



The Influence of Preferential Trade Agreements on the Implementation of Intellectual Property Rights in Developing Countries



A First Look

By Ermias Tekeste Biadgleng, UNCTAD
Jean-Christophe Maur, World Bank Institute



United Nations



International Centre for Trade
and Sustainable Development

Issue Paper No. 33

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Published by

International Centre for Trade and Sustainable Development (ICTSD)
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7 Chemin de Balexert, 1219 Geneva, Switzerland
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Publisher and Director: Ricardo Meléndez-Ortiz

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Acknowledgments

The paper benefited from significant contributions and comments by Kiyoshi Adachi, Ahmed Abdel Latif and Pedro Roffe. We would like to thank Carly Huth, Mineko Mohri, and Wei Zhuang for their valuable assistance during the preparation of the research. Inputs from Henning Grosse Ruse-Khan, Pedros Mavroidis, Sisule Musungu, Santiago Roca, Maximiliano Santa Cruz, Malcolm Spence, Christoph Spennemann and David Vivas-Eugui are gratefully acknowledged. The authors also wish to thank participants in the ICSTD-UNCTAD-WBI workshop on “The Negotiation and Implementation of IPR Provisions in Free Trade Agreements: Experiences and Lessons for Developing Countries”, held in Geneva on 15 April 2009, and the “CARIS Annual Conference 2009”, held at the University of Sussex on 14-15 September 2009.

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The views expressed in this paper are those of the authors and do not necessarily represent those of ICTSD, UNCTAD and the World Bank, its Executive Board, member governments, or affiliated organizations.

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Citation: Biadgleng, Ermias and Maur, Jean Christoph; 2011; *The Influence of Preferential Trade Agreements on the Implementation of Intellectual Property Rights in Developing countries: A First Look*; UNCTAD - ICTSD Project on IPRs and Sustainable Development; Issue Paper No. 33; International Centre for Trade and Sustainable Development and United Nations Conference on Trade and Development, Geneva, Switzerland.

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ISSN 1684-9825

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LIST OF ABBREVIATIONS AND ACRONYMS

Berne Convention	Berne Convention for the Protection of Literary and Artistic Works
Budapest Treaty	Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure
CAFTA/DR-CAFTA	US-Dominican Republic-Central America Free Trade Agreement
CAN	The Andean Community
EPA	Economic Partnership Agreement
EU	European Union
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GIs	Geographical Indications
Hague Agreement	Hague Agreement Concerning the International Registration of Industrial Designs
ICTSD	International Centre for Trade and Sustainable Development
IP	Intellectual Property
IPRs	Intellectual Property Rights
Madrid Protocol	Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks
NAFTA	North American Free Trade Agreement
Nice Agreement	Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks
Paris Convention	Paris Convention for the Protection of Industrial Property
PCT	Patent Cooperation Treaty
PLT	Patent Law Treaty
PTA	Preferential Trade Agreement
PTPA	US-Peru Trade Promotion Agreement
Rome Convention	Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations
TLT	Trademark Law Treaty
TRIPS	Agreement on Trade Related Aspect of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
US	United States
UPOV	International Convention for the Protection of New Varieties of Plants
USTR	Office of the United States Trade Representative
Washington Treaty	Treaty on Intellectual Property in Respect of Integrated Circuits
WCT	WIPO Copyright Treaty
WIPO	World Intellectual Property Organization
WPPT	WIPO Performances and Phonograms Treaty
WTO	World Trade Organization

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FOREWORD

As signs of the stalemate in the multilateral trading system become unequivocal, Preferential Trade Agreements (PTAs) are acquiring an ever-greater importance in trade liberalization and in shaping the trade obligations of many countries.

In the area of intellectual property (IP), there has been considerable analysis, in recent years, of the IP provisions in PTAs particularly those between industrialised countries and developing ones. Such analysis has mostly focused on the nature of these obligations - often labelled 'TRIPS-plus' as they go beyond the requirements of the WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPS) - and the extent to which they could possibly affect the use of TRIPS flexibilities aimed at safeguarding certain public interest and development objectives.

However, there has been much less study about the actual implementation of IP obligations in PTAs. *The Influence of Preferential Trade Agreements on the Implementation of Intellectual Property Rights in Developing Countries: a First Look* aims precisely to bridge this research gap. It attempts to better understand how PTAs have influenced IP regimes in developing countries and then goes to highlight some of the challenges facing these countries in the implementation process. This is by no means an easy task. First, little information is available on what countries do *after* signing these agreements. Second, the nature of IP commitments under PTAs requires a relatively extensive review of legislation, regulations and practices.

The paper defines implementation as the steps required to comply with a trade agreement and to administer its provisions. It also examines a broader notion of implementation as it relates to the wider set of policies that are required to take full advantage of the trade effects created by the agreement.

The paper finds that PTAs are clearly drivers of significant reform in developing countries, as was rightly suspected by those who noted the far reaching nature of the provisions in these agreements; second, and importantly, the implementation challenge for developing countries is real and complex. In effect, implementation does not stop with the transposition of international trade obligations into the domestic legal system. Rather, it continues with the need to modify laws and enforcement practices. There is also the need to revisit international agreements with third parties, the interpretation of commitments, reporting requirements, as well as compatibilities with the domestic legal infrastructure and capacity. The paper thus emphasizes that PTAs become "live" agreements that must be actively managed over time. It demonstrates the variation in implementation of often similar obligations among PTA signatories, some adopting more innovative approaches, while others fail to make adequate use of flexibilities in existing obligations.

The paper does not pretend to be exhaustive in view of the great number of existing PTAs and the diversity of developing countries parties to them as well as the diversity of IP obligations they include. Rather it draws on some of the most compelling examples to advance its arguments and illustrate key findings.

One lesson that emerges from the paper is that countries engaged in negotiations over PTAs should already bear in mind the possible implementation challenges at the negotiation stage taking into considerations some of the examples it points out to. After signing the PTAs, the implementation of the process requires a detailed examination of the nature of obligations contracted and adequate use of any flexibility available and where necessary further elaboration of concepts and legal terms.

In a knowledge-based economy, a better understanding of intellectual property rights is imperative for informed policy making in virtually all areas of development. This has been the central objective of the UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development that was launched in July 2001. The project focuses on ensuring a proper balance between the different interests at stake in designing appropriate intellectual property regimes that are supportive of development objectives and compliant with international commitments. An additional central objective has been to facilitate the emergence of a critical mass of well-informed stakeholders in developing countries - including decision-makers and negotiators as well as actors in the private sector and civil society - able to define their own sustainable human development objectives in the field of intellectual property and effectively advance them at the national and global levels.

We sincerely hope you will find this issue paper a useful contribution to efforts aiming at ensuring an effective and balanced implementation of IP provisions in PTAs in conformity with obligations undertaken and taking advantage of available policy space so as to ensure such implementation is supportive of public policy objectives.



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EXECUTIVE SUMMARY

Preferential trade agreements (PTAs) are gaining prominence among trade liberalization efforts. Yet little remains known about the extent to which the intellectual property (IP) provisions of PTAs translate into actual changes in domestic institutions and laws. This paper investigates one important dimension of this question by looking at disciplines covering intellectual property rights (IPRs) and surveying the implementation of agreements negotiated by the European Union and the United States with developing countries. The EU and United States are the two chief proponents of stronger standards and enforcement of IPRs. This work is among the first to look at implementation issues related to IPRs in the PTA context.

Intellectual property rules in PTAs create actual and substantial implementation obligations for developing country partners. Implementation of PTA obligations often requires changes in legislation, adaptation on the part of domestic institutions, and modification of national procedures to implement new policies.

Importantly, implementation does not stop with the transposition of international trade obligations into the domestic legal system. Rather, it continues with the need to modify enforcement, and frequently involves a *de jure* or *de facto* right of oversight from the trade partner. This suggests therefore that PTAs become “live” agreements that must be actively managed over time.

The study also shows that implementation efforts - arguably to be expected when signing a trade agreement - also create specific (and perhaps unexpected) challenges for developing countries. These include the need to revisit international agreements with third parties, disagreements over the interpretation of commitments, precise reporting requirements, possible incompatibilities with the domestic legal infrastructure and capacity limitations.

1. SETTING THE SCENE

Linkages between trade policy and intellectual property rights (IPRs) have been actively pursued over the past 15 years. This takes its source from the increasing frustration of exporters of strong intellectual property (IP) content industries, and the United States' (US) lead in using trade instruments to enforce IPRs, first unilaterally (under Section 301 and the Generalized System of Preferences) and then in the context of regional and multilateral trade agreements.¹

In 1994, the North American Free Trade Agreement (NAFTA) became the first bilateral regional trade agreement to contain extensive IP provisions. This coincided with parallel negotiations under the Uruguay Round of the General Agreement on Tariffs and Trade (GATT). Under the aegis of members such as the US, the European Union (EU) and Switzerland, the 1994 GATT Agreement for the first time included a broad coverage of trade-related IPRs. The Agreement on Trade Related Aspect of Intellectual Property Rights (TRIPS) linked IP norm setting to international trade disciplines. The adoption of TRIPS has not, however, spelled the end of resorting to preferential trade agreements (PTAs)² to advance higher IP standards. All EU and US PTAs continue to include extensive IPR provisions. Many of these agreements are "TRIPS-plus", in the sense that they are adopted to enhance the protection required by the TRIPS Agreement.³ Bilateral investment treaties have also sought to protect IPRs.⁴

Preferential trade agreements provide the opportunity for both the US and EU to advance a standard setting agenda that they would at best only accomplish multilaterally with considerable effort. The backlash following the TRIPS Agreement has been considerable, and developing countries have since found a much more powerful voice in the WTO. Arguably, also, another rationale for incorporating IP disciplines in PTAs is to ensure better enforcement. Since higher standards of protection are pursued in PTAs than provided for multilaterally, they must have been considered as superior either in that they offer more possibilities to negotiate new IP standards or that they enable better implementation and enforcement prospects. This belief is clearly shared not only by the promoters of PTAs, but also by other less willing partners, judging by the strong reaction from those who perceive themselves as importers or users of IP intensive goods and services against the IP provisions of PTAs. However, the conjecture that PTAs will lead to higher standards of IPRs in partner states in practice is yet to be substantiated.

The purpose of this discussion paper is to provide an examination of the impact of PTAs on the implementation of new IP policies and procedures in developing countries. By doing so, we will attempt to answer the following questions: to what extent are PTAs changing the landscape of IP protection and enforcement in developing countries? If the changes are significant, what implementation strategies should developing countries adopt?

