ECIPE WORKING PAPER • No. 02/2007

A Transatlantic Divide?

The US and EU's Approach to the International Regulation of Intellectual Property Trade-Related Agreements

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ABSTRACT

The TRIPs plus phenomenon (additional steps to strengthen the Agreement on Trade-Related Aspects of Intellectual Property Rights) tends to be attributed to the regional and bilateral efforts of the United States. This paper suggests that such a perception is mistaken. The EU certainly seeks to secure TRIPs plus provisions with its negotiating partners. However, the paper also suggests that, compared to the United States, the EU's approach towards the international regulation of IPRs is less effective and does not fully meet the EU's objectives in this field. The United States employs a more "hands-on" strategy at the regional and bilateral level, while the EU's tendency to incorporate international conventions and treaties into its regional and bilateral agreements suggests that it still favours the multilateral approach. But the European Commission seems to become more proactive in the international regulation and enforcement of IPRs and should coordinate its efforts with the United States.

JEL Code: F13, F14, F19, F21, F53

Keywords: Trade Policy, Free Trade Agreements, Intellectual Property Rights, International Policy Coordination

INTRODUCTION *

Any discussion on trade-related intellectual property agreements is far from being natural and straightforward. Unlike other trade agreements, the international regulation of intellectual property rights (IPRs) ultimately deals with a unique commodity—knowledge. And, in contrast to other resources and commodities that are traded globally, knowledge is not scarce. Indeed, one of the most dominant features of knowledge products are that they are generally difficult and costly to create (such as medicines, software or a music record), but once created they can be easily used and copied. The creation and distribution of knowledge products are therefore subject to different legal and regulatory requirements (IPRs).[1] At the global trading arena these requirements are manifested through international intellectual property (IP) agreements. International IP agreements seek to define the manner in which knowledge products will be protected, traded, exploited and used. Put differently, international IP agreements do not aim to promote the movement of knowledge-products vis-à-vis the unrestricted copying of such products, but rather through the establishment of clear rules that define the relationship between owners and users of knowledge.

IPRs are rapidly becoming one of the most influential and controversial issues in today's knowledge-based society. At the macro level, IP affects a wide range of issues, such as international trade-policy, the legal manifestation of ownership of breakthrough technologies, foreign direct investments, innovation climates, competition rules, monopolistic behaviour and public health. At the micro level, IPRs are strongly embedded in contemporary business models.

To date, the 1995 World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) established the highest and most comprehensive level of IP protection at the multilateral level. To all intentions and purposes TRIPs was established as a right-holders' agreement. It was envisaged, advocated and lobbied by the developed countries, in particular the United States and the EU, seeking to maintain the vital interests of their knowledge-based industries. In its early stages the TRIPs Agreements were described as a "revolution in international intellectual property law."[2]

Nevertheless, the process of implementing the TRIPs agreement in developing countries and least developed countries turned out to be particularly complex and "painful", particularly in the area of pharmaceutical IPRs. The debate over the positive and negative consequences of the internationalization of IPRs via the TRIPs Agreement was as emotional as it was rational. Since 2001 negotiations no longer focused on the implementation, but rather on the "flexible" interpretation of TRIPs—or in other words on the manner in which developing and least developed countries could essentially avoid or bypass the agreement. As a result, the TRIPs framework was more or less paralysed (a result that represents the WTO as whole).

On the other hand, there is growing evidence suggesting that since the year 2000, regional and bilateral trade agreements between developed and developing countries have tended to implement IP provisions that go beyond the level of protection provided by TRIPs Agreements. These agreements are categorised as "*TRIPs plus*".

Yet, the TRIPs plus phenomenon tends to be attributed to the regional and bilateral efforts of the

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United States. A typical portrayal of such a view can be found in a recent Oxfam report arguing that:

> *"while other rich countries and particularly the member countries of the European Union have not pursued a TRIPs plus agenda, their inaction has left the USA free to impose stricter intellectual property rules on poor countries."*[3]

This paper suggests that such a perception is mistaken. The EU certainly seeks to secure TRIPs plus provisions with its negotiating partners. However, the paper also suggests that, compared to the United States, the EU's approach towards the international regulation of IPRs is less effective and does not fully meet the EU's objectives in this field. The paper also finds that the EU, perhaps being mindful of its weakness in this field, is becoming more proactive in the international regulation and enforcement of IPRs.

The paper does the following: First, it identifies key elements that are fundamental to IP trade agreements and which are subject to ongoing negotiations (as well as conflicts) at the international, regional and bi-national levels. The section builds upon an earlier research template provided by this author for the analysis of IP agreements and negotiations.[4]

Second, the paper analyses the difference between the United States and EU approaches to the protection of IPRs in regional (regional trade agreements—RTAs) and bilateral trade agreements (free trade agreements—FTAs).

Finally, the paper focuses on the practical translation of TRIPs plus provisions in United States-led and EU-led regional and bilateral agreements, as well as comparing the degree of effect of the two approaches.

While this paper attempts to provide yet another layer of the political economy of IPRs, it should also be stated what it does not intend to do. It does not provide an analysis of the IP system from a social welfare perspective or of the economic implications of the international IP system. This was done extensively in this author's previous publications, and therefore there is no point in repeating it. Nor does it intend to express a moral judgment on the nature of the TRIPs plus phenomenon, though it should be disclosed that this author belongs to the camp of its supporters.

KEY COMPONENTS OF INTERNATIONAL IP AGREEMENTS

In general terms, international IP agreements aim to achieve two major goals. The first is to level the playing field and establish the ground rules according to which trade in IP-related products should take place. The second is to standardize the level of IP protection granted by signatories to international IP agreements.

The Structural Framework Of International Ip Agreements

Although the structural framework relevant to international IP agreements is similar, at least in theory, to agreements in other fields of international trade, it is still important to describe key elements in this framework, as this will enable us to treat IPRs as an isolated factor. One should bear in mind that, in practice, the structural framework of international IP agreements is translated into a unique set of day-to-day requirements and operations that are very different from those in other fields of trade.

The first and most fundamental element in international IP agreements is the principle of "national treatment", which requires member countries to treat the nationals of other countries no less favourably than their own. National treatment will thus enable foreigners to exploit their IPRs in countries other than their own.

The International Convention for the Protection of Industrial Property (1883) is probably the

first agreement in which the principle of national treatment was adopted with regard to IPRs.[5] The principle of national treatment is also implemented in today's IP agreements, such as Article 3 of the TRIPs Agreement and Article 1703 of the North American Free Trade Agreement (NAFTA). However, at this early stage, it should be noted that since signatories to international IP agreements may still have considerable gaps in the scope of their IP legislation, the principle of national treatment, in itself, is insufficient. Without standardizing the scope and level of IP protection granted by member countries, the principle of national treatment, as well as any other component of an agreement, is ineffective.

Secondly, international IP agreements require the establishment of administrative procedures that would allow IP owners to exploit their products *de facto*. The most basic requirement in this context is the establishment of an "entry point" for the registration of IPRs (patents, trademarks and plant varieties). An efficient patent and trademarks office is measured by the legal and technical expertise of its staff as well as by its technological infrastructure. Furthermore, international IP treaties that focus on the operational dimension of IPRs at the cross-national level, such as the WIPOs' Patent Cooperation Treaty (PCT),[6] are also heavily dependent on the effective administration and management of IPRs at the national level.

The administrative dimension of IPRs also encompasses informational and educational activities that aim to provide basic knowledge on the different aspects of Iprs. This basic information—which deals with what is a patent, how to register a trademark, why the unauthorized copying of a disc is considered counterfeiting, etc—is pivotal to the implementation of an "IP culture."

