medicines more difficult to achieve. These provisions might reinforce the dominant position of strong firms and make the entry of new competitors more difficult. There is thus a need to implement these provisions in a dynamic way in order to preserve a competitive environment and enable sanctions on possible abuses of dominant positions. In this area there is room for creative implementation. Box 3 summarizes the way Chile has implemented the provisions of the FTA with the USA regarding the protection of undisclosed information.

Box 3: Undisclosed information: Chile

Protection will not be granted or continue in cases of:

- Anticompetitive behavior;
- Public health, national security, non-commercial public use, national emergency;
- The pharmaceutical product is subject of a compulsory license;
- The product has not been commercialized in Chile within 12 months from the date of registry or sanitary approval in the country; and
- The product has a registry or authorization in a foreign country of more than 12 months.

Source: Decree 153 (2005) of the Health Ministry, Mechanisms for the Protection of Undisclosed Data

III.5 Modernizing IP-related Regulatory Regimes and Institutions

As suggested at the outset, the implementation should attempt to minimize costs and should be undertaken in a manner coherent with other regulatory regimes. The FTAs in some areas call also for adjustment and compensatory schemes. At first sight, the health sector appears to be one of the most affected in calling for such adjustment systems.

We are dealing here with a very large area that can only be treated superficially within the ambit of this note. One of the main arguments advanced by advocates of FTAs is that they provide an opportunity for reform and modernization. They place the country in question in the “first league,” in the group of advanced economies. One of the challenges faced by developing countries is that, in the area of IP, these countries import systems of protection that have been tried and experienced in more advanced and legally complex countries that, among other things, possess a system of “checks and balances”. This system is codified in legislation and regulation, and some of it arises out of judicial interpretation.²³

The implementation of the FTAs should be used as an opportunity for reform and modernization that would involve investment in securing appropriate institutions and human resources. One area that calls for reform, relates to competition laws and policies, which, in developing countries, have taken years to evolve. Competition and IPRs should not be seen as contradictory but rather as interdependent elements. This means that the efficiency of the IP system is at stake whenever competition is distorted or artificially restrained. Only a fully

²³ See Abbott (2006).

competitive market is likely to minimize the social costs resulting from the fact that IP protection cannot be adjusted to individual needs.²⁴

Besides competition policy, a well-structured IP system needs to be coherent with the national innovation system and with the structures and institutions that support such a system. It is interesting to recall that in the recent FTAs negotiated by the USA, respectively, with Peru and Colombia, there is recognition of the importance of promoting technological innovation, disseminating technological information and building technological capacity including, through collaborative scientific research projects. To this end, “the Parties shall give priority to collaborations that advance common goals in science, technology, and innovation and support partnerships between public and private research institutions and industry. Any such collaborative activities or transfer of technology shall be based on mutually agreed terms.”

As implied earlier, one specific area that appears to be affected by the FTAs is the health sector. Once more, the FTAs transpose systems of protection that have been developed in advanced economies where the institutional base is much more advanced and able to absorb the costs associated with higher levels of protection on pharmaceutical products.

Again, those countries possess “checks and balances” that might compensate for the adjustment costs that the new regimes might impose. Insurance coverage and social security systems, including subsidies, will protect populations from the high cost of new medicines. Equally, sophisticated systems of price control assist in securing access to medicines for all. An example of such a system is Canada’s Patented Medicine Prices Review Board (PMPRB). The Board was created in 1987 under the Patent Act as an independent quasi-judicial tribunal. The PMPRB limits the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure they are not excessive.

²⁴ See UNCTAD (1997).

IV. CONCLUDING OBSERVATIONS

IP matters until very recently were perceived as esoteric, the reserved domain of experts and industrial sectors closely related to the system. The emergence of TRIPS and the inclusion of IP matters in FTAs have altered this perception. Civil society actors have become active in underlining the implications of the IP system particularly on access to medicines, nutrition, and access to knowledge. Non-governmental actors have criticized the overprotection trends of recent years and questioned in general the link between trade and IP matters. NGOs have been active in raising doubts as to the merits of including IP chapters in the FTAs. This note does not deal with these broad important questions but reviews the main implementation challenges faced by developing country partners and suggests ways of implementing the new IP obligations in a forward-looking manner consistent with the levels of development and technological needs of those countries.

Considering the important socio-economic implications of the IP system, reform and implementation should constitute a participatory and coherent process where producers, competitors, and consumers have a voice. At the level of the government, an inter-ministerial approach should assist in the process of taking into consideration the public interest in its different sensitivities and expressions, particularly with respect to health, nutrition, education and industrial and technological development. Here there is a key role for civil society actors that have already shown their commitment to this aspect of economic law. Regardless of the position taken in the process of negotiation of the FTAs, once negotiated, the implementation process is unavoidable with implications for all segments of society. NGOs should continue playing their critical role by making sure that the implementation takes into account these different perspectives and assumes a creative and forward looking approach not limited to window dressing changes of only a defensive nature.

In brief, the negotiation and implementation of FTAs are not simple processes. They pose important challenges for the developing country partners. While market access gains in those agreements might be ephemeral, the transformation of the industrial and technological base of a country might be long lasting. The implementation process should aim at it.

LIST OF REFERENCES

- Abbott, Frederick M.** (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 12, (available at <http://www.ictsd.org/iprsonline/>).
- Correa, Carlos** (2004), *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79.
- Fink, Carsten & Patrick Reichenmiller** (2005), Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements, *Trade Note 20*, The World Bank Group.
- Garrisson, Christopher** (2006), *Exceptions to Patent Rights in Developing Countries*, UNCTAD-ICTSD, Issue Paper No. 17 (forthcoming).
- Okediji, Ruth** (2006), *The International Copyright System: Limitations, Exceptions and Public Interest Considerations for Developing Countries*, UNCTAD-ICTSD, Issue Paper 15.
- Reichman, Jerome** (2003), *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and Overview of the Practice in Canada and the United States of America*, UNCTAD-ICTSD Series, Geneva.
- Roffe, Pedro** (2004), *Bilateral Agreements and a TRIPS-Plus World: the Chile-USA Free Trade Agreement*, TRIPS Issues paper 4, QUNO, Geneva (available in English and Spanish at www.qiap.ca or www.geneva.quno.info).
- Roffe, Pedro & Maximiliano Santa Cruz** (2006), *Los Derechos de propiedad intelectual en los acuerdos de libre comercio celebrados por países de América Latina con países desarrollados*, CEPAL, Serie Comercio Internacional 70.
- Sell, Susan** (2003), *Private Power, Public Law: The Globalization of Intellectual Property Rights*, Cambridge University Press.
- Suthersanen, Uma** (2006), *Utility Models and Innovation in Developing Countries*, UNCTAD-ICTSD, Issue Paper 13.
- UNCTAD** (1997), *The TRIPS Agreement and Developing Countries*, United Nations publication, Sales No. E.96.II.D.10.
- UNCTAD-ICTSD** (2005), *Resource Book on TRIPS and Development*, Cambridge University Press, available at <http://www.iprsonline.org>.
- UNCTAD-ICTSD** (2006), *Negotiating Health: Intellectual Property and Access to Medicines*, Roffe, Tansey & Vivas editors, Earthcan, London.
- Vivas, David & Johanna von Braun** (2006), "Beyond FTA Negotiations –Implementing the New Generation of Intellectual Property Obligations", in *Intellectual Property and Information Wealth*, forthcoming (Peter Yu, editor).



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