2. PTAS AND IPRS: A POPULAR MATCH

2.1 The Pervasiveness of IP Provisions in PTAs

The world's two largest economies, the US and the EU, are the main proponents of IP rules in regional trade agreements.⁵ A very notable fact is that these agreements pursue the offensive rule-making agenda initiated with TRIPS, seeking to push higher standards or limit the flexibilities allowed under international agreements. The TRIPS-plus characteristics and potential implications of these new agreements have been treated relatively extensively in the literature.⁶

TRIPS-plus measures arise in most forms of IP protection. They frequently reflect evolutions in the design of IP protection motivated by technological and economic changes. For

instance, TRIPS-plus measures may require partners to adopt new conventions not included in other (older) trade agreements, or cover new forms of IP that are becoming economically more important and for which protection has only been recently designed (such as the patenting of life forms or copyright applying to electronic content). The pervasiveness and sophistication of TRIPS-plus measures indicate the relative importance of IP protection as an offensive agenda for its proponents. TRIPS-plus measures are not solely restricted to codifying IP protection rules, but in some instances also concern enforcement measures (see Table 1). The language used in PTAs shows that, despite being a relatively new area, the sections on IPRS are among those with the highest proportion of provisions using legally binding language.⁷

Table 1. TRIPS-plus provisions in the US-Peru and EU-Peru/Colombia FTAs

US-Peru FTA	EU-Peru/Colombia FTA
Ratification of various WIPO Treaties and UPOV 1991	Ratification of various WIPO Treaties
Geographical Indications (GIs) and trademarks	
• No visual perceptibility requirement for trademark registration	• May adopt visual perceptibility requirement for trademark registration
• Provisions on GI application procedures	• Definition of GIs and list of established GIs
• GI protection refusal: when likely to cause confusion with a trademark	• Protection Refusal: when likely to mislead in light of a well-know trademark
• No mandatory registration of trademark license	
Copyright	
• WCT and WPPT standards	• WCT and WPPT standards
• Not less than 70 years of protection	• 70 years of protection
• Encrypted Satellite Signals	• Limitations of liabilities of internet service providers
• Limitations of liabilities of internet service providers	

Table 1: *Continued*

US-Peru FTA	EU-Peru/Colombia FTA
Patents and undisclosed information	
• Standards on novelty and grace period, inventiveness and industrial application	
• Amendment of patent application	
• Grounds for revocation	
• Extend terms of patent, other than pharmaceutical patent	• May provide for patent term extension for pharmaceutical patents
• 10 years for agricultural test data exclusivity	• 10 years for agricultural test data exclusivity
• Normally 5 years for pharmaceutical test data	• Normally 5 years for pharmaceutical test data
Enforcement	
• Damage, discovery and evidence	• Damage, discovery (right of information) and evidence
• <i>Ex officio</i> border measures with respect to goods in transit	• Border measures by both right holders and <i>ex officio</i> authority to include goods in transit

Source: UNCTAD and ICTSD (2011).

The evidence on TRIPS-plus provisions advanced by the US and EU is suggestive of their desire to use PTAs as a lever for stricter IP rules. Obviously, using negotiating capital without the prospect of implementing and enforcing these rules at the domestic level would make little sense. Recent provisions covering domestic enforcement mechanisms applicable to traded goods and services are further evidence of the desire to influence implementation.

While there is an overall tendency to negotiate TRIPS-plus provisions in most EU and US Free Trade Agreements (FTAs), the level of ambition varies depending on the period when the agreements are negotiated and trading partner. Since May 2007, under the influence of a Democratic Party-dominated Congress, the US has voted for a revision of the negotiating mandate in PTAs and adopted a more flexible framework, effectively stepping back from some of the most ambitious TRIPS-plus provisions adopted so far.⁸ On the EU side, however, there is a recent tendency to negotiate far-reaching provisions, notably on enforcement and protection of pharmaceutical and agro-chemical test data. An example of this is the EU's Economic Partnership Agreement (EPA) with the Caribbean countries (members

of the Caribbean Forum, CARIFORUM) and the agreements with Colombia and Peru. The agreements thus contain variations in their level of ambition. Time factors and country specific factors will contribute to determining the extent to which the enforcement of PTA provisions is sought.

2.2 The Role of PTAs in Implementation

How can we explain the success of PTAs in helping to secure the implementation of IP standards and compliance by trading partners? In this section, we suggest several possible mechanisms where PTAs may offer *comparative* value added. When trying to answer this question, we should indeed bear in mind the other available alternatives provided by multilateral trade and IP-specific agreements, *ad hoc* bilateral agreements, investment treaties, private remedies, etc.

1. Innovation: PTAs, as a negotiating forum, offer more possibilities to develop new approaches than multilateral agreements do, in providing scope for the inclusion of recent regulatory advances. Because of their bilateral nature, PTAs may offer prospects for future amendments or later additions through

the regular bilateral meetings of institutions created to manage the agreement.

2. **Asymmetry (in some cases) and low number of signatories:** Another aspect linked with negotiation is the asymmetric and bilateral nature of deal making. The negotiations allow developed countries advance their regulatory preferences in developing countries. A clear example is the case of Geographical Indications (GIs). An important sector for the EU, the GI agenda is not making any consequential progress in the WTO Doha Round negotiations. GIs rules are more effectively pushed through bilateral means. Additionally, for developed countries intent on exporting their own norms, PTAs allow them to pick and choose trading partners and influence the shaping of the world trading system along these norms. The negotiating dynamics around IPRs in PTAs are different from those related to preferences. Concessions given on IP rules can only be given to a partner on an MFN basis because applying different IP regimes by country of origin would be both impracticable and does not make sense economically.⁹ The MFN implications of concession on IP rights under PTAs should have provided developing countries an incentive to negotiate IP rights at multilateral level, for example, at the WTO. Concessions at WTO are the results of multilateral negotiations and developing countries could secure trade concessions from developed countries far better than they can under PTAs. On the other hand, it provides an incentive for exporters of specific norms to bargain at the bilateral level, as there will be a first mover advantage if coordination at the multilateral level to gain wider acceptance of a given rule proves difficult.

Another dimension of the asymmetry is the recent interest of large trading partners, such as the EU and the US, to seek greater control of how the developing country partners transpose and enforce PTA provisions.¹⁰ In the case of the US, this has taken the form of the “certification” process, by which the US executive branch asserts whether the implementation of the agreement is

satisfactory before it can enter into force.¹¹ Developing countries that signed PTAs with United States had to amend some of their domestic legislation to meet the changes requested during the certification process. Similarly, more emphasis on enforcement, and on the procedures that countries adopt to ensure compliance with domestic legislation, is being sought in relation to IP.

3. **Bargaining trade-offs:** As they cover the liberalization of many goods and sectors, trade agreements generally offer interesting bargaining prospects, allowing for the trading of concessions in different sectors of interest to each party. For developing countries in the Uruguay Round, there was a clear bargain between accepting TRIPS rules as part of a package offering further market access in agriculture and labour-intensive goods.¹² Likewise, IP rules in PTAs can be exchanged for preferential market access and other concessions (including the provision of technical assistance).

4. **Withdrawal of concessions threat:** A corollary to this is that trade agreements offer the possibility to nullify concessions in the case of non-enforcement and, sometimes, recourse to alternative dispute settlement mechanisms. Schiff and Winters (1998) argue that bilateral agreements may actually be better suited for locking-in domestic policies because enforcement threats are more credible.¹³ Regional and bilateral agreements limit the possibility of free riding and coordination problems that may arise in multilateral forums. There is also more scope for retaliation as concessions may go beyond just tariffs. It is not obvious, however, that the possibility of retaliation is such an important motive. First, the advantage of retaliation within an agreement over other forms of unilateral action, e.g. under the Generalized System of Preferences or the Special 301¹⁴ for the US, which also enables the withdrawal of trade concessions, is not clear. Neither is the efficacy of such retaliation measures. Indeed, Deere (2009) argues that Special 301 measures have not deterred countries from using TRIPS

flexibilities.¹⁵ Chile, for instance, is resisting calls to meet claimed implementation requirements for its FTA with the US despite being put on the 301 Priority Watch List.¹⁶ The fact that PTAs have been used to promote higher IP standards when the 301 legislation was already in force may also suggest that the US was not managing to achieve its objectives with unilateral pressure alone.

5. **Dispute settlement mechanisms:** PTAs differ from multilateral agreements under the WTO in terms of the IPRs they cover. They also offer a variety of options regarding dispute settlement procedures from judicially based ones (for instance using standing tribunals such as the Andean Tribunal of Justice) to diplomatic and less formal approaches. They may allow for different remedies such as authorizing non-violation and situation complaint, unlike TRIPS that suspended the application of such complaint on disputes concerning the protection of IPRs. Such differences may go either way and render PTAs relatively more or less attractive than WTO agreements.

6. **The use of soft law:** Some PTAs include a large amount of non-binding language reflecting best-endeavour efforts. EU agree-

ments contain a large share of what is called “legal inflation”.¹⁷ PTAs that take a “soft law” approach may provide mechanisms that do not share the prescriptive nature of “hard law” but nevertheless contribute to implementation and enforcement. “Soft law” provisions offer more flexibility and may be used to lead to further regulatory cooperation between parties,¹⁸ providing a mandate for experts to find areas of cooperation. Arguably, IP provisions are less subject to the use of non-binding language than other fields, as shown by Horn *et al.* (2009).¹⁹ However, one type of “soft law” provision in PTAs that may help adoption of standards by parties is the flexibility to establish dedicated institutions (working parties, committees, etc.) between partners (which is more difficult to achieve in the WTO). While parties may be bound to establish such institutions, their role is generally broad and loosely specified, hence the characterization as “soft law” instruments. The merits of such committees vary, promoting cooperation in areas such as notifications to other members, monitoring of enforcement, information exchange, consultations and provisions for positive and negative comity.²⁰ IP committees are, for instance, established in agreements signed by Japan with Chile, Malaysia, Philippines, Singapore and Thailand.

3 WHAT IS IMPLEMENTATION ABOUT? METHODOLOGICAL CONSIDERATIONS

First, a word of clarification about what we consider to be the implementation question. The purpose of this paper is not to assess the economic impact of taking commitments on higher IP standards in PTAs. The focus is narrower: to check whether PTAs lead to actual changes in domestic IP protection, or in other words to see whether countries fulfil their obligations and, more interestingly, what fulfilling these obligations precisely entails. This assessment is made regardless of the final economic implications of reforms, which must be left to other studies.

Much of the discussion on recent PTAs has been about the nature of IP commitments. There has been less attention directed to how commitments have been implemented by partner countries. This is a less trivial question that it would seem for at least two reasons. First, little information is available on what countries do after signing agreements and the binding nature of agreements depends on how credibly trade partners can retaliate in case of violation of the agreement. A second reason is that the nature of IP commitments under PTAs requires a relatively extensive review of legislation, regulations and practices. This complexity can also be a source of “mis-implementation”. Finally, while some commitments are very precise, others are vaguer, and it is not clear exactly how they are to be implemented. For instance, the Morocco-EU Association Agreement (1996) mentions IP protection according to the “highest international standards”, whereas the EU-Egypt Agreement cites the “prevailing international standard”. What such broadly stated provisions mean in practice is far from clear.

This paper refers to the question of implementation as the steps required to comply with the agreement and to administer the new provisions. We also briefly consider a relevant broader notion of implementation as it relates to the wider set of policies that are required to take full advantage of the trade

effects created by the agreement (see section 4 below).²¹

Implementing the provisions of an agreement requires different levels of intervention. First, institutional changes may be needed, as implementation of new areas of policy may call for setting up new regulatory agencies. More frequently, existing administrative institutions must be reorganized to accommodate the need to strengthen their capacity to face new demands (such as new IPRs and increased demand for IP protection).

Second, regulatory reforms - the drafting of new IP laws - will be required if PTAs impose new forms of protection that do not yet exist in domestic law. The nature of domestic legal systems, and whether international treaties are considered to be of direct effect (as in civil law systems) or not (as in common law systems), will have an impact on the need to rewrite domestic legislation. However, given how general the provisions of PTAs are, some degree of legislation will be needed to clarify the nature of the international obligations and make them “useable” for domestic enforcement. Therefore we would expect that if PTAs are creating new obligations and are enforced, this would be visible in the legislative corpus.

The third dimension of implementation consists of the administrative and operational changes required to comply with the agreement. Staff and system resources may have to be reallocated or created to implement the agreement, especially when compliance with new regulations is required. This also includes the management of the agreement itself, including transparency and monitoring requirements.

Fourth, enforcement of the newly adopted regulations needs to be considered. This also relates to the allocation of staff and resources to guarantee that the law is applied. “Quality” of enforcement considerations also apply.

Fifth, administrative and judicial systems may also require additional expertise and staffing to deal with the legal challenges brought about by the implementation of highly specialized regulations.