In this context, much has been discussed about the need to provide technical assistance to developing and least developed countries (LDCs) in the field of IPRs. It is a known fact that LDCs, as well as some developing countries, are bound to face considerable obstacles in the process of meeting their international IP obligations. Many of these countries have incompatible, and in some cases non-existent, IP mechanisms, both at the legislative and operational levels.[7] Nevertheless, it is not currently clear to what extent international IP agreements emphasize this dimension and monitor its implementation. For example, TRIPs Article 67 clearly states that developed countries should provide technical and financial assistance to developing countries and LDCs. International organizations and institutions, such as the WIPO, the World Bank, and the WTO itself, as well as governments such as the US, the European Commission, the UK, France, Germany etc, provide technical, educational and, to some extent, technological assistance to developing countries and LDCs.[8] Nevertheless, the current state of play suggests that such assistance is under-supplied.

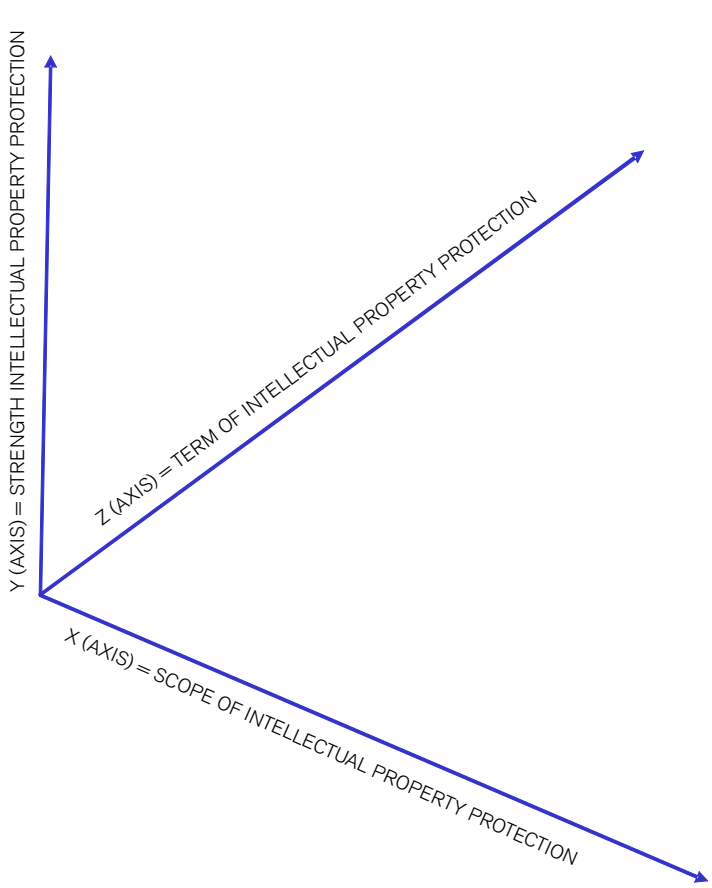
A third element crucial to international IP agreements is enforcement. Here, one has to focus both on the domestic and international arenas. The former focuses on the need to provide civil, judicial and criminal procedures in order to prevent, or at least to inhibit, the infringement of IPRs. Common measures include injunctions—"to prevent the entry into channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right"—damages for injuries and the destruction of infringed goods without compensation of any sort.[9] Members of international IP agreements are also required to adopt adequate border measures aimed at preventing the importation and circulation of counterfeit and pirated IP-related goods. The establishment or designation of specialized IP courts is also becoming a prerequisite of the international regulation of IPRs.

In the international arena, it is important that IP agreements create or use special consultation and coordination bodies, as well as dispute settlement mechanisms, that are either shared by other fields of trade (such as the WTO-style of Dispute Settlement Body) or designated specifically for IPRs (such as the WIPO's Arbitration and Mediation Center).[10]

The level of protection in international IP agreements

It is possible, and even simpler than giving a written description, to geometrically portray the level of IP protection as a three-dimensional matrix (see Figure 1). This allows one to describe more accurately the process and patterns through which international IP agreements set or standardize the level of IP protection.

FIGURE 1: GEOMETRIC MEASUREMENT OF THE LEVEL OF IP PROTECTION



Source: Pugatch M P, "The international regulation of IPRs in a TRIPs and TRIPs plus world." *Journal of World Investment and Trade*, vol 6:3 (July 2005), pp. 430-465.

The first dimension (the X axis) focuses on the scope of protection: how wide is the market exclusivity granted by IP protection. For example, do international IP treaties and agreements differ in their approach to the issue of national and international exhaustion of IPRs and to the parallel trade of IP-related products?[11] To what extent do exclusive IP rights have to follow or comply with other international agreements that focus on competition rules or anti-competitive practices, as in the case of the WTO? Are specific forms of IPRs, such as patents, more narrowly or broadly defined in different international IP agreements at the multilateral and regional levels?

The second dimension (the Y axis) concerns the strength of exclusivity (or the degree of monopoly) granted by different international IP agreements. This dimension focuses not only on the strength of IP provisions per se but also on the ability of member countries to over-ride or bypass these provisions. For example, a celebrated case concerning the strength of copyright provisions focuses on the extent to which international IP treaties should incorporate cyber copyrights aimed at preventing the downloading of songs and movies via the Internet. It is fascinating to learn whether there

is a trend in international IP agreements (multilateral, regional and bilateral) to make the United States Digital Millennium Copyright Act (DMCA) the new standard level of copyright protection. The ongoing debate on pharmaceutical patents and access to medicines in LDCs is another notable example of the attempt to re-define the ability of member countries to override existing IP provisions. Specifically, this very complicated debate now focuses on the implementation of the WTO Decision of 6 December 2005 concerning the exportation of generic substitutes of patented medicines to countries with insufficient or no manufacturing capacities in the pharmaceutical sector (so-called WTO Paragraph 6 Agreement).[12]

International IP agreements are also measured by their ability to define or to create new forms of IPRs, thereby making the exclusive rights associated with these provisions much stronger and more dominant. One of the most interesting cases in this context is the extent to which trade secrets are treated as an independent and "stand-alone" form of IPRs. The strongest expression of this debate concerns pharmaceutical data exclusivity aimed at protecting and safeguarding the data submitted by pharmaceutical companies to regulatory authorities for the purpose of obtaining marketing approval for new drugs.[13] For example, TRIPs Article 39.3 does not currently specify the minimum or maximum period of data exclusivity to be required by WTO Members (the term of data exclusivity in Europe and in the United States is ten and five years, respectively). Secondly, Article 39.3 is not clear-cut, when referring to the use of such information by the authorities, particularly in cases of indirect reliance, as to when a Member country may choose to rely on the proprietary information of the original product in order to compare it to the chemical and toxic levels of a potential generic substitute (via bio-equivalency tests).

The third dimension (Z axis) focuses on the different periods of IP protection. The most natural and straightforward line of investigation is to track the different IP terms that are embedded in international IP agreements (twenty years for patents, fifty or seventy years for copyrights and an indefinite period for trademarks). However, a more interesting and subtle research would explore the extent to which different IP agreements enable (or even require) the extension of the basic term of protection, such as in the case of patents for pharmaceuticals and copyrights for artistic creations.

To sum up, an investigation of the ongoing trends in the international regulation of IPRs across the multilateral, regional and bilateral agreements should take into account both the structural framework of international IP agreements (national treatment, administrative procedures and enforcement mechanisms) and the level of IP protection as expressed by the scope, strength and term of IP rights.

Empirical discussion

The previous Sections of this paper have set the theoretical and structural context in which the international regulation of IPRs may be analysed. This section focuses on the empirical dimension.

The question that has tended to dominate research in this area in recent years focused on the extent to which regional and bilateral trade agreements (RTAs and FTAs) extend beyond the level of protection provided by the TRIPs Agreement (so-called TRIPs plus provisions). One can argue quite safely that since the year 2000 there has been growing evidence suggesting that RTAs or FTAs between the United States and the EU, on the one hand, and developing countries, on the other hand, have been based on TRIPs plus provisions, including those in the field of data exclusivity.

For example, a study carried out in 2002 by the Organisation for Economic Co-operation and Development (OECD) argued that most "RTAs dealing with intellectual property rights have more far-reaching provisions than those found in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights."[14] Similarly, a 2005 study by the World Bank found that "in investment and

intellectual property rights, North-South agreements have enjoyed considerable success in promulgating comprehensive new rules that go beyond multilateral agreements" and that the "embedded IPR in all FTAs are essentially 'TRIPs plus'."[15] Other studies have also reported on the various elements that are subject to TRIPs-plus provisions, such as patents, data exclusivity and copyrights.[16]

Identifying the ongoing trend towards TRIPs-plus agreements is a crucial and a fundamental element in the analysis of the international regulation of IPRs.

However, in this paper we seek to further analyze the TRIPs plus phenomenon – analyzing the differences between the United States and EU approaches in their attempts to strengthen the level of IP protection, especially *vis-à-vis* developing countries.

Second, the paper focuses on some specific IP characteristics of regional and bilateral trade agreements between developed and developing countries (in other words, "North–South" agreements), especially on elements that are particularly important to our understanding of the TRIPs plus phenomenon and its implications.

3. COMPARING UNITED STATES AND THE EUROPEAN UNION

When comparing regional and bilateral trade agreements between the United States and the EU, on the one hand, and developing countries, on the other hand, it is possible to highlight the following two conclusions:

- Both the United States and the EU secure a TRIPs plus level in their RTAs and FTAs with other countries.

- Hitherto United States-led agreements seem to be more effective, not least because they are much more detailed and comprehensive than EU-led ones—both in terms of the agreements' structural frameworks (i e enforcement, administration, etc) and their specific IP provisions.

It should be noted that there is a methodological problem in comparing United States-led and EU-led RTAs and FTAs. The former seems to be focused solely on commercial issues while the latter have a much broader political agenda that also focuses on foreign policy. Thus, a typical EU-led FTA (EU-Chile Free Trade Agreement) state that:

> *"The main objective of the political dialogue between the Parties is the promotion, dissemination, further development and common defence of democratic values, such as the respect for human rights, the freedom of the individual and the principles of the rule of law as the foundation of a democratic society."*

Nevertheless, since IPRs play an important part in EU-led FTAs, it is important to examine the issue isolated from the general context of such FTAs, if one is to objectively assess the effects of EU-led agreements on the international regulation of IPRs in developing countries.

The United States–the "nanny" approach

While the TRIPs Agreement is based on the "minimum-level" approach—specifying the minimum IP commitments of WTO Members, US-led RTAs and FTAs are in essence based on a "to-do-list" approach (some would argue, a "nanny" approach).

US-led RTAs and FTAs essentially identify specific IP amendments and actions that its trading partners should implement.

At the regional level, Chapter Fifteen of the Central American–Dominican Republic Free Trade Agreement (CAFTA–DR) of May 2004 is probably the clearest example of the manner in which the US pursues its TRIPs plus framework.[17]

The CAFTA–DR Agreement includes all three structural elements mentioned earlier in this paper: national treatment, enforcement and administrative provisions.

With regard to national treatment, Article 15.1(8) states:

> *"In respect of all categories of intellectual property covered in this Chapter, each Party shall accord to nationals of the other Parties treatment no less favourable than it accords to its own nationals with regard to the protection and enjoyment of such intellectual property rights and any benefits derived from such rights"(footnotes omitted).*

Article 15.1(9) allows Signatories to derogate (text language) from the principle of national treatment in cases where it

> *"is necessary to secure compliance with laws and regulations that are not inconsistent with this Chapter [15]" and when it "is not applied in a manner that would constitute a disguised restriction on trade."*

Enforcement requirements are specified in Article 15.11, including that:

> *"Final judicial decisions or administrative rulings of general applicability pertaining to the enforcement of intellectual property rights shall be in writing and shall state any relevant findings of fact and the reasoning or the legal basis on which the decisions and rulings are based."*
>
> *Each Party shall publicize information that it may collect on its efforts to provide effective enforcement of intellectual property rights.*
>
> *In civil, administrative, and criminal proceedings involving copyright or related rights, each Party shall provide that the person whose name is indicated as the author, producer, performer or publisher of the work, performance or phonogram in the usual manner shall, in the absence of proof to the contrary, be presumed to be the designated right holder in such work, performance or phonogram.*

CAFTA–DR requires its signatories to significantly strengthen their civil and administrative procedural remedies. Special attention is given to the authority of the courts to order infringers to pay compensation to right-holders on the basis of a coherent and transparent calculation that takes into account,

> *"inter alia, the value of the infringed-upon good or service based on the suggested retail price or other legitimate measure of value that the right holder presents."*[18]

Articles 26 and 27 require CAFTA–DR signatories to strengthen their criminal remedies—such as imposing "sentences of imprisonment or monetary fines, or both, sufficient to provide a deterrent to future acts of infringement"— to carry out independent criminal investigations "without the need for a formal complaint by a private party or rights holder" and to grant incentives to service providers (usually Internet providers) to co-operate with copyright owners in deterring the unauthorized storage and transmission of copyrighted material.

Similar to provisions at the regional level, comprehensive structural provisions for the strength-

ening of IP protection also exist at the bilateral level, such as in the United States–Chile FTA (2003), the United States–Singapore FTA (2003), the United States–Morocco FTA (2004), the United States–Bahrain FTA (2004), and, to some extent, the United States–Jordan FTA (2000).[19]

There is growing evidence that the United States-led FTAs are effective in terms of the ability to secure TRIPs plus provisions.

Countries such as Singapore,[20] Jordan and Bahrain have significantly strengthened their IP regimes.

Furthermore, an analysis of the so called "Special 301" Reports of the United States Trade Representative (USTR) further suggests that practical results in the level of IP protection are generally being secured under such RTAs and FTAs.[21] Section 301 (commonly referred o as Special 301) of the Trade Act of 1974, particularly after its amendment by the Omnibus Trade and Competitiveness Act of 1988, enables the USTR to identify Priority Foreign Countries, which according to US criteria, provide inadequate protection for IPRs, thereby causing the greatest adverse impact on rights holders. The 301 process can eventually lead to a situation in which the US may take unilateral actions and possibly impose sanctions against countries that were found to be strong violators of IP rights. The Special 301 lists include two additional categories—Priority Watch List and a Watch List—for countries whose actions meet some, but not all, of the criteria for identifying priority foreign countries. Countries placed on the Priority Watch List are the focus of increased bilateral attention concerning the problem areas.

Generally speaking the US approach does seem to provide more concrete results with regard to the level of IP protection secured at the bilateral level. In fact, it is possible to use the 301 lists to examine the extent to which United States-led FTAs have been effective in strengthening the level of IP protection in the destination countries:

> Qatar – was placed in 2002 under the category of Watch List and has been removed from the list in 2003.
>
> Dominican Republic – was placed in 2002 under the category of Priority Watch List and has been downgraded to the status of Watch List in 2004, given the strengthening of its IP regime.
>
> Kuwait – has been downgraded to the status of Watch List in 2006, given the strengthening of its IP regime (the United States and Kuwait signed the Trade and Investment Framework Agreement in February 2004).
>
> Guatemala – has remained under the Watch List category, though the USTR report for 2006 suggests that Guatemala has made progress in meeting its obligations under the CAFTA–DR.[22]
>
> Chile – which marks the exception to the above, has remained under the Watch List category, though the USTR report for 2006 suggest that Chile did not meet its FTAs obligations.[23]

The November 2006 United States–Russia Bilateral Market Access Agreement on Intellectual Property Rights further demonstrates the ability of the United States to secure a stronger commitment[24] for the protection of IPRs by its trading partners. One just needs to look at the detailed "Action list of Critical IPRs Issues" to understand how detailed the US demands are.[25]

Moreover the United States President's 2007 Trade Policy Agenda provides an even greater emphasis on the protection of IPRs at the regional and bilateral levels, *inter alia* using the 301 process:

> *"In the area of intellectual property, the President's trade policy will continue to recognize the fundamental role of American creativity and innovation in sustaining the nation's economic strength. Faced with the burgeoning global problem of counterfeiting and piracy, the Administration will work with other countries to strengthen IPR protection and enforcement… The "Special 301" process is an essential element in the ability of the United States to engage these and other trading partners, and the Administration will be intensifying its efforts in constructive engagement with the trading partners listed in the annual Special 301 report with the goal of helping these trading partners to achieve stronger IPR regimes."*

EU–the "generalist" approach

Compared to those of United States agreements, the IP provisions of new-generation FTAs (so called Association Agreements) between the EU and developing countries are much more general and less issue-specific.