Lastly, in some instances PTAs may not require any changes to domestic regulation and procedures when they are already in existence. This does not mean PTAs have no impact on implementation: they also affect the policy conduct of signatory countries by providing an external policy anchor, enabling governments to conduct reforms for which they have weak political support at home.

3.1 How to Follow the Progress of Implementation?

Institutional and regulatory changes are highly visible. Therefore, a first step in assessing the influence of PTAs on domestic IPR protection is to identify whether legislative changes have been made to comply with the provisions of PTAs. This requires compiling an inventory of IP laws and IP commitments and comparing the two.

An example of legal change subsequent to the signing of a PTA is Nicaragua's amendment of several laws to specifically comply with the US-Dominican Republic-Central America Free Trade Agreement (CAFTA) signed in April 2006. The text of the amendments refers directly to the obligations under the PTA and the provisions concerned.²²

The text of IP provisions contained in PTAs can easily be consulted on various publicly accessible databases. Turning to changes in domestic legislations, institutions overseeing the agreements may provide some form of monitoring. For instance, the WTO provides periodical country Trade Policy Reviews (TPRs) that are prepared separately by the Member State and the WTO Secretariat. The TPRs provide information on steps taken by countries on their IP regime and reforms due to PTA commitments. The World Intellectual Property Organization (WIPO) also maintains registers of

national IP laws.²³ Monitoring efforts under PTAs do not seem to be performed systematically or made publicly available.²⁴

Finally, mention must be made of unilateral monitoring efforts. Several of these occur at the initiative of major trading partners (e.g. the US, EU, Canada, Japan and Australia), who periodically review what they perceive to be trade barriers in foreign markets.²⁵ Focusing specifically on IP protection, the Office of the United States Trade Representative (USTR) conducts an annual review of the global state of IP protection and enforcement in the context of its "Special 301" legislation. The reviews often refer to commitments in US FTAs. Private interest groups, such as the International Intellectual Property Alliance (IIPA) and Pharmaceutical Research and Manufacturers of America (PhRMA) contribute to the review by making their own submissions. Overall, unilateral monitoring cannot be expected to reflect an objective assessment of implementation - and often tend to overstate the case for implementation. Nevertheless, they provide indications of where trading partners expect change and compliance to take place.

A key issue is determining causality between PTA commitments and national reform decisions. First, other sources of international pressure may have caused countries to change their policies. In particular, when PTA commitments are repeating those under TRIPS, it is difficult to distinguish the contribution of bilateral agreements in ensuring that WTO commitments are met. It is also hard to deny that PTAs may not have any influence as well. TRIPS-plus provisions therefore provide a specific interest in this respect. Bilateral investment treaties (BITs) also offer a venue to push for high IPR standards in order to avoid investors' disputes.²⁶ The role of BITs in this regard requires further study.²⁷ Unilateral pressure from either other governments or foreign private sector lobbies also contributes to the adoption of higher standards.²⁸

Arguably, information on enforcement is much harder to gather since it is not quantifiable by

one easy summary indicator, such as whether a law has been passed or not. Further information should be gathered through the institutional arrangements contained in the various PTAs, for instance through reporting obligations, monitoring instruments, notes of committee meetings and dispute settlement reports. However, it is unclear whether much of this actually exists and is publicly available.

Country-level case studies can complement the factual survey by including decisions affecting the institutions implementing IP protection and enforcement. These include the setting up of new, dedicated organizations and implementing units; the creation of new branches in the administration; or evidence of the allocation of personnel resources towards implementing provisions of an agreement.

Finally, court decisions, including levels of remedy, and quantities of products seized could be useful indicators. Likewise, the number of IPR applications (patents, trademarks, copyrights, etc.) may provide useful clues as to changes in the use of a system following the adoption of new commitments in international agreements. For instance, patent applications - a costly process for firms to go through - could be expected to rise in a system offering stronger protection. Evidence of the level of patents filed can also provide an indication of how capacity levels can be affected by international obligations. The WIPO Statistics Database, for instance, maintains a database of patent applications in its member countries and WIPO administered international filing procedures, such as the Patent Cooperation Treaty (PCT).

4. HAVE PTAS INFLUENCED IP REGIMES IN DEVELOPING COUNTRIES?

Binding commitments in PTAs create the expectation that their provisions will alter and influence partner countries' domestic institutions, laws and practices related to IPRs. The resulting adjustment in terms of national IP laws and practices will vary depending on the gap between the PTA obligations on IPRs and the existing level of IP protection in the contracting parties. Taking GIs as an example, the adjustment would vary depending on whether countries protect GIs as part of their system of trademark protection or separately from it, whether they have a long or limited history and experience in the field of GIs protection, and whether they are seeking to advance GIs protection or not.

In this section, we review several categories of existing changes in national institutions, laws and practices, and adaptation measures illustrating the influence of PTAs on the domestic implementation of IPRs. Then, looking beyond the effect of PTAs on domestic changes in the IPR infrastructure, we discuss specific challenges for the implementation of IP provisions of PTAs by developing country partners.

4.1 Adoption or Modification of IP Laws to Transpose PTA Provisions

Implementation of IP provisions in PTAs may require the adoption of new legislation, regulations and procedures, as well as accession to international conventions. Practices on administration and enforcement of IPRs can change with the adoption of new laws or the modification of existing ones. In the case of PTAs with the US, changes to national legislation to comply with the PTA's IP

provisions are a pre-requisite of full entry into force (the so-called "certification process"). We provide several examples below.

Recent PTAs have generally resulted in very substantial legal implementation efforts. The EU and US PTAs have, however, quite different implications, since US FTAs insist on defining substantive legal obligations, while EU agreements tend to focus, at least until recently, on adherence to international conventions.

Among recent agreements, Costa Rica amended several major domestic IP laws in order to comply with CAFTA.²⁹ The amendments cover, among others, the laws on patents, designs, industrial designs and utility models, trademarks and other distinctive signs, copyright and related rights, undisclosed information, and enforcement. In March 2006, Nicaragua approved laws reforming the protection of copyright and related rights, programme-carrying satellite signals, patents, utility models and industrial designs, and trademarks and other distinctive signs.³⁰ Peru too had to take on a large legal reform agenda to implement the US-Peru Trade Promotion Agreement (PTPA).³¹ The Dominican Republic has reported its legislative reforms for compliance with CAFTA to the WTO (see Box 1). Older agreements have also led to modifications in national legislation. Chile and Morocco introduced a number of important changes to their IP legislative frameworks in order to comply with their PTAs with the US, signed in 2003 and 2004 respectively.³² A recent study on the implementation of PTAs details very extensive domestic legislative reforms for the protection of IPRs triggered by these agreements.³³

Box 1: Implementing CAFTA - changes to the Dominican Republic's IP laws

[...]. During the period under review, the Dominican Republic amended its intellectual property legislation in order to bring it up to date and adapt it to its international commitments, mainly those under the DR-CAFTA. These changes were made by means of Law No. 424-06 of 20 November 2006, which in turn was amended by Law No. 93-06 of 22 December 2006 and by Law No. 2-07 of 8 January 2007. On 6 December 2006, the Law on the Protection of Plant Breeders' Rights (No. 450-06) was enacted. Notification of these laws to the WTO is still pending.

[...]. Among the changes introduced by Law No. 424-06 in the industrial property sphere are the extension of the term of a patent when a delay is attributable to the authority, a term of protection for information submitted for approval of new pharmaceuticals (five years) and agricultural chemicals (ten years), the introduction of olfactory and sound marks for odours and sounds and new provisions on border measures, including an obligation on the DGA to act automatically to withhold the clearance of counterfeit goods.

[...]. In the area of copyright, the main changes include the extension of the term of rights from 50 to 70 years, clarification of the rights of performers and producers of phonograms, and reinforced civil, criminal and administrative proceedings against infringements of copyright, including giving competent judges the power to seize infringing goods and destroy the equipment used to manufacture them. The new Law also includes provisions on prohibitions relating to technological measures, information on management of rights and codified programme-carrying signals transmitted by satellite. In this respect, Law No. 424-06 goes beyond the obligations in the TRIPS Agreement.

Source: WTO (2008a), Trade Policy Review, Report by the Dominican Republic, p.71.

Unlike their US equivalents, most of the EU PTAs with developing countries did not, until recently, incorporate substantive provisions relating to IP legislation. They instead focus mainly on reiterating commitments to TRIPS, the adherence to a set of international IP agreements and conformity with the prevailing or highest international standards.³⁴

One exception relates to the protection of GIs. The EU has agreements on the protection of GIs with Chile, Mexico and South Africa. The agreements demand the phasing out or de-registering of trademarks that conflict with terms describing European GIs, in exchange for tariff free export to the EU market. In addition, a new development in the EU's approach to PTAs has seen substantive provisions on IPRs and enforcement included in the recent EPA agreement with CARIFORUM, although it contains a longer transition period for implementation. The EU also entered into association agreements with Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua

and Panama, and trade agreements with Colombia and Peru. These agreements are still in the process of ratification and formalization and are not yet relevant for analysis of implementation. These agreements started to incorporate IP issues with greater detail.

Have European provisions on GIs led to changes? Should this be the case, we ought to witness the adoption of laws relating to the de-registration of trademarks that are agreed to constitute European GIs. South Africa has not changed its approach to the protection of GIs as a form of trademark, and has not adopted specific legislation on the protection of GIs. It continues to rely on laws related to trademark (1993), the registration of liquor products (1989) and agricultural product standards (1990).³⁵ Although the agreement on wine and spirits entered into force provisionally in January 2000, South Africa has still not ratified the agreement and insists on further negotiations.³⁶ Chile has, on the other hand, implemented its commitments on GIs and

secured elimination of customs duties on its wines and spirits exports to the EU market.³⁷

Finally, there is a need for a separate evaluation of the implications of PTAs on domestic IP legislation in the case of developing countries that are not yet members of the WTO. Algeria and Lebanon agreed that they will ensure accession to the TRIPS Agreement and its effective implementation within five years from the entry into force of their agreement with the EU. Indeed, Lebanon has taken steps to reform its IP laws by releasing drafts of a number of key legislative acts on trademarks, copyright, industrial designs and GIs.³⁸

The amendments to numerous laws covering a broad scope of IPRs are suggestive of the implications of the ambition contained in PTAs. However, the true extent of these changes can only be measured by comparing - before and after PTA implementation - standards for the availability, protection and enforcement of IPRs. Ultimately, the changes in domestic law implementing PTA obligations imply changes in the rights and obligations of various economic actors.

4.2 Adherence to International Conventions Required by PTAs

An important component of the provisions of EU and US PTAs is the promotion of adherence to a second generation of multilateral treaties developed in WIPO around and after the adoption of TRIPS. Both EU and US PTAs call for partner countries to ratify international IP conventions, particularly WIPO treaties and the International Convention for the Protection of New Varieties of Plants 1991 (UPOV 1991). This is in stark contrast to TRIPS, which only requires compliance with provisions concerning the standards of protection under the Paris Convention for the Protection of Industrial Property (Paris Convention), the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) and the Washington Treaty on Intellectual Property in Respect of Integrated Circuits (Washington Treaty). With respect to the Rome Convention

for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (Rome Convention) the requirement under TRIPS is limited to general principles, such as national treatment and standards on limitations and exceptions.

However, not all PTAs impose ratification of WIPO treaties and UPOV 1991 as a mandatory obligation.³⁹ Many include a mix of mandatory and best endeavour clauses for accession. When doing so, PTAs both repeat similar obligations taken under TRIPS and push for partners' accession to new categories of international IP agreements not contained in TRIPS. In addition, the South Africa-EU Trade, Development and Cooperation agreement does not include binding obligations to ratify treaties (Article 46).