A typical EU-led FTA, such as the EU–Israel FTA (2000), the EU–Chile FTA (2002), the EU–Jordan FTA (2002) or the EU–Mexico FTA (2001–2002) includes two general provisions: "Objective" and "Scope."

The "Objective" provision requires signatories to "*grant and ensure adequate and effective protection of the highest international standards including effective means of enforcing such rights*."[26] The "Scope" provision enumerates the different forms of IPRs that the FTA covers, such as copyright, patents, industrial designs, geographical indications (GIs), trademarks and layout-designs (topographies) of integrated circuits, and the protection of undisclosed information.[27]

Instead of specifying the IP requirements that signatories should implement (as in the United States model), EU-led FTAs specify the different agreements and treaties signatories should implement.

Typical EU-led FTA, such as those mentioned above, require its signatories to implements different international agreements, treaties and conventions based on three levels of expectations.

The first level relates to international conventions that require "*adequate and effective implementation*"—such as the TRIPs Agreement, the Paris Convention for the Protection of Industrial Property (Stockholm Act, 1967); the Berne Convention for the Protection of Literary and Artistic Works (Paris Act 1971); the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (Rome, 1961) and the International Convention for the Protection of New Varieties of Plants 1978 (the 1978 UPOV Convention) or the International Convention for the Protection of New Varieties of Plants 1991 (the 1991 UPOV Convention.

The second level relates to conventions that should be implemented and ratified by the years 2007 and 2009—such as the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of Registration of Marks (Geneva Act, 1977, amended in 1979); the World Intellectual Property Organization Copyright Treaty (Geneva, 1996); the Patent Cooperation Treaty (Washington, 1970, amended in 1979 and modified in 1984); and the Convention for the Protection of Producers of Phonograms against the Unauthorized Reproduction of their Phonograms (Geneva 1971).

The third level concerns agreements that require implementation at "*the earliest possible opportunity*"—such as the Protocol to the Madrid Agreement concerning the International Registration of Marks (1989); the Madrid Agreement concerning the International Registration of Marks (Stockholm Act 1967, amended in 1979); and the Vienna Agreement establishing an International Classification of Figurative Elements of Marks (Vienna 1973, amended in 1985).

Finally, unlike the United States model, EU-led FTAs do not have specific IP provisions that deal with enforcement, civil and criminal remedies, or administration. Some EU-led agreements, such as the EU–Jordan FTA, have a consultation mechanism, according to which:

> *"If problems in the area of intellectual, industrial and commercial property affecting trading conditions were to occur, urgent consultation shall be undertaken, at the request of either Party, with a view to reaching mutually satisfactory solutions."*[28]

As will be discussed later, it would seem that, given its generalist approach, the EU finds it difficult to ensure that its trading partners implement their IP commitments, and also to successfully track their progress.

However, there are specific cases in which the EU went beyond the above pattern to demand a higher level of IP protection from its trading partners, a standard, which will be based on that of the EU. For example, the Partnership and Co-operation Agreement (PCA) between the EU and Ukraine (1998) requires that the latter would implement IP protection standards similar to those existing in the EU by the end of 2003:

> *"Pursuant to the provisions of this Article and of Annex III, Ukraine shall continue to improve the protection of intellectual, industrial and commercial property rights in order to provide, by the end of the fifth year after the entry into force of the Agreement for a level of protection similar to that existing in the Community, including effective means of enforcing such rights."*

More importantly, the European Commission, perhaps being mindful of the EU's weakness in this field, is becoming more proactive in the international enforcement of IPRs. This can be seen in both the EU enforcement strategy of 2004 and in the EU's IP objectives under the so-called "Global Europe" initiative of 2006. Both are discussed below.

A) Strategy for the enforcement of IPRs in third countries

In June 2004, the European Commission issued its new proposed strategy for the enforcement of IPRs in third countries.[29] The new EU IP enforcement strategy was officially launched on 10 November 2004 and advocated by Trade Commissioner Pascal Lamy.[30] Among other things, the Commission seeks to make more active use of the EC's Trade Barriers Regulation mechanism in cases where the IP interests of European right-holders are compromised:

> *"No rule can be really effective without the threat of a sanction. Countries where IP violations are systematic could be publicly identified. As a last resort, consideration should be given to resorting to dispute settlement mechanisms provided for in multilateral and bilateral agreements. The existing Trade Barriers Regulation (TBR) mechanism could be a starting-point."*[31]

Indeed, EU officials involved in the making of the above strategy argue that the:

> *"Enforcement Strategy aims to contribute to improving the situation in third countries by ensuring that right-holders are effectively protected against the misappropriation of their property, and citizens in general are protected against the dangers of piracy and counterfeiting."*[32]

An example of the use of this strategy (or at least of a more active EU action on IPRs) is provided later in this article with regard to the case of Turkey and pharmaceutical data exclusivity. Another example, also related to pharmaceutical IPRs, concerns the European Commission's ongoing dispute with the Government of Israel. According to the EU, Israel's policies and legislation in this area run contrary to its obligations under the EU–Israel FTA of 2000.[33]

Another expression of the shift in the EU's approach towards on-the-ground implementation is the EU–Russia agreement on the Common Economic Space. The Roadmap on the Common Economic

Space was adopted at the EU–Russia Summit in Moscow on 10 May 2005. The document sets out a number of principles and priority activities. With regard to IPRs, the EU states that the:

> *"enforcement of IPR (Intellectual Property Rights) is the central focus point of the dialogue, which fosters closer cooperation of customs, police, administrative and judiciary bodies to ensure that rights-holders benefit from effective protection of their rights. It also encompasses exchange of information on strategies to fight against counterfeiting and piracy."*[34]

B) The Global Europe framework

In October 2006, the EU Trade Commissioner, Peter Mandelson tabled a new trade policy strategy of DG Trade.[35] Linking this strategy to the Lisbon Agenda (which seek to make the EU the most competitive building block in the world by 2010), Mandelson emphasized five elements[36] and highlighted the need to protect IPRs, as well as setting out priority countries for IP enforcement and co-operation, as one of the key strategies of DG Trade,

As discussed in the following section, a closer look at the IPR elements in the new Global Europe framework suggests that the DG Trade tends to admit that its IP-trade policy strategy has not been as effective as hoped. For example, in a working paper accompanying the Global Europe strategy paper, the European Commission argues:

> *"Other priorities include ASEAN, Korea, Mercosur, Chile, Russia and Ukraine which present high levels of production, transit and/or consumption of IP infringing goods. The latter three countries have already committed to adopt the highest standards of IPR enforcement in bilateral agreements with the EU; they need to step-up their efforts and tackle serious deficiencies."*[37]

As such the EU sets more specific objectives with regard to the international regulations of IPRs via FTAs (one could argue that such measures seek to partially emulate United-States-led FTAs). According the Global Europe framework, the EU

> *"should seek to strengthen IPR provisions in future bilateral agreements and the enforcement of existing commitments in order to reduce IPR violations and the production and export of fake goods."*[38]

4. MANIFESTATION OF *TRIPS PLUS* PROVISIONS IN US-LED AND EU REGIONAL AND BILATERAL AGREEMENTS

This section focuses on the practical translation of TRIPs plus provisions in US-led and EU-led regional and bilateral agreements, and compares the effectiveness of the two approaches.

There are three types of knowledge subjects (or fields of technology) that are part of a significant strengthening of IPRs:

- Pharmaceutical IPR ~~da~~ta exclusivity for regulatory data and patents for pharmaceutical products.

- Copyrights and related rights for artistic works and creations (music, software, books, etc).

- Trademarks and geographical indications (GIs) as information for consumers of goods and services.

Pharmaceutical IPRs

Data Exclusivity

Pharmaceutical IPRs remain the most politically contested subject. It would seem that since the TRIPs Agreement came into effect the issue of access to patented medicines in developing and least developed countries has been high on the agenda—at times, the only item on the negotiation table. In fact, since the end of 1999—following the failure of the Seattle WTO Ministerial Conference and the much-debated case of the dispute over patented Aids medicines in South Africa[39]—the TRIPs Agreement has become more or less synonymous with pharmaceutical patents. The debates on pharmaceutical IPRs remain so heated that this it has temporarily paralyzed the TRIPs Agreement as a vehicle for negotiation, amending and expanding other forms of IPRs.

At the same time US-led FTAs and RTAs have strengthened the IP provisions of pharmaceutical products and regulatory information to an extent that they may be considered "TRIPs-plus-plus" provisions.

Data exclusivity is one of the most burning issues in the current discussion on pharmaceutical IP policy-making. In brief terms, data exclusivity is aimed at protecting and safeguarding pharmaceutical registration files—the data submitted by pharmaceutical companies to regulatory authorities, such as the United States Food and Drug Administration and the European Agency for Evaluation of Medicinal Products (EMEA), for the purpose of obtaining marketing approval for new drugs.[40]

Proponents of data exclusivity consider it an integral and inseparable part of the array of IP protections of pharmaceutical products, while its opponents argue that data exclusivity is a monopolistic extension of the patent system.

The underlying logic of data exclusivity suggests that it is an expression of trade secrets and that it should be independent of patents. Compared with patents, the market power of data exclusivity is, in theory, less restrictive, mainly because it does not legally prevent other companies from generating their own registration data. However, in practice, the vast financial resources and extended time required for gathering and generating pharmaceutical registration data for a new drug create a market barrier that is too high for generics-based pharmaceutical companies.

The data included in the registration file of a pharmaceutical product is disclosed to the health regulatory authorities. Without this data, a drug cannot be approved for market use. This implies that the term "unfair commercial use" in this context is linked to the responsibility of governments to protect this data.

There are two layers to this responsibility. The first—non-disclosure—is quite straightforward. Non-disclosure aims to ensure that rival companies (usually generics companies) do not gain access to the registration file of the original product.

The second layer—non-reliance—is less obvious. Non-reliance aims to prevent the authorities themselves from relying on the registration file of an original in order to compare it to the chemical and toxic levels of a potential generic substitute (so-called bio-equivalence tests). The issue of non-reliance can be further complicated by the issues of direct and indirect reliance or active and passive reliance. Suffice it to say that, while the United States and the EU take the position that any form of reliance is prohibited, some countries, such as Canada, argue that the term reliance is subject to interpretation.

Internationally, the distinction between patents and data exclusivity as an expression of trade secrets (or undisclosed information) is based, *inter alia*, on the provisions of NAFTA Article 1711 and the TRIPs Agreement. TRIPs Article 39.3 states that:

> *"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed*

> *test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use."*

However, TRIPs Article 39.3 leaves three major issues unresolved. First, it does not specify the minimum period of data exclusivity required of WTO Members; as discussed below, the term of data exclusivity in Europe and in the United States is ten and five years, respectively. Second, Article 39.3 is not clear-cut, when referring to the use of such information by the authorities, particularly in cases of reliance, as to when a Member country may choose to rely on the proprietary information of the original product in order to compare it to the chemical and toxic levels of a potential generic substitute (via the so-called bio-equivalence tests). Finally, it is not clear what types of activities are within the scope of "considerable efforts."

In contrast, the two existing prototypes of data exclusivity at the national level are those of the United States and the EU. Data exclusivity in the United States is provided for by Section 355 of the Federal Food, Drug, and Cosmetic Act of 1997.[41] The United States model provides a five-year period of data exclusivity to new drugs and three years of data exclusivity to new indications of existing drugs. In December 2003, the European Parliament harmonized and upgraded Directive 2001/83/EC in order to provide a data exclusivity period of ten years (or more accurately adopted the "8-plus 2-plus 1" formula: 8 years data exclusivity, 2 years of marketing exclusivity and an additional year of protection for new indications of existing products).[42]

Coming back to the regional and bilateral level, it is very clear that in the case of data exclusivity the United States is *the demandeur*. The current international standard for the protection of data exclusivity—as set by FTAs and RTAs between the United States and developing countries—is based on the United States standard of protection. To recall a few examples, Article 15.10 of the CAFTA–DR requires the establishment of data exclusivity legislation consisting of a minimum five-year protection period, non-disclosure and non-reliance, including cases in which marketing authorization was granted to a third party in another country.[43] Article 17.10 of the United States–Chile FTA (2003) places similar mechanisms of data exclusivity (five years of protection and non-reliance/non-disclosure), as does Article 16.8 of the United States–Singapore FTA (2003) and Article17.1 of the United States–Australia FTA (2004).[44]

The United States is also using the threat of trade retaliation against developing countries, in which the absence of data exclusivity legislation results in a serious commercial clash between the local subsidiaries of research-based multinational pharmaceutical companies and powerful local generics-based companies that are often perceived as "national champions."

The EU, on the other hand, seems to avoid referring to the issues of data exclusivity in its bilateral and regional negotiations. This is somewhat surprising given the fact that the level of EU data exclusivity is much higher than that of the United States.

In this context the case of Israel is of particular interest, since it allows us to compare the extent to which the United States and the EU are able to secure *TRIPs plus* results using their different approaches to the international regulation of IPRs.

The 1985 FTA between the United States and Israel, which was the first FTA to be concluded by the former, does not refer to IPRs.

On the other hand, as noted above, the EU–Israel FTA, which entered into effect in 2000, requires the parties to "*grant and ensure adequate and effective protection of the highest international standards including effective means of enforcing such rights.*" Nevertheless the EU–Israel FTA did not seem to have any effect on the issue of data exclusivity in Israel. The local generic pharmaceutical industry in Israel is highly successful both locally and internationally. Indeed, Teva is the biggest

multinational generic pharmaceutical company in the world. Thus, despite its FTA with the EU, and given its non-IP commitments in the US-FTA, Israel refused to introduce data exclusivity in its legislation, arguing that its refusal to do so is not inconsistent with the obligations of TRIPs Art 39.3 (see discussion above).