Requirements for the ratification of treaties could be complicated for countries that signed PTAs with different countries. The US-Chile FTA, for example, simply requires Chile to undertake reasonable efforts to ratify or accede to the Patent Law Treaty (PLT, 2000), the Hague Agreement Concerning the International Registration of Industrial Designs (Hague Agreement, 1999) and the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol, 1989) in a manner consistent with its domestic law.⁴⁰ Chile is also merely encouraged to classify goods and services according to the classification of the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks (Nice Agreement, 1979). However, Chile committed under its agreement with the EU to ratify the PLT and Nice Agreement by 2009. On the other hand, accession to the Hague Agreement and the Madrid Protocol remains optional, as in the US agreement.⁴¹ Chile is committed to ratifying the Patent Cooperation Treaty under both PTAs with the US and EU.

4.2.1 Ratification of WIPO treaties

Developing countries that have signed PTAs assume commitments to accede and implement multilateral IP treaties. The Budapest Treaty

on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty) and the PCT are the two instruments that most frequently appear in PTAs. The PCT has so far achieved a higher degree of adherence than the Budapest Treaty. Apart from Algeria, all countries with PTA obligations for accession to the WIPO Copyright Treaty (WCT) and WIPO Performances and Phonograms Treaty (WPPT) have complied with their obligations. Finally, in October 2008, after several years of delay, the Chilean legislature approved a law that will allow the government to sign the PCT, a requirement under its FTA with both the US and the EU.⁴² Chile became a member of the PCT in June 2009.

In some instances, accession to WIPO treaties is not due to the PTA provisions, even when there are mandatory requirements to do so. Morocco was a member of the Madrid Protocol prior to its FTA with the US, although the FTA lists accession to the Protocol as one of its commitments. In another example, Article 14.2 (9)(a) of the US-Bahrain FTA requires the use of the Nice classification of goods and services for trademark registration without mentioning accession to the agreement. However, Bahrain acceded to the Nice Agreement independent of its commitment under the FTA with the US. Finally, the US-Jordan FTA imposes obligations to implement the WCT, WPPT, UPOV 1991 and the Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks (1999) without imposing obligations to accede to the instruments (Article 4 (1) of the US-Jordan FTA, 2000). Jordan has complied with its obligations both by making changes to domestic law and through the ratification of treaties. The 2008 amendment of the Jordanian Trademark Law added the WIPO Joint Recommendation on well-know marks.⁴³ Jordan has ratified the WCT and WPPT.

Based on the status of notification of treaties under the WIPO website, the study has identified variations in level of implementing the PAT obligation for the WIPO treaties. Bahrain, Costa Rica, El Salvador, Honduras,

Nicaragua, Oman and Peru are the most PTA complaint countries in terms of ratification of WIPO treaties. At the time of writing this paper, Dominican Republic has yet to accede to the Budapest Treaty as required under CAFTA. Egypt has yet to ratify the Budapest Treaty and Rome Convention as required under its PTA with the EU. Algeria has adhered to only one WIPO treaty among the six treaties it committed to ratify under its agreement with the EU. Chile had not ratified the Nice Agreement, the Locarno Agreement establishing an International Classification for Industrial Designs, or the Strasbourg Agreement Concerning the International Patent Classification, as demanded by its agreement with the EU. Finally, Jordan had not ratified the Madrid Protocol, PCT and TLT that it committed under its agreement with the EU.⁴⁴ Lebanon and CARIFORUM States still enjoy a transition period to accede to treaties under their PTAs with the EU.⁴⁵

4.2.2 Accession to UPOV 1991

Several EU and the US PTAs require accession to UPOV 1991, with a mixed record of implementation among partners. Among the countries obliged to accede to UPOV 1991 that have done so are Morocco (under the agreements with both the US and EU),⁴⁶ Jordan and Tunisia (in 2004 and 2009 respectively, under their agreements with the EU), and Oman (in 2003, under its agreement with the US). Among CAFTA members, Costa Rica and the Dominican Republic have acceded to UPOV 1991.

On the other hand, Chile, Nicaragua and Panama, members of UPOV 1978, are expected to accede to UPOV 1991 under their FTA with the US, but none have yet done so. Neither Peru nor Bahrain has yet acceded to UPOV 1991, as demanded by their agreements with the US.⁴⁷ All these countries can, however, still accede to UPOV 1991 after completing the internal process of ratification and with their acceptance by UPOV members.

Among the EU agreements, Algeria has agreed to ratify UPOV 1991 after an implementation

period of five years, or alternatively to comply with its obligations by implementing an adequate and effective *sui generis* system of plant variety protection *if both parties agree*. To date, Algeria has not acceded to UPOV 1991 and there is no evidence that the EU has accepted Algeria's regime for the protection of plant varieties. Finally, Egypt has not acceded to the UPOV 1991, for reasons explained in detail below in Section 5.2.

4.3 Changes in Institutions and Enforcement Practices

The implementation by developing countries of IP provisions mandated by PTAs can result in several institutional changes in the administration of IPRs. For example, the EU-Morocco Association Agreement requires Morocco to provide suitable and effective protection of intellectual, industrial and commercial property rights, in line with the *highest international standards*. As a result, the 2005 EU-Morocco Action Plan⁴⁸ required Morocco to ensure a level of protection similar to that of the EU, and to implement measures to improve monitoring (administrative and judicial) structures for the registration and granting of rights as well as rights management. This included an opposition system for trademarks and preliminary examination for patents. In response, Moroccan Law No. 31-05 established a system for opposing trademarks and GI registration, modernized the procedure for filing IP applications, and introduced electronic filing of applications for the registration of trademarks.

The Guatemalan legal reforms for the implementation of CAFTA (Decree No. 11 2006) reinforced the National Intellectual Property Committee, incorporating additional government agencies, and expanded the coverage of enforcement to include customs inspection. There is no direct commitment under CAFTA that stipulates how to coordinate and organize government efforts for the enforcement of IPRs. However, under Article 15.11 (2) it states that parties "understand

that the decisions that a party makes on the distribution of enforcement resources shall not excuse that Party from complying with the IPRs Chapter".⁴⁹ Considering the extensive provisions on enforcement, CAFTA countries have to improve their institutional coordination for the enforcement of IPRs.

Peru's agreement with the US, the PTPA, requires a system of registration of trademarks that includes an opportunity for the applicant to respond to communications from the trademark authorities, contest an initial refusal, and appeal to the judiciary any final refusal for registration. It also requires an opportunity for interested parties to oppose a trademark application or to seek cancellation of a registered trademark. In implementing this obligation, Peru's Legislative Decree No. 1073 re-organized Indecopi (Peruvian IP office) and upgraded the existing Trademark Office to a new Trademark Department and Trademark Commission. The Trademark Commission has jurisdiction to decide on oppositions to trademark applications, nullities and cancellations, and first instance jurisdiction over proceedings regarding infringements of trademark rights. The Commission also has the authority to elaborate policies, manuals and regulations. The Trademark Department acquired first instance jurisdiction to decide on administrative proceedings that are not under the jurisdiction of the Commission. There are also similar changes to the administration of patents.⁵⁰

On the enforcement of IPRs, PTAs often call for stronger measures than those expected under TRIPS. Among recent agreements illustrating this, US FTAs and the EU-CARIFORUM EPA contain detailed substantive obligations on the procedures for IPR enforcement, which include implied changes in legislation. For instance, Chilean Law 19,914 increased the penalty for criminal infringement in order to implement the provisions of its PTA with the US. Morocco passed a new set of customs regulations reinforcing border measures at the beginning of 2006.⁵¹ Guatemala has reported that it has reinforced the Special

Prosecutor's Office for Intellectual Property Offences, resulting in more offenders being successfully pursued and convicted. The same office also undertook the training of staff to enhance the implementation and monitoring of Guatemala's international agreements, including CAFTA.⁵² Institutional changes may also follow: in Morocco, the National Industrial Property and Anti Counterfeiting Committee (CONPIAC, under its French acronym) started to operate in April 2008, bringing together different government agencies and the private sector,⁵³ in order to increase efforts to combat counterfeiting.⁵⁴

The examples above point clearly to changes in enforcement arrangements to meet PTA obligations. However, these changes in laws and regulations are only part of the story. A more challenging aspect in assessing whether PTAs indeed affect enforcement relates to whether the right holders make use of the new provisions to enforce their rights; and whether the number of court proceedings and rulings, as well as damages awarded, have increased. The question is important since in civil matters the primary responsibility for enforcing IPRs, as private rights, rests with the right holders. Reports on IPR enforcement by governments, business associations and right holders' advocacy groups, and the USTR, as well as TPR reports by the WTO Secretariat, largely focus on measures taken by the government and much less so on civil legal actions.

4.4 PTA Provisions, Institutions and Other Mechanisms Shaping the Domestic Implementation of IP Policy

As outlined in the first section, PTAs also contain monitoring mechanisms. These include transparency and reporting requirements (prevalent in US PTAs), consultations with expert committees or other bodies (more prevalent in EU PTAs), and dispute settlement mechanisms.

Agreements stipulate the formation of joint committees or councils for the overall implementation of the agreement, as well as sector specific committees and working groups. If

consultations held or recommendations made by the monitoring organs cannot resolve a particular dispute, both US and EU PTAs provide for an arbitration panel that can rule on the dispute. Once a panel decides on a particular case, and compliance is not achieved or agreed otherwise, the PTAs provide for procedures to allow the complaining party to suspend trade concessions.⁵⁵ To our knowledge, no dispute settlement proceedings have arisen from a failure to implement or comply with the IPR provisions of a PTA.

There is, however, evidence of continued influence shaping the IP agenda of developing countries following PTA negotiations. This has occurred in a variety of ways: through the certification of compliance process (a US procedure), unilateral trade reviews and the joint activities of monitoring organs.

The certification of compliance is the process that takes place *after the negotiations* through which the US Congress requires the USTR to check whether the trade partner has implemented all of its obligations before the agreement can enter into force.⁵⁶ Certification of compliance on IPR obligations has been a particular issue for the entry into force of US PTAs with Morocco and Australia, and in CAFTA. The certification process in the case of CAFTA required up to 11 months of work on implementation, demonstrating the intensity of the process.⁵⁷

In the case of the US-Chile FTA (one of the early FTAs), the certification process was not as thorough. Chile implemented the IP provisions of the agreement under the new Industrial Property Law no. 19,914, adopted on 19 November 2003. The agreement entered into force on November 2004.⁵⁸ Chile was later criticized for failing to meet its obligations under the FTA in the annual US Special Section 301 review. In January 2006, the US indicated its concerns over the adequacy of test data protection, insufficient coordination between health and patent authorities, and failure to fully implement legislation to comply with the FTA upon the expiry of the transition period for the implementation of the PTA in

several areas, including copyright and patent term extension.⁵⁹

Chile introduced a new law (no. 20,160) in January 2007 modifying the previous law on the protection granted for patents and trademarks, including the possibility of extending the patent period of pharmaceutical products as a result of delays in the granting of marketing approval (a specific request contained in the FTA).⁶⁰ However, the US continued to challenge Chile on the adequacy of test data protection and other provisions in its 2007 and 2008 Special Section 301 review reports. Chile initiated a new bill on copyright. Once again, the 2009 Special Section 301 review expressed concerns in relation to the bill.⁶¹ The US also acknowledged the implementation steps taken by Chile, offering a glimpse of the efforts needed to meet the requirements of US FTAs.⁶² In 2010, Chile was still on the Section 301 Priority Watch List, although it enacted a new copyright law in May 2010.

The case of Chile and the US demonstrates that the unilateral trade review mechanism leads to a continuous dialogue between PTA partners. The 2009 Special Section 301 review also expressed concern about the weak enforcement of IP laws in several other FTA partners, such as Guatemala, the Dominican Republic and Costa Rica (especially related to copyright piracy and trademark counterfeiting), while acknowledging the legislative reforms taken to implement their commitments under CAFTA.