Consequently, the absence of data exclusivity legislation in Israel became one of the major commercial disputes between the United States and Israel.[45] The ongoing pressures on the Government of Israel by the United States resulted in the establishment of an inter-Ministerial committee for the enactment of a data exclusivity bill. The inter-Ministerial committee issued its recommendations in February 2004, and the Government approved these recommendations in September 2004.[46] However, the USTR argued that the proposed bill does not meet the minimum United States standard. In 2005 the USTR placed Israel in its Priority Watch List arguing that

> *"Based on Israel's implementation of an inadequate data protection regime, as well as its apparent intention to pass legislation to weaken patent term adjustments, Israel is being elevated to the Priority Watch List."*[47]

Similar language was expressed in the USTR 301 report for 2006. The EU has also expressed similar concerns:

> *"Israel, as a Member of the WTO, was required to fully implement the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) no later than on 1.1.2000 … The proposed (data exclusivity) legislation nevertheless falls short of both European industries and the European Commission's expectations."*[48]

The case of the FTA between the EU and Ukraine further suggests that the EU's approach towards the protection of IPRs at the bilateral level does not currently secure the EU's objectives to the full. In its Trade Barrier Report of May 2006, the European Commission notes:

> *"The Commission is still concerned about the situation in Ukraine. While Ukraine has made considerable progress in adopting a legislative framework that complies with the requirements of TRIPS and the EU–Ukraine Partnership and Co-operation Agreement (PCA), the lack of enforcement of IPR and, resulting thereof, the high level of piracy and counterfeiting, remains a real concern for the EU and its enterprises."*[49]

A notable exception to the EU's rather lax approach in this regard is the launch of an investigation by the European Commission against Turkey in December 2003, following a complaint by the European Federation of Pharmaceutical Manufacturers and Associations (EFPIA). The investigation concerns obstacles to trade allegedly caused by Turkish practices and measures involving lack of transparency and discriminatory application of the pharmaceutical import, sales and marketing system, including a "lack of protection of commercially sensitive data submitted as part of the marketing approval procedure."[50]

Pharmaceutical patents

It would seem that the multilateral level (i e the TRIPs Agreement) and the bilateral and regional levels are subject to opposite trends. On the one hand, since the year 2000 the TRIPs patent regime has become weaker. The 2001 Doha Declaration on the TRIPs Agreement and Public Health led to a reduction in the protection of patented medicines.[51]

Specifically, paragraph 5(b) and (c) of the Declaration allows WTO Members to use compulsory licences, without pre-conditions, in times of national emergency (to be determined by each and every Member). Paragraph 5d re-affirms the right of WTO Members to adopt the principle of international exhaustion, i e to deal with the parallel importation of patented medicines. Also, paragraph 7 grants LDCs an additional period of ten years to implement their patent obligations under the TRIPs Agreement—i e up to January 2016.

The Doha Declaration on the TRIPs Agreement and Public Health also acknowledged that countries with insufficient manufacturing capabilities would not be able to use the tool of compulsory licences that would allow local companies to manufacture original patented drugs. It instructed the Council for TRIPs to find an expeditious solution to this problem by the end of 2002. In reality, it took the WTO almost two years of political negotiations to reach a solution on this issue—the Decision of the General Council of 30 August 2003 on Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health.[52] Finally, on 6 December 2005 (slightly ahead of the Ministerial Meeting in Hong Kong) WTO members agreed to embed the paragraph 6 amendments into the TRIPs Agreement (via the creation of a new article—TRIPs 31*bis*).[53]

On the other hand, and in quite stark contrast, United States-led FTAs and RTAs establish a level of pharmaceutical patent protection that is much higher than the level provided by the TRIPs Agreement, including in the following areas.

Article 15.9(5) of the CAFTA–DR) impose restrictions on signatories' patent laws permitting commercial experiments in patented pharmaceutical drugs as part of the process of obtaining marketing approval for a generic substitute (so called "Bolar" provisions). These restrictions aim to prevent any local interpretation that would allow generics-based companies to produce or to market, domestically and abroad, any substitutes to the original prior to patent expirations.

It should be noted that these restrictions stem from the results of the highly celebrated patent dispute between the EC and Canada on the issue of commercial testing of patented pharmaceutical products.[54]

United States-led FTAs and RTAs allow pharmaceutical patent owners to extend the term (period) of their patent protection in two cases. First, they may do so if there is an unreasonable delay in the process of granting a pharmaceutical patent by the authorities. An unreasonable delay is usually defined as a "delay in the issuance of the patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made…"[55] The term of patent protection may be extended in a case where there is "unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product."[56] In other words, if there is an unreasonable delay in the process of authorizing a patented drug for market use, which, in turn, shortens the effective term of protection, the patent owner should be compensated by extending the patent term. There are no specific definitions in United States-led RTAs and FTAs about the minimum or maximum extension periods in this case. One has to bear in mind that a pharmaceutical patent may be extended in Europe and in the United States by an additional period of up to five years. In the EU, Regulation EC 1768/92 allows a pharmaceutical company to extend the term of its patent by an additional period of up to five years as long as the effective patent life does not exceed fifteen years from the date of marketing authorization (this mechanism is called a Supplementary Protection Certificate).[57] In the United States, the 1984 Drug Price Competition and Patent Term Restoration Act (known as the Hatch-Waxman Act) increased the effective patent term of protection by an additional maximum period of five years.[58] These policies aim to allow originators to extend the effective term of patent protection for a new pharmaceutical product given the gap between the time a patent is granted for a new molecule and the time the drug is authorized for marketing.

Some FTAs[59] grant pharmaceutical patent owners the right to prevent parallel trade in patented pharmaceutical products. Activity of such kind relates mostly to the importation of patented pharmaceutical products from low-price countries into high-price countries through channels other than those authorized by the local patentee or licensee. As stated in Article 16.7(2) of the United States–Singapore FTA:

> *"Each Party shall provide a cause of action to prevent or redress the procurement of a patented pharmaceutical product, without the authorization of the patent owner, by a party who knows or has reason to know that such product is or has been distributed in breach of a contract between the rights holder and a licensee, regardless of whether such breach occurs in or outside its territory. Each Party shall provide that in such a cause of action, notice shall constitute constructive knowledge."*

This is a significant element, which contradicts the principle of international exhaustion of IPRs outlined in the TRIPs Agreement.

In order to make the global parallel import of patented pharmaceuticals (or any other patented products) legal, countries must adopt the principle of international exhaustion. Specifically, they must enter into an agreement stating that once a patentee has sold his product in one country he has exhausted his right to prevent the resale of that product to other countries. Though not explicitly recognizing the principle of international exhaustion, the TRIPs Agreement essentially allows for parallel imports to take place under its newly established IP regime. It does so by denying Members the possibility of bringing cases concerning international exhaustion to the Dispute Settlement Body. As stated in TRIPs Article 6:

> *"For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 [National Treatment and Most-Favoured-Nation Treatment] nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."*

The TRIPs Agreement also links Article 6 to Article 28 (exclusive patent rights) via a footnote to the latter stating:

> *"This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods is subject to the provisions of Article 6."*

As previously explained, the ability of WTO Members to adopt a regime of parallel imports was further strengthened by the Doha Declaration on the TRIPs Agreement and Public Health.

With regard to the EU approach to patented pharmaceuticals, as in the case of data exclusivity, EU-led RTAs and FTAs do not deal much with this issue.

Copyrights and trademarks

United States-led FTAs and RTAs pay specific attention to copyright provisions, perhaps more than to any other IP form, even patents. Although it is not possible to examine in this article all the aspects that concern copyrights and related rights, this section highlights some of the major provisions in United States-led FTAs and RTAs.

Copyrights

United States-led FTAs and RTAs increase the level of copyright protection established by the TRIPs Agreement by incorporating the following provisions and requirements.

They strengthen the ability of copyright holders to prevent the reproduction of their works "in any manner or form, permanent or temporary (including temporary storage in electronic form)". The term "electronic form", which is included in various United States-led FTAs and RTAs, is of particular importance, as it allows rights holders to control (prevent) the reproduction of their work—such as software—via temporary electronic copies, subject to some exemptions that do not unreasonably conflict with the commercial interests of the rights holders and do not conflict with the normal exploitation of the work.[60]

Further, the United States-led FTAs and RTAs extend the term of copyright protection to a period that is equal to the author's life plus seventy years from the time of his or her death or, in cases of works generated by legal entities (such as software), the period is set to seventy years from the end of the calendar year of the first authorized publication of the work.[61] In comparison, the related copyright terms in TRIPs Article 12 are calculated on the basis of fifty years.