Transparency requirements are closely associated with the monitoring of implementation. The US PTAs specifically mention transparency in the context of IP,⁶³ with requests for information and statistics on efforts to enforce IP.⁶⁴ A revealing example is the side letter agreed with the Dominican Republic under CAFTA, entitled “Letter on IPR Procedures”. It imposes rigorous reporting requirements related to enforcement. The Dominican Republic is required to provide written quarterly reports on progress in pursuing television broadcasting piracy, including specific criminal, administrative and civil

investigations and actions. The US has since credited the Dominican Republic for complying with the reporting requirements, which included reports on the seizure of equipment from six television operators and legal proceedings against several broadcasters.⁶⁵

Turning now to the EU, we also see an active post-negotiation agenda. The EU has devised periodical action plans with its PTA partners to implement the agreements’ IP provisions. For instance, the 2007 EU-Egypt Action Plan agreed by the Association Agreement Council commits Egypt to:

- Accede to and apply the standards stated in the conventions within the stipulated timeframe;
- Strengthen the enforcement of IPRs within TRIPS requirements, and reinforce the fight against piracy and counterfeiting, increase awareness and encourage the establishment and effective functioning of associations of rights holders and consumers;
- Initiate a policy dialogue covering all aspects of IPRs, including further legal/administrative improvements, etc.⁶⁶

The action plans with the rest of the EU’s Mediterranean partners reveal similar elements. Those with Lebanon and Morocco go even further and make reference to ensuring a level of IP protection similar to that of the EU and to strengthening enforcement. For this purpose, Lebanon is expected to introduce new legislation (notably on trademarks and GIs), ensure conformity with TRIPS requirements and strengthen its administrative capacity for enforcement.⁶⁷ Although these action plans are written in very general terms, they are implemented effectively, as noted above in the case of Morocco with the establishment of a system for opposing trademark and GI registration and modernized procedures for filing IP applications and registering trademarks.

As the impact of the process for certification of implementation discussed above demonstrates,

the signing and implementation of PTAs by developing countries does not necessarily end further demands to modify domestic IP laws. The above exploration shows that post-PTA negotiations and bilateral consultations,

as well as unilateral monitoring mechanisms by developed country PTA partners, form a driving force behind the implementation of changes to domestic IP policies by developing country partner.

5. BEYOND COMMITMENTS: THE CHALLENGES FACING IMPLEMENTATION

The implementation obligations on partners to EU and US PTAs are substantial. An important question to consider, then, is whether various policy challenges and institutional capacity limitations in those partner countries impede implementation. Policy challenges vary, from the margin of flexibility for interpretation when transposing PTA obligations into national law, to compatibility with domestic law and other international agreements. Institutional challenges relate to the effective distribution of responsibilities, availability of resources and capacity to administer and enforce IPRs.

Two types of difficulties arise in implementation. First, the problems can be technical, implying unforeseen legal difficulties or capacity limits. Second, on the other hand, there can be a gap between what has been politically negotiated and what can be politically implemented: changes of governments are particularly illustrative in this regard. In a way, they might reflect some degree of misjudgement on the part of negotiators as to the interest of their constituencies in carrying out the required changes. Thus, implementation problems can reveal the overall preference of the majority for a particular rule, more than being an actual practical implementation issue. That said, however, political issues at the implementation stage may also reflect the lack of “policy space”, or flexibility in transposing the internationally agreed rule into domestic law.

The first policy challenge rests with the margin of flexibility for interpretation available for countries when transposing PTA commitments into domestic law. The transfer of international obligations into a domestic legal framework is indeed subject to some interpretation, something that some countries have used to their advantage, while others have not been able to.

Secondly, the administrative capacity of countries to meet their obligations matters

particularly for developing countries, in terms of personnel and expertise needs. In some instances, this involves the capacity to set up new institutions; the ability to establish new procedures; and the ability to mobilize budget resources. In PTAs involving the EU and the US, the question of capacity is to some extent recognized with transition periods to implement new requirements. However, there seems to be a tendency to provide less and less space for capacity constraints in US PTAs.⁶⁸ This has taken the form of shorter implementation periods and in several agreements the explicit mention that capacity should not be invoked as a reason for the lack of enforcement of IP laws, such as in agreements with Bahrain, Chile, Morocco, Oman, Singapore and DR-CAFTA countries.⁶⁹

Another aspect of implementation challenges is the compatibility of new commitments with other commitments countries may have entered into, as this is not always fully taken into account when agreements are negotiated. A broad approach would also include their compatibility with other policy objectives being pursued by national governments, given the linkages that may exist between IPRs and other sectors.

5.1 Implementation and the Margin of Flexibility for Interpretation

Provisions of US PTAs on IP protection have been expanding over time so that they now require detailed obligations. Generally, EU PTAs with developing country partners do not contain substantive provisions on IPRs, except for the general principle of adhering to the highest standards of protection and ratification of WIPO treaties and UPOV 1991. The EU approach to the inclusion of IPRs under PTAs has changed recently, with provisions on IPRs under the CARIFORUM, CAFTA, Peru and Colombia PTAs. However, our examination of the margin of flexibility for interpretation in

implementing PTA provisions is limited to US PTAs for the purposes of this enquiry, since many of the EU PTA obligations on IPRs are under transition periods or are yet to be implemented.

5.1.1 The case of extension of patent duration to compensate delays during marketing approval

A first interesting case is that of Australia. When implementing its obligations under its FTA with the US relating to patent term extension, Australia was able to limit the use of patent extension to certain categories of products. Australian patent law imposes *additional* substantive conditions for the extension of patent duration for “pharmaceutical substances”. Accordingly, the extension of the patent term is possible if three conditions are met: i) the patent claim contains at least one “pharmaceutical substance *per se*”;⁷⁰ ii) that *the product* is included in the Australian Register of Therapeutic Goods; and iii) marketing approval was issued less than five years after the filing of the patent. Australian patent law also includes specific procedures for opposition to patent term extension.⁷¹ In addition, the US-Australia agreement explicitly provides, in a footnote, that the notion of “pharmaceutical substance” - the term used in Australian patent law - is treated as synonymous with the concept of “pharmaceutical product” used in the text of the FTA. The footnote allows Australia to preserve its rules on eligibility for extension of patent terms to compensate for delays in the marketing authorization process.

The Australian Patent Office has rejected requests to extend the duration of patent protection in cases where it found that the innovation in the patent claim does not concern the pharmaceutical substance *per se*. These cases include when the patent claim was primarily related to the arrangement of

pharmaceutical substances; a new method of delivery of a known substance; or to the use or method of producing a substance.⁷²

The US FTAs with Bahrain, Chile, Jordan, Morocco, Panama and Singapore, as well as CAFTA, have similar provisions regarding the extension of patent terms for “pharmaceutical products”. However, these agreements do not include any footnote similar to that of the US-Australian FTA regarding what constitutes a “pharmaceutical product”. For example, Costa Rica under its CAFTA obligations now extends patent terms for cases of both delay in processing the patent application and delay in registering pharmaceutical products.⁷³ For patent extension eligibility, Costa Rican law does not seem to provide any further substantive conditions or additional definitions other than that of “pharmaceutical product”. Thus, the law extends patents to *all* pharmaceutical products covered by patents, including when the product has been registered abroad, and when the scope of the patent does not mainly concern the substance (neither of which would be permitted under Australian law).

Australian law also imposes *additional* limitations on patent rights during the extended period of protection (see Box 2 below). Recent FTAs, such as the US-Korea FTA, eliminate this possibility.⁷⁴ On the other hand, signatories of earlier FTAs could follow the Australian approach by setting additional limitations to the rights conferred by the patent extension. This possibility does not seem to have been seized: e.g. Costa Rican law does not foresee any such additional limitations. This is despite CAFTA remaining silent about any equivalence between rights in the extended patent period and rights in the original period of the patent, thus leaving a margin of flexibility for interpretation towards more limited rights under patent extension.

Box 2. Australian Patent Law: Limitation to the exclusion of rights of patentee if extension of patent term is granted

If the Commissioner grants an extension of the term of a standard patent, the exclusive rights of the patentee during the term of the extension are not infringed:

(a) by a person exploiting:

a pharmaceutical substance *per se* that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or

a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification;

for a purpose other than therapeutic use; or

(b) by a person exploiting any form of the invention other than:

a pharmaceutical substance *per se* that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or

a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification.

Source: Australia Patent Act 1990, SECT 78.

CAFTA members could arguably follow the Australian approach to impose further substantive eligibility requirements for patent extension and limitation of patent rights during the extended period. This is a solution that at least one CAFTA member, Costa Rica, does not seem to have adopted.

5.1.2 The case of pharmaceutical data exclusivity

Although all US FTAs with developing country partners require data exclusivity for pharmaceuticals and agro-chemicals, the scope of protection has gradually expanded over the years. Two exceptions, however, are in CAFTA and PTPA, where the signatories are given the flexibility to set the same start date for the period of exclusivity with that of the start date of the same data in the US.⁷⁵ CAFTA and PTPA require the availability of protection for all new pharmaceutical products data containing any chemical entity not previously approved in its territory that requires considerable effort to generate. The protection should normally

be five years from the date on which approval was granted to market the product, taking into account the nature of the data and the efforts and expenditures to produce them.

Peru's Legislative Decree No. 1072 on pharmaceutical data protection implemented this flexibility by broadly repeating the language contained in the provisions of the PTPA with the US. Peru provided a definition of the concept of "new chemical entities" in greater detail, which depending on its practical implications could provide more regulatory space.⁷⁶ However, a better mechanism for the operation of the implementing legislative decrees would be required to address the public health aspect of data protection.⁷⁷ In particular, in relation to the five-year normal protection period for data exclusivity, Peruvian law does not further define what is considered as being "normal", thus not seizing the opportunity to define protection periods of less than five years. Neither does the Decree specify the practical considerations involved in determining what constitutes a "considerable effort" to generate

data.⁷⁸ The task of evaluating this is left to “health authorities” without giving any specific guidelines or principles. The Decree also further recognizes the possibility for the five-year term of protection to start concurrently from the date the product is approved in countries with higher sanitary vigilance (mainly Western European countries, Japan, Australia and the US). In the future, Peru may provide a better implementation mechanism through its regulations implementing the legislative decree.

A further example of implementation language clarifying the scope of PTA obligations is found in other agreements, such as the one with Chile, which limits the availability of data protection to pharmaceutical products that have been marketed in the national territory in the year after the grant of marketing approval.⁷⁹ If the grant of marketing approval is based on the pharmaceutical test data but the pharmaceutical product has not been marketed within a year, the test data submitted for approval purposes will not be protected. There are also indications that El Salvador, the Dominican Republic, Guatemala, Honduras and Nicaragua have introduced similar legislation. The practice of making data protection dependent on the registration and marketing of the product within the domestic market within a specific time period would encourage early registration of drugs after first registration abroad, so that the period of protection for the pharmaceutical test data starts early.⁸⁰

These examples of implementation of patent term extension and data exclusivity obligations demonstrate the need for a detailed examination of implementing legislation, in order to determine the adequate use of any flexibility available, and whether further elaboration of concepts and legal terms is desirable.⁸¹

However, negotiated flexibility in implementation is not the sole explanation for differences in the transposition of PTA provisions into domestic legislation. There may be various reasons why implementing legislation fails to

consider optimal alternatives that could carve out small but important domestic regulatory space. First among them, the pressure for early entry into force of PTAs may not leave time for adequate expert scrutiny of and public debate on the implementing legislation. For instance, the government of Peru had to secure special executive power from the legislature, delegating the legislative power to government for 180 days. After six months, the government issued 99 executive decrees, which facilitated the early entry into force of the agreement with the US, but without any broad public debate on the legislative policy issues.⁸²

The certification process for entry into force of US PTAs regulates implementation efforts by partner countries and can thus restrict the options available to countries when implementing domestic legislation. Although a possibility, there is as yet no clear-cut evidence that the US government has rejected any domestic legislation that is technically consistent with the agreement on the premise that it had recourse to a certain interpretation of the language of the agreement. This is however likely to be a question of interpretation, as there is a precedent that countries, such as Peru, have had to revise legislation passed to implement the agreement (presumably because it was not consistent with the agreement).

Finally, technical assistance/capacity building related to IP from developed country PTA partners may focus on ensuring the entry into force of the agreement and its implementation, rather than using options for interpretation that may be available in PTAs.

5.2 Managing the IP Spaghetti Bowl: Specific Hurdles in Adhering to International Treaties

Accession to some international treaties involves the express agreement of existing members, or addressing relationships with other agreements, including regional agreements. For instance, the TRIPS Agreement, the Rome Convention and the WPPT address the question

of remuneration rights of performers and producers of phonograms with slight differences and alternative options. Countries that have agreements with the EU, such as Egypt and Chile, have committed to ensure accession to or implementation of the Rome Convention. Chile is also required in its agreement with the EU to accede to the WPPT, and many other developing countries that signed PTAs with the EU. The remuneration rights of performers and producers of phonograms over the use of phonograms published for commercial purposes is subject to various conditions and limitations that countries may impose under the TRIPS Agreement (Articles 3(1) and 14(4)), the Rome Convention (Articles 12 and 16) and the WPPT (Articles 4(2), 15 and 16). The obligation to provide national treatment with respect to remuneration rights is limited to the extent of protection available under these agreements. Countries can also exclude the remuneration right altogether or restrict the rights based on means of communication, such as broadcasting by wire or wireless means.

The US is not a member of the Rome Convention (that Chile must implement under its agreement with the EU). It implements Article 15(1) of the WPPT on equitable remuneration of rights only “in respect of certain acts of broadcasting and communication to the public by digital means, for which a direct or indirect fee is charged for reception, as provided under the US law”.⁸³ On the other hand, Chile implements the Rome Convention on remuneration rights of performers and producers of phonograms to *any direct use* for broadcasting or for any communication to the public (i.e. without reservation of the mode of transmission).

Therefore, Chile registered its reservation to Article 15 of the WPPT in May 2003 to the treaty so as to ensure that it does not provide higher protection (benefits) to nationals of countries that do not implement the full extent of rights under the Rome Convention or under the WPPT. The notification indicates that Chile applies the remuneration right to the extent provided by the Rome Convention, or under its laws and on a reciprocal basis.⁸⁴

Australia and Costa Rica have also registered their reservations under Article 15 of the WPPT.⁸⁵ On the other hand, neither Bahrain, the Dominican Republic, El Salvador, Guatemala, Honduras, Jordan, Nicaragua, Oman, Panama nor Peru have notified their position on the scope of remuneration rights or any condition of reciprocity. This failure to notify a reservation under Article 15 of the WPPT created the possibility for better protection for US performers and producers of phonograms in their territory to the full extent provided by the WPPT, while their own performers and producers would receive lesser protection in the US as declared by the latter.

Accession is sometimes not automatic upon ratification. Accession to UPOV 1991 requires the consent of the existing member states that examine the conformity of the national legislations to the provisions of UPOV 1991. Guatemala has reported the ratification of UPOV 1991 and two WIPO treaties (the Budapest Treaty and the PCT) to comply with its obligations under CAFTA.⁸⁶ However, Guatemala was requested by the Council of UPOV to make changes and amend the provision on exceptions to plant breeder’s right under its national legislation in order to “give effect” to the provisions of UPOV 1991.⁸⁷ Guatemala needs to approve the implementing legislation with the requested changes in order to become a member of the UPOV. Interestingly, the Dominican Republic was not requested to make any changes to its laws when it was accepted as a member of UPOV 1991 in June 2007.⁸⁸

In a related example, Egypt has not acceded to UPOV 1991 although it committed to do so in its Association Agreement with the EU. The main obstacle seems to be a provision in the plant variety chapter of Egypt’s IP law (2002) that requires applicants for plant breeder’s right to disclose the source of the plant genetic resource relied on in developing the new plant variety, and whether the plant genetic resource was acquired through legitimate means. This requirement for disclosure seems to have been interpreted

by UPOV as an additional criterion for the granting of plant breeder's right; hence Egypt has to change its law in order to accede to UPOV 1991.⁸⁹ The fact that discussions leading to the adoption of the Egyptian IP law in 2002 occurred concomitantly to the negotiations of the Association Agreement reflects the importance of ensuring close coordination between domestic legislative processes and negotiation of IP obligations in PTAs.

There is finally the question of the compatibility of PTAs with regional IP systems. A particular aspect of regional integration is cooperation among developing countries. Regional arrangements have played an important role in helping implement international obligations by taking into account the specific circumstances of those countries, especially when they had to implement the TRIPS Agreement.⁹⁰ In the Andean countries, the process of TRIPS implementation has been carried out through the Andean Community (CAN, under its Spanish acronym) under CAN Decision 486.

The Eurasian Patent Organization, the CAN and the Cooperation Council for the Arab States of the Gulf have a regional standard on IPRs. Although not related to regional economic and political cooperation, the African Intellectual Property Organization (OAPI) also maintains substantive standards on IPRs for its members in West and Central Africa. There are also regional organizations, such as the African Regional Intellectual Property Organization (ARIPO) that administer procedures and processes for the granting of IPRs.

In the context of TRIPS implementation, Andean countries could have chosen to take a national approach rather than a collective one. It can be presumed that besides the political economy advantage, the sharing of deep expertise in domains that are fairly complex could have supported the regional approach. Given that Andean countries had similar policy objectives relating to IPRs, harmonization guarantees the case for the adoption of IP systems that accommodate development priorities, including the use of flexibilities available under TRIPS.

In the case of the CAN, the IP standards negotiated in US FTAs derogate from those established by the Andean Community itself. Peru had to request an authorization from other CAN members to opt out of community law and adopt its own IP law implementing its PTPA obligations with the US. Failing this, the alternative for Peru was considered by some to include leaving the Community.⁹¹ This reflects how the implementation of PTA commitments can influence regional integration efforts that have been underway for many decades, in this case the CAN's common IP regime.

5.3 Compatibility of PTA Implementation with Other International Agreements and Domestic Laws

Some PTAs contain provisions affirming the rights and obligations of the partners under the TRIPS Agreement.⁹² The TRIPS-plus standards of protection promoted under PTAs go much further than the TRIPS Agreement and, as such, there are potential areas where compatibility becomes an issue.

For instance, the renewal of trademarks should be available indefinitely according to Article 18 of the TRIPS Agreement. Thus, EU PTAs that demand the de-registration of domestic trademarks in conflict with GIs may be challenged under the TRIPS Agreement. TRIPS does not deal with the voluntary abandonment of IPRs: the EU and its partners can only be presumed to implement the de-registration obligations with the consent of the trademark owners in order not to breach their TRIPS obligations. One way around this is to compensate trademark owners. De-registration of trademarks is costly, in terms of the loss of brand marketing awareness and the need to re-brand products.⁹³ In the case of the EU's agreement with South Africa and Chile, the *quid pro quo* during negotiations seemed to have been preferential access to the European market in exchange for de-registration. However, the implementation of the obligation is facing challenges in South Africa due to demand for compensation from affected companies.⁹⁴ Finally, this also

illustrates the potential compatibility issues between commitments in PTAs and domestic laws, especially constitutional norms. There are indeed claims that the trademark de-registration requirement under the EU-South African agreement on wines and spirits contravenes the South Africa's constitutional norms against the expropriation of property without prompt compensation.⁹⁵

Another potential area of conflict with the TRIPS Agreement relates to the application of border measures against goods in transit suspected of infringing IPRs.⁹⁶ CAFTA, for example, provides that:

Each Party shall provide that its competent authorities may initiate border measures *ex officio*, with respect to imported, exported, or in-transit merchandise suspected of infringing an intellectual property right, without the need for a formal complaint from a private party or right holder. (CAFTA Article 15.11 Para. 23)

Likewise, the CARIFORUM EPA enables right holders to request the suspension of the release of goods during "entry or exit of the customs territory" (Article 163). Both CAFTA and the CARIFORUM EPA cover goods that are purely in transit.⁹⁷

The issue of border measures against goods in transit has become contentious in the WTO General Council and the TRIPS Council. Developing countries, citing cases of border seizure of generic pharmaceuticals in transit in European ports, asserted that the practice violates the freedom of transit under Article V of the GATT and amounts to extraterritorial enforcement of patent rights. They also asserted that the practice contradicts the Doha Declaration on TRIPS and Public Health and undermines the Paragraph 6 system of the Declaration establishing the procedures for the production of pharmaceuticals under compulsory license for export to countries with limited or no manufacturing capacity.⁹⁸ The European Commission, however, asserted that TRIPS permits the application of border measures to goods in transit, and the measures

by EU customs officials do not apply to IPRs in third countries - hence, no extraterritoriality.⁹⁹ Later, during bilateral negotiations with India, the European Commission signalled the possibility of modifying the relevant legislation to mandate the seizure of goods in transit "to the extent necessary to clarify the procedures relating to medicines in transit".¹⁰⁰ The Commission launched a public consultation to review the legislation on customs enforcement of IP in March 2010.¹⁰¹ India and Brazil initiated consultations with the EU - a procedure mandatory before launching dispute settlement proceedings in the WTO - in a bid to challenge the WTO consistency of the EU's laws and practices.¹⁰²

5.4 Complementary Policies and Safeguards

Beyond the strict implementation of the provisions of agreements, countries also have the possibility to implement complementary policies and devise safeguards that can be applied in relation to IPRs.

Perhaps nowhere is this question more important than in the context of the protection of public health. PTAs routinely recognize the need for safeguards with provisions or side letters recognizing the freedom of countries to take appropriate measures as recognized by the Doha Declaration on TRIPS and Public Health. However, countries implementing PTA obligations should make sure that there is indeed compatibility between TRIPS safeguards and PTA obligations.

The implementation of new PTA provisions can undermine TRIPS flexibilities. For instance, data exclusivity required by some PTAs could prevent market approval of a medicine produced under a compulsory license, and in some PTAs there are restrictions on the parallel importation of drugs.¹⁰³ There is evidence indicating that at least Chile recognized the implications of the data exclusivity provisions and as a consequence adopted legislation providing grounds for the suspension/revocation of data exclusivity when the drug

is subject to a compulsory license - one of the key tools supported by the Doha Declaration on TRIPS and Public Health.¹⁰⁴

Beyond legal measures that effectively allow for generic competition, the affordability of medicine can be ensured with arrangements for bulk purchase arrangements that reduce costs. Regional cooperation is one option. Latin American and Caribbean countries have joined forces in order to reduce the price of ARVs and HIV diagnostic tests by reaching agreements with both originator and generic manufacturers.¹⁰⁵ However, prices are still higher than those for generics in other non-PTA countries, such as India.¹⁰⁶

In this context, assessing the impact of IP provisions in PTAs on the prices of medicines can be a useful undertaking. In effect, such impact assessment can provide indicative guidance about future levels of health and social insurance spending given the likely increase in the prices of medicines. Several national case studies have been carried out in this area and in particular those of Costa Rica and Dominican Republic provide a useful reference point.¹⁰⁷

Among the important complementary policies to consider when implementing IP legislation, the regulation of anti-competitive practices has an important role to play in addressing IP-related abuses of dominant market positions. Some PTAs contain declarations to the effect that the provisions on IPRs do not prevent partner states from adopting measures necessary to prevent anticompetitive practices that may result from the abuse of IPRs.¹⁰⁸

Even before considering how competition law can interact with IPRs, the design of IPRs themselves will determine to what extent exclusivity (and, by implication, competition in the absence of exclusivity) is allowed. IP provisions of PTAs prescribe the patentability criteria, rights conferred by patents, conditions on regulatory exceptions, and comparable issues on other categories of IPRs.¹⁰⁹ Some US PTAs already rule out parallel importation in the case of patents,¹¹⁰ but many other PTAs remain silent as to the grounds for issuing

compulsory licenses. Chile's Law No. 19,914, which modified copyright law to implement the provisions of its PTA with the US, provides one example of interpretation allowing for some relaxation of the rules. The law established that the first sale, or another transfer of property, in Chile or abroad, exhausts the right to national and international distribution with respect to the original or copy. Moreover, Chile adopted in May 2010 a new copyright law that will provide for exceptions to the rights of the copyright holder for the adaptation of works for accessibility by visually impaired persons.