These FTAs and RTAs (such as Article 15.5(6) of the CAFTA–DR) also set strict rules against the circumvention of technological protection measures (TPMs) and digital rights management (DRMs) used by authors, performers and producers of phonograms or any means employed to protect their copyrighted works. These provisions are based on the Digital Millenium Copyright Act (DMCA, adopted by the United States Congress in 1998.[62]

Further obligations concerning copyrights and related rights include provisions of rights management information, protection of satellite signals and internal domain names.

The EU, in comparison, adheres to the multilateral approach. As mentioned earlier in this article, a typical EU-led FTA requires signatories "*to accede to and to ensure an adequate and effective implementation of the obligations arising from the following multilateral conventions*" including the WIPO Copyright Treaty of 1996 and the WIPO Performances and Phonograms Treaty of 1996, by January 2007, and the Convention for the Protection of Producers of Phonograms against the Unauthorized Reproduction of their Phonograms of 1971, by January 2009.[63]

Trademarks

Compared with the TRIPs Agreement, United States-led FTAs and RTAs expand the level of trademark protection by doing the following.

They expand the types of identifying marks that are eligible for trademark registration. For example, Article 15.2(1) of the CAFTA–DR states, that *"each Party shall provide that trademarks shall include collective, certification and sound marks, and may include geographical indications and scent marks."* Similar provisions exist in the United States–Chile FTA (Article 17.2(1)); the United States–Singapore FTA (Article 16.2(1)); and the United States–Jordan FTA (Article 4.6).

United States-led FTAs and RTAs also strengthen the demand that a trademark shall not be unjustifiably encumbered by special requirements, such as use with another trademark or use of the trademark in a special form or manner. This requirement, which is particularly relevant to branded pharmaceutical products, builds on Article 20 of the TRIPs Agreement. Pre-TRIPs legislation concerning the labelling of branded pharmaceutical products in several developing countries, such as Brazil, required that the size of the trademark would be smaller than the name of the generic substance. Alternatively, countries required that the packaging of such products would be of a certain colour, effectively making the trademark much less recognizable. Therefore, TRIPs Article 20 prohibits activities aimed at reducing the distinctiveness of branded pharmaceutical products, as opposed to generic ones. However, in cases where foreign branded products are produced locally, Article 20 does allow WTO Members to demand that the trademarks of such products be accompanied by the names of local producing companies.

The wording of the provisions of FTAs and RTAs place further restrictions on such requirements by stating that:

> *"Pursuant to Article 20 of the TRIPS Agreement, each Party shall ensure that its provisions mandating the use of a term customary in common language as the common name for a product including, inter alia, requirements concerning the relative size, placement, or style of use of the trademark in relation to the common name, do not impair the use or effectiveness of a trademark used in relation to such products."*[64]

However, these provisions also usually state that they are not intended to affect the use of common names of pharmaceutical products in prescribing medicine, i e preventing physicians from using the common pharmaceutical name (usually by stating the active ingredient) when prescribing a drug.

The United States-led FTAs and RTAs extend the renewal period of trademark registration to a period of not less then ten years (as a standard, trademarks can be reviewed indefinitely). The renewal period in TRIPS Article 18 is not less then seven years.

These FTAs and RTAs also strengthen the protection of well-known marks[65]

Interestingly, while the EU takes its usual generalist approach in the case of trademarks, referring to the need to adhere to multinational treaties, it is much more specific on the issue of GIs.

For example, Roffe finds that, as regards the EU–Chile FTA:

> *"... probably, the most significant intellectual property related provisions are contained in Annex V, on the 'Agreement on the Trade in Wines' and Annex VI concerning Spirits. These annexes include provisions on the reciprocal protection of geographical indications related to wines and spirits, and the protection of traditional expressions [of both Parties]."*[66]

He concludes that

> *"the Association Agreement between Chile and the EU is also a TRIPs plus Agreement especially on the protection of geographical indications."*[67]

Based on the above analysis, *Table 1* (see page 20) compares United States-led and EU-led regional and bilateral agreements. As explained in Section II, above, comparison is based on structural elements (enforcement and administration) and the level of IP protection (scope of monopoly, strength of monopoly and term of protection). The Table uses the TRIPs Agreement as the base line and attaches ordinal values to the different agreements. Ordinal values vary between 1 (TRIPs plus), 0 (TRIPs) and -1 (less then TRIPs).

TABLE 1: LEVEL OF IP PROTECTION IN UNITED STATES-LED AND EU-LED REGIONAL AND BILATERAL AGREEMENTS AS COMPARED TO PROTECTION UNDER THE TRIPS AGREEMENT

	UNITED STATES -LED FTAS AND RTAS	EU-LED FTAS AND RTAS
Approach to the protection of IPRs	*To-do-list "nanny approach"*	*Generalist–incorporating international treaties*
New "standard" agreement of IP protection	*Chapter 15 of the* Central American-Dominican Republic Free Trade Agreement- (CAFTA–DR) *(2004); United States–Chile* FTA *(2003), the United States–Singapore* FTA *(2003), the United States–Morocco* FTA *(2004), the United States–Bahrain FTA (2004), and, to some extent, the United States–Jordan* FTA *(2000).*	*Association Agreements, such as, the Euro-Mediterranean Association Agreements (2002) the EU-Chile FTA (2002), and the EU–Ukraine Partnership and Co-operation Agreement (*PCA*) (1998);* EU–Russia agreement on the Common Economic Space (2005)
Enforcement provisions	*1*	*No reference (with the exception of Ukraine and Russia)*
Administration procedures	*1*	*No reference*
Data exclusivity (pharmaceuticals)	*Scope of Monopoly = 1* *Strength of Monopoly = 1* *Term of Protection = 1*	*Scope of Monopoly = 0* *Strength of Monopoly = 0* *Term of Protection = 0*
Patents (pharmaceuticals)	*Scope of Monopoly = 1* *Strength of Monopoly = 1* *Term of Protection = 1*	*Scope of Monopoly = 1** *Strength of Monopoly = 0* *Term of Protection = 0*
Copyrights	*Scope of Monopoly = 1* *Strength of Monopoly = 1* *Term of Protection =1*	*Scope of Monopoly = 1** *Strength of Monopoly = 1** *Term of Protection = 0*
Trademarks	*Scope of Monopoly = 1* *Strength of Monopoly = 1* *Term of Protection =1*	*Scope of Monopoly = 1** *Strength of Monopoly = 0* *Term of Protection = 0*
Geographical Indications	*Scope of Monopoly = 0* *Strength of Monopoly = 1* *Term of Protection =1*	*Scope of Monopoly = 1* *Strength of Monopoly = 1* *Term of Protection = 1*

-1 = Level of protection less than that of the TRIPs Agreement ; 0 = Level of protection equal to that of the TRIPs Agreement; 1 = TRIPs -plus level of protection.

* By reference to international treaties, not to the TRIPs Agreement.

Source: Pugatch (2005).

5. CONCLUSIONS AND POLICY RECOMMENDATIONS

Based on this analysis above, the paper finds the following:

1. Both the United States and the EU secure a *TRIPs plus* level in their RTAs and FTAs with other countries.

2. However, United States-led agreements are much more detailed and comprehensive than EU-led ones, both in terms of the agreements' structural frameworks (i e enforcement, administration, etc) and the level of IP protection (relating to the different forms of IPRs). With regard to the interpretation of specific IP provisions, the United States is employing a more "hands-on" strategy with regard to the international regulation of IPRs at the regional and bilateral level.