Although many PTA partner developing countries can be credited with having competition regulations and authorities, there is no evidence that competition policy tools have indeed been used to fight abusive business conduct related to the use of IPRs.

5.5 Administrative and Enforcement Capacity, and Technical Assistance

Provisions in PTAs on IPRs require extensive institutional and technical capacity for the administration and enforcement of IPRs, especially as they go beyond the obligations of the TRIPS Agreement. In recent agreements, there has been more focus on IP-specific technical assistance,¹¹¹ although provisions on technical assistance remain very general.

For example, in the US-Chile FTA, Article 17.1 (14) defines means by which the Parties will cooperate in order to strengthen the development and protection of IP, including through education and dissemination projects and training courses. Examples of these trade-related capacity building activities include a 2007 Foreign Criminal Enforcement Training and a 2008 technical assistance and orientation visit to familiarize Chilean government officials with pharmaceutical regulatory policies.¹¹² Under CAFTA, the provision is seemingly reinforced by a link with commitments related to trade capacity building in general. The EU's agreements also cover areas of technical cooperation with respect to IPRs, including

legislative advice and personnel training to the other party. Collaboration is also emphasized in the EU's PTAs in the cooperation provisions, particularly with respect to the fields of science and technology.

The approaches taken under EU and US PTAs are converging in favour of support for upgrading the IP infrastructure and enforcement. However, the EU is found to be more open to the needs of developing countries.¹¹³

The quality of technical assistance, in negotiating and implementing PTAs, is an important element in addressing the policy challenges of domestic implementation. Although countries have reformed their institutional set ups for the administration and enforcement of IPRs in their domestic legislation, there is no clear evidence pointing to the provision of technical and infrastructural capacity building from PTA partner countries.

6. CONCLUSION

This paper began by pointing out the need to investigate the implementation of the IP provisions of Preferential Trade Agreements and their influence on domestic policies in developing countries. It provided a review of reforms undertaken by developing countries that can be directly linked to the signing of PTAs. It also looked at disparities between international commitments and actual domestic implementation, as well as levels of accession to international treaties. The main conclusions from this research are two-fold: first, PTAs are clearly drivers of significant reform in countries, as was rightly suspected by those who noted the ambition of the provisions in these agreements; second, and importantly, the implementation challenge for developing countries is real and complex.

The tasks facing countries implementing the IP provisions of their agreements with developed countries are in many respects considerable as they relate to the administration of IPRs:

- Often a near complete overhaul of the IP legislative framework is required, as in the case of Chile, and this work can span several years.¹⁴ For instance, Chile - a country with good administrative capacity - is still implementing some aspects of its PTA with the US signed in 2003. Likewise, it took more than 10 years for Morocco to make the major legal changes needed.
- Beyond legal changes at home, this research also demonstrates that important administrative capacity building efforts are required with the establishment of new bodies, such as structures for the registration and granting of rights as well as rights management.
- Judicial capacity building must also accompany such efforts in order to provide for rights to administrative appeal (such as in the case of Peru and the creation of the Trademark Commission) and the necessary expertise to rule on them.

- Implementation also concerns enhanced enforcement efforts and stricter future compliance with PTA provisions. Enhanced enforcement arguably implies devoting more resources to tackle IPRs infringement. In Morocco, for instance, this translated into the creation of a new agency. It also implies, in some instances, a change in the type of penalties employed, as some FTAs require criminal proceedings, which also has an impact on the judicial system.
- Finally, compliance with international conventions and treaties is an important dimension of the PTAs we reviewed. While this may look relatively innocuous on paper, accession to treaties and international norms is not always a pain-free process either.

The list above paints a picture of high complexity, arising not only because of the higher standards of IP protection but also because of the narrow scope for interpretation and legal innovation when transposing these obligations into domestic law. Adopting new IP standards requires making the IP system compatible with the legal practices of the implementing country and a useful tool for domestic constituencies. In practice, this paper uncovered several instances where the implementation stage has revealed unexpected issues:

- In some instance, it created unforeseen and serious challenges for developing countries. Notably these included legal compatibility between domestic and international law, which are either still unresolved (e.g., in the case of Egypt's effort for accession to UPOV 1991 and South Africa's difficulty of implementing obligations on GIs) or were resolved at by opting out from other commitments (e.g., in the case of Peru's opting out from its obligations under the CAN community rules);
- More generally, it seems that developing countries may not have entirely assessed

the precise meaning of the commitments they were entering into. They may in some cases also have failed to make use of available flexibilities for the interpretation of international legal obligations into domestic law (Chile being the counter-example). Arguable, the extent developing countries can use flexibilities provided under PTAs can be influenced by the extent their developed country partners accommodates their need to use the flexibilities. However, there is also evidence that some countries, such as Australia and Chile, have taken a proactive approach to this issue.

The implementation itself, whether through literal transposition of the law or through adaptation, leads to different outcome depending on the implementing country's legal system and how stakeholders respond to the changes. Implementation does not stop with transposition into the domestic legal system. Rather, it continues with significant changes in enforcement and, potentially, reviews and interactions with the trade partner. This suggests therefore that PTAs become "live" agreements that must be actively managed over time.

The research also reveals gaps in assessing the challenges related to institutional capacity for the administration, registration and enforcement of IPRs, including legal proceedings. There are also gaps in assessing the actual changes brought about by PTA implementation. These might include, for example the number of legal proceedings, judgments and orders; and empirical indicators as to changes in the payment of royalties related to IPRs and in the patterns and quantities of licenses traded between PTA partners (we refer to these gaps as the 'operational' aspect of PTA implementation). IP laws affect in the first instance private sector operators and therefore surveys of the costs and challenges they face consequent to PTA implementation should be conducted. Equally, further research is required to provide country-specific recommendations for ways to manage the implementation and transposition of PTA standards into domestic law, and evaluate the financial and administrative cost of implementation and additional legislative measures required. Finally, the implementation by developed country partners of the provisions that might be beneficial to developing countries, such as the technology transfer provisions in the EU-CARIFORUM agreement, also require further assessment.

ENDNOTES

- 1 Mercurio, (2006), p. 215.
- 2 For the purpose of this Issue Paper, ‘preferential trade agreements (PTA)’ includes all bilateral agreements with the main theme of trade, including association agreements, and economic partnership agreements of European Union, as well as free trade and trade promotion agreements of the United States.
- 3 For instance, Mercurio (2006, p. 219) defines TRIPS-plus as: (a) inclusion of new areas of IPRs; or (b) implementation of more extensive levels or standards of IP protection than is required by TRIPS; or (c) elimination of an option or flexibility available under TRIPS. Note that in some cases (a) is also called “WTO-Extra”.
- 4 UNCTAD, (2007).
- 5 Counting the agreements with EFTA countries as one, and removing the agreements signed with countries that have since entered the EU. The EU also has a number of agreements with non-WTO members, among them Lebanon, Algeria, Syria and the Palestinian Authorities.
- 6 Vivas-Eugui, (2003); Roffe, (2004); Vivas-Eugui and Spennemann, (2006); Santa Cruz, (2007); Abbott, (2006).
- 7 Of 14 agreements, 12 use binding language, in the areas of Customs Administration, Export Taxes, Antidumping, Countervailing Measures, State Aid, and TRIPS. Horn et al., (2009), p. 13.
- 8 United States Congress, 2007, A new Trade Policy for America.
- 9 Article 4 of the TRIPS Agreement make MFN an obligation for WTO Members and exceptions to the MFN principle with respect to substantive standards are not foreseen.
- 10 Gonzàles, (2009).
- 11 See for example, Congress (2005), with respect to conditions for the entry into force of CAFTA, which includes verification by the Executive of the compliance measures taken by CAFTA partners.
- 12 WTO accession is used in a similar way, as acceding countries are often requested by the US and EU to adopt TRIPS-plus standards. Braga and Cataneo, (2009).
- 13 Schiff and Winters, (1998), p. 177-195.
- 14 Special 301 Report is the report prepared by the Office of the United States Trade Representative on the protection of IPRs in foreign countries. The report identifies ‘those foreign countries that (A) deny adequate and effective protection of intellectual property rights, or (B) deny fair and equitable markets access to United States persons that rely upon intellectual property protection, and (2) those foreign countries ... that are determined by the Trade Representative to be priority foreign countries’ (United States, Trade Act of 1974, as amended by s amended by the Omnibus Trade and Competitiveness Act of 1988 and the Uruguay Round Agreements Act).
- 15 Of course, the flexibilities are legal under the WTO. However, the US has favored a narrow interpretation of these when developing countries have advocated for the opposite view. Unilateral pressure from the US could therefore have been used to limit recourse to flexibilities. Deere, (2009), p. 164-167.
- 16 Chile remained among the countries under the priority watch list under the USTR, Special Section 301 Report of 2011.

- 17 Legal inflation is a reference to provisions of PTAs that are not legally enforceable. A good example of legal inflation can be found in the development-related provisions of the European PTAs. Horn et al., (2009), p.5. For example, the EU-CARIFORUM PTA provides under Article 135 that the parties recognize “that the promotion of creativity and innovation is essential for the development of entrepreneurship and competitiveness and the achievement of the overall objectives of this Agreement.” However, Article 143 of the same PTA state that ‘the EC Party and the Signatory CARIFORUM States shall comply with (a) the World Intellectual Property Organisation (WIPO) Copyright Treaty (Geneva, 1996)” Article 135 is a legal inflation, since it does not create enforceable obligation compared to Article 143.
- 18 Dawar and Holmes, (2010).
- 19 Horn *et al.*, (2009), p. 13.
- 20 Dawar and Holmes, (2010). Under the concept of positive comity, cases involving anti-competitive practices originating in one country but affecting another can be referred to the competition agency of the country where such practices originated for appropriate action. Principles of negative comity mean that countries (Parties) would take into account the important and clearly stated trade interests of other countries before action is taken in particular cases.
- 21 See also Gonzàles (2009).
- 22 This is only one illustrative example. All countries that have signed agreements with the US, starting with Chile, have gone through a massive process of legislative and regulatory changes, as is implied by other examples in the remainder of the text. Nicaragua, (2006), Article 2 of the amendment to Law 354 on Patents.
- 23 WIPO, Collection of Laws for Electronic Access (CLEA).
- 24 NAFTA has a Secretariat of its Free Trade Commission unlike other United States PTAs while CAFTA don't provide for Secretariat serving the its Free Trade Commission. See Article 2201 & 2202 of NAFTA and Article 19 of CAFTA.
- 25 US National Trade Estimate: http://tcc.export.gov/Country_Market_Research/National_Trade_Estimates/index.asp/; EU Market Access Database: http://madb.europa.eu/madb_barriers/barriers_select.htm/; Japan's report on compliance of trade partners with WTO and PTAs: http://www.meti.go.jp/english/report/index_report.html/; Canada CIMAR Database of Trade Barriers: <http://w01.international.gc.ca/CIMAR-RCAMI/index.aspx/>.
- 26 Correa, (2004).
- 27 Castro, (2006); Correa, (2004); and Biadgleng, (2006).
- 28 We have already mentioned the “Special 301” legislation in use in the US.
- 29 Cost Rica (2008), Law No. 8686.
- 30 Nicaragua, laws on copyright and related rights (Law No. 577), protection of programme-carrying satellite signals (Law No. 578), patents, utility models and industrial designs (Law No. 579), and trademarks and other distinctive signs (Law No. 580). All Available WIPO, Collection of Laws for Electronic Access (CLEA).
- 31 These include the Legislative Decree No. 1075, approving the Supplementary Provisions to Decision 486 of the Andean Community (CAN) Commission that establishes a Common Industrial Property System, of 28 June 2008; the Legislative Decree No. 1074, approving

the Rule on Protection of Safety and Efficiency Information in the Marketing Authorization Procedure of Chemical Pesticides for Agriculture Use, of 7 June 2008; the Legislative Decree No. 1072, regarding the Pharmaceutical Test Data Protection and other undisclosed data of pharmaceutical products, of 27 June 2008; the Legislative Decree 1092, approving Border Measures for the protection of copyrights or related rights and trademark rights, of 27 June 2008; and the Legislative Decree 1076 on Copyright of 28 June 2008. All Available WIPO, Collection of Laws for Electronic Access (CLEA).

- 32 WTO, (2009a); Economist Intelligence Unit, (2009), p. 2. The terms of protection of broadcasting organizations remain 50 years from the year of broadcast. Chile introduced a new law (No. 20,160) that came into force in January 2007 modifying the law on the protection for patents and trademarks (Leon, 2007).
- 33 Roffe and Genovesi (2010).
- 34 Santa Cruz, (2007), p. 10-11.
- 35 Van der Merwe, (2009), p. 189. South Africa has not ratified its agreements with the EU on wines and spirits due to a failure to negotiate with local trademark owners to phase out the use of terms claimed as European GIs in the bilateral agreement. See Ronnie, (2006a) and (2006b).
- 36 USDA, (2009), p. 5.
- 37 See Chile's Ministry of Foreign Affairs, Decree 233 (2006), and European Communities, Decision No.1/2006.
- 38 European Commission. (2005). EU-Lebanon Action Plan 2005.
- 39 See European Commission, Treaty Office Database, EU-South Africa Agreement on Trade, Development and Cooperation (1999), Article 46.
- 40 See USTR, Trade Agreements, US-Chile FTA (2003).
- 41 See European Commission, Treaty Office Database, EU-Chile (2004), Article 170 (d).
- 42 Economist Intelligence Unit, (2009), p. 30. The PCT establishes an international patent filing system, whereas the PLT establishes rules of procedures for the granting and administration of patent applications. The US requires Chile to accept the PCT but not the PLT. However, the EU obliges Chile to accept the PLT.
- 43 Nabulsi, (2009), p. 17.
- 44 Please see further at WIPO, Treaties and Contracting Parties.
- 45 See European Commission, Treaty Office Database, EU-Lebanon Association Agreement (2005), Annex 6, Article 1 and 2; and EU-Algeria Association Agreement (2005), Annex 6, Article 1.
- 46 WTO, (2009a), para. 152.
- 47 This is despite the certification process by the US prior to ratification of the agreement.
- 48 Note that nine years elapsed between the agreement and the action plan. In the interim no one really could interpret what "highest international standards" and other legally vague provisions in the agreement actually meant.
- 49 This is a standard provision in all US FTAs.

- 50 Peru, 20, New Organizational Law of Indecopi, Legislative Decree No. 1073, 2008.
- 51 WTO, (2009a).
- 52 WTO, (2008b).
- 53 These are: Ministry of Industry, Trade and New Technology; Ministry of Justice (Civil Affairs Directorate); Ministry of the Economy and Finance (ADII); Ministry of the Interior (Economic Affairs Coordination Directorate and Directorate General of National Security); Royal Police Force; Ministry of Agriculture (Plant Protection, Technical Control and Suppression of Fraud Directorate); Ministry of Tourism and Handicrafts (Directorate for Protection of the National Heritage, Innovation and Promotion); and the OMPIC.
- 54 WTO, (2009a).
- 55 See, for example, European Commission, Treaty Office Database, EU-Chile PTA, Article 188.
- 56 USTR, (2007).
- 57 *Ibid.*, p. 2.
- 58 Economist Intelligence Unit, (2009), p. 15.
- 59 USTR (2006), Special 301 Report.
- 60 *Ibid.*, p. 29.
- 61 Noting in particular that: “While Chile is considering legislation to implement various provisions of the FTA regarding Internet service provider liability, limitations and exceptions to copyright protection, and enforcement and penalties against copyright infringement, modification of these laws is needed in order to bring it into line with multilateral and bilateral commitments”. USTR, (2009), Special 301 Report, Summary.
- 62 *Ibid.* Implementation progress noted includes:
- Creation of a specialized brigade within the Chilean police force to handle IPR crimes;
 - The establishment of National Institute for Industrial Property to oversee administrative actions related to industrial property;
 - Accession to the Patent Cooperation Treaty fulfilling a commitment under the US-Chile FTA;
 - Several pending bills to implement provisions of the FTA and pending processes for the ratification of UPOV and TLT.
- 63 See, for example, USTR, Trade Agreements, US-Chile FTA, Article 17.4.
- 64 USTR, Trade Agreements, CAFTA, Article 15.11 (4).
- 65 US State Department, (2009a).
- 66 European Commission, (2007a), Recommendation 2.4 (c).
- 67 European Commission, (2007b), European Neighborhood Policy and (2005), EU-Lebanon Action Plan, p.15.
- 68 Fink (2011).

- 69 Fink, (2011).
- 70 The definition of “pharmaceutical substance *per se*” excludes patent claims such as those relative to the use of a substance, a method of preparing a substance, or a method of administrating and delivering a drug, etc.
- 71 Australian Legal Information Institute, Patent Act 1990, Article 70 and 75.
- 72 Tadgell, (2009), p. 3. The Australian court rejected the request for extension of the duration of the patent protection in one case concerning a container provided with a nozzle for delivering the substance by nasal administration, since the substance only formed a part of a method or process for the delivery of a drug. See Tadgell (2009) for a list of recent decisions on patent term extension.
- 73 Acuna, (2009).
- 74 The US FTA with Korea provides that any restoration of patent term shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions applicable to the original patent. USTR, Trade Agreements, Korea-US FTA, Article 18.8.6 (b). Although Peru and Colombia are not obliged to provide patent term extension for pharmaceutical products, if they chose to do so, they are obliged to confer all of the exclusive rights of a patent during the extended term of protection.
- 75 USTR, Trade Agreements, US-Peru FTA, Article 16.9 (6)(c).
- 76 Peru (2008) Legislative Decree No. 1072.
- 77 *Ibid.*
- 78 Delion and Rodrigues, (2009).
- 79 See Chile’s Law No. 19,996 (2005) amending Law No. 19.039, Article 91.
- 80 Cullen, (2007), fn. 41.
- 81 Limitations in domestic implementing legislation for PTAs are not unique to developing country partners. Australia’s implementing legislation for its PTA with the US was also criticized. See Varghese (2004):
- In several areas, the proposed implementation either goes further than AUSFTA requires or fails to take advantage of exceptions and limitations that AUSFTA allows. More generally, the Bill introduces no new mechanisms to counter-balance the more protective copyright regime, such as a broad ‘fair use’ exemption or stronger competition laws. The result is that, in several respects, this Bill would give Australia a more protective copyright regime than the US.
- 82 Roca, (2009).
- 83 WIPO, (1999b).
- 84 WIPO, (2003).
- 85 WIPO, (2009); and WIPO, (2007).
- 86 WTO, (2009d), p.118.
- 87 UPOV, (2006a), para. 23; and UPOV, (2006b), para. 12.
- 88 UPOV, (2007), para. 3. Another CAFTA country, Nicaragua, is a member of UPOV 1978.

- 89 Abdel Latif, (2009), slide no. 8.
- 90 Deere, (2009), p. 217-220.
- 91 Bilaterals.org, (2008). Other members of the CAN are also said to have threatened to withdraw.
- 92 See USTR, Trade Agreements, CAFTA, Article 15.1 (7), which states: “the Parties affirm their existing rights and obligations under the TRIPS Agreement and intellectual property agreements concluded or administered under the auspices of the World Intellectual Property Organization (WIPO) and to which they are party”.
- 93 Kerr, (2006), p. 10. Australia, a developed country, earmarked finance for rebranding and labeling support. It also indicates legislation is necessary to implement the obligations with respect to GIs. See Commonwealth of Australia, (2009), p. 13. See also the South African Port Producers Association’s efforts to rebrand wines using the word ‘Port’, which is required to be phased out under the agreement between South Africa and the EU; available at: <http://www.sappa.co.za/>.
- 94 Ronnie, (2007).
- 95 USDA Foreign Agricultural Service, (2009), p. 5.
- 96 For a more extensive treatment of the issues, see Seuba (2009).
- 97 Other than those goods in transit but involve repackaging, re-exportation transactions, or placement in warehouses for sale or offer-to sale to third country importers and other transactions that would infringe on the domestic rights of the IP rights holder.
- 98 See WTO, (2009b), para. 122-191; and WTO, (2009c), para. 72-97.
- 99 WTO, (2009c), para. 72-97.
- 100 ICTSD, (2010), p. 9.
- 101 European Commission, (2010).
- 102 WTO, (2010a); and WTO, (2010b).
- 103 Baker, (2009).
- 104 Spennemann, (2007).
- 105 UK All Party Parliamentary Group on AIDS, (2009), p. 32.
- 106 Enemark *et al.*, (2004), p. 29.
- 107 Hernandez-Gonzales and Valverde (2009); and Rathe *et al.*, (2009),
- 108 USTR, Trade Agreements, CAFTA, Article 15.1 (15) and US-Chile FTA, Article 17.1 (13).
- 109 USTR, Trade Agreements, CAFTA, Article 15.9 (5); US-Chile FTA, Article 17.9 (4); and US-Morocco FTA, Article 15.9 (6).
- 110 USTR, Trade Agreements, US-Morocco FTA provides at Article 15.9 (4) that:
- “Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory [...]

[footnote 9] [fn. 9 - A Party may limit application of this paragraph to cases where the patent owner has placed restrictions on import by contract or other means.]”

See also, USTR, Trade Agreements, US-Australia FTA, Article 17.9 (4).

111 Roffe *et al.*, (2007), p. 9.

112 USAID, (2009).

113 Roffe *et al.*, (2007), p. 14.

114 Roffe, (forthcoming).

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Founded in 1996, the International Centre for Trade and Sustainable Development (ICTSD) is an independent non-profit and non-governmental organisation based in Geneva. By empowering stakeholders in trade policy through information, networking, dialogue, well targeted research and capacity building, the Centre aims to influence the international trade system such that it advances the goal of sustainable development.

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ABOUT UNCTAD

Established in 1964, the United Nations Conference on Trade and Development (UNCTAD) is the focal point within the United Nations for the integrated treatment of trade, development and interrelated issues in the areas of finance, technology and investment. UNCTAD seeks to promote the integration of developing countries into the world economy by providing a forum for intergovernmental deliberations, research and policy analysis, and related technical assistance. UNCTAD's programme on the development dimensions of IPRs seeks to help developing countries participate effectively in international discussions on IPRs and – at the national level – to help ensure that their IP policies are consonant with development objectives.