3. The EU's tendency to incorporate international conventions and treaties into its regional and bilateral agreements suggests that it still favours the multilateral approach. That said, on the issue of GIs, the EU's approach is more proactive and specific, hence closer to the United States approach.

4. FTAs and RTAs led by the United States are showing growing evidence of effective results. This can be seen in the cases of Singapore, Jordan and Bahrain and also to some extent in the cases of Qatar, the Dominican Republic, Guatemala and Kuwait. The exception in the case is Chile, which according to the USTR does not implement the IP provisions specified in its FTA.

5. In contrast, when put to the test of practical implementation, the EU's approach towards the establishment of TRIPs plus provisions is not particularly effective. This can be seen in the cases of Israel, the Ukraine, Russia and Chile.

6. The European Commission, perhaps being mindful of the EU's weakness in this field, seems to become more proactive in the international regulation and enforcement of IPRs. This can be seen in the Strategy for the Enforcement of IPRs in Third Countries, which was officially launched in November 2004, and in the EU' IP objectives under the Global Europe Initiative of October 2006.

The analysis above also leads to five key policy recommendations:

1. The *TRIPs plus* phenomena are too broad and deep to be addressed by general and, to some extent, vague concepts, such as the term "highest international standards" that frequently appears in EU-led FTAs. The rising increase in the importance of IPRs and the rapid pace of technological advancement across the board requires that *TRIPs plus* agreements become much more specific and accurate. In this context United-States led-FTAs seem to be a more appropriate framework for the execution of such agreements.

2. Consequently the EU needs to both broaden the use of its new IP Enforcement Strategy in Third Countries, as well as to consider shifting to agreements that are more specific in terms of their IP demands. In this context the 2006 Global Europe initiative is a step in the right direction.

3. Stronger collaboration and coordination is needed between the United States and the EU with regard to international regulation of IP agreements. With the on-going comma-like status of the multilateral level (WTO TRIPs agreement), the two major trading blocs should further co-ordinate their efforts.

   Co-ordination and collaboration are important with regard to countries that have not yet concluded their IP negotiations neither with the United-States or the EU, especially dominant countries such as India and China. They may also be effective for countries that do not have FTAs that address IP issues with the United States, on the one hand, and which seem to attach a "flexible" interpretation to the IP level provided by their FTAs with the EU, on the other hand. It should be noted that such collaboration is starting to take place. The

European Commission argues that *"In parallel, the Commission's presence in China has been reinforced; we have launched a joint programme of co-operation on IPR enforcement with the US and have an IP Dialogue with Japan."*[68]

4. There is a greater need to strengthen the mandate of the monitoring and enforcement committees established under United-States and EU-led FTAs in order to ensure that such agreements are better implemented.

5. Politically speaking, and paradoxically as it may sound, countries that wish to have a lower level of IP protection than the one provided under the current FTAs should strive to make the TRIPs Agreement stronger rather than "celebrate" its flexibilities.

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ENDNOTES

1. For a discussion on the economic of IPRs see Hindley (1971); Pugatch (2004).

2. Reichman (1998). The above quote appears in p 583.

3. Oxfam (2006).

4. Pugatch, M P (2005).

5. For an in-depth historical review of the Paris Convention, see Penrose (1951), chapters 3 and 4; Ladas (1975), chapter 4.

6. The PCT makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application. For an overview of the PCT, see the WIPO Website.

7. UNCTAD (1996), pp 19-26; ESCWA (1998), pp 15-20.

8. One of many good examples concerning technical assistance is the WIPO's division on small and medium size enterprises (SMEs); Also see the EU's development website; and the United States trade representative trade capacity building website.

9. See TRIPs articles 41–61 for the enforcement of IPRs, and TRIPs article 64 for dispute settlement.

10. For more information on the WIPO's arbitration and mediation center, see the WIPO website.

11. For the issue of international exhaustion of patent rights, see Abbott (1998), pp 607–636.

12. WTO (2005a).

13. WTO (1994), TRIPs article 39.3.

14. OECD (2002).

15. World Bank (2004).

16. Pugatch (2005); Abbott (2004); Vivas-Eugui (2003); Roffe (2004).

17. CAFTA–DR (2005), chapter 15, "Intellectual property.".

18. Ibid, Article 15.1(7)(b).

19. United States–Chile free trade agreement (2003); United States–Singapore free trade agreement (2003); United States–Morocco free trade agreement (2004); United States– Bahrain free trade agreement (2004); United States–Jordan free trade agreement (2000).

20. For the case of Singapore see IPOS website.

21. USTR, website.

22. USTR (2006a).

23. Ibid.

24. US–Russia (2006).

25 Russia–WTO (2006).

26. EU–Israel Association Agreement (2000); EU–Chile Association Agreement (2002); EU–Jordan Association Agreement (2002); EU–Mexico economic partnership, political coordination and cooperation agreement (2000).

27. Ibid.

28. EU–Jordan Association Agreement (2002), Article 56.

29. European Commission (2004).

30. Lamy (2004). European Commission, Directorate General for Trade, EU Strengthens Fight Against Piracy and Counterfeiting Beyond its Borders, Brussels, 10 November 2004.

31. European Commission (2004), "Intellectual property : strategy for the enforcement of intellectual property rights in third countries, p.11; legislation concerning the Trade barriers regulation can be found in European Commission (1994), laying down community procedures in the field of the common commercial policy in order to ensure the exercise of the Community's rights under international trade rules, in particular those established under the auspices of the WTO.

32. Vandoren & Martins (2005).

33. European Commission (2004) "Letter to the Ministry of trade, industry and labour of Israel." Brussels: Directorate General for Trade, 6 December (Trade/D2/GP/pg, D/2004/ 16226), letter is in author's records; Manor (2006).

34. European Commission (2006c).

35. Mandelson (2006).

36. Ibid.

37. European Commission (2006a), p 21.

38. European Commission (2006b), p 13.

39. See, for example, Jeter (2001), p A1.

40. For a review of data exclusivity see Pugatch (2006); Pugatch (2003-2004).

41. US Food and drug administration (1997).

42. Legislative Resolution on the Common Position Adopted by the Council with a View to Adopting a European Parliament and Council Regulation Laying Down Community Procedures for the Authorization and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency, 10949/2/2003–C5-0463/2003–2001/0252(COD), Strasbourg, 17 December 2003, P5_TA-PROV(2003)0577; Official Journal (2001).

43. CAFTA-DR (2005), footnote 15.

44. United States–Chile free trade agreement (2003), footnote 17; United States–Singapore free trade agreement (2003), footnote 17; United States–Australia free Trade Agreement (2004).

45. See the USTR (2003).

46. Manor (2004); Wagner (2004); The Marker (2004).

47. See USTR (2006a) and USTR (2006b).

48. Market access sectoral and trade database (2006a).

49. Market access sectoral and trade database (2006b).

50. Official Journal (2003).

51. DOHA WTO Ministerial (2001).

52. WTO (2003).

53. WTO (2005b).

54. For an overview of the WTO dispute between the EC and Canada, see Pugatch (2004), pp 180–187.

55. CAFTA–DR (2005), Article 15.9(6)(a), footnote 15; United States–Chile free trade agreement (2003), Article 17.9(6), footnote 17; or four years and two years, respectively, in United States–Singapore free trade agreement (2003), Article 16.7(7), footnote 17.

56. CAFTA–DR (2005), Article 15.9(6)(b);

57. Council of the European Communities (1992).

58. For an overview of the Hatch-Waxman Act, see Mossinghoff (1999), pp 187-194; Grabowski & Vernon (1986), pp 195-198.

59. See United States–Singapore free trade agreement (2003), footnote 17, Article 16.7(2);

United States–Australia free trade agreement (2004), footnote 33, Article 17.9(4); and United States–Morocco free trade agreement (2004), footnote 17, Article 15.9(4).

60. CAFTA–DR (2005), Article 15.5(1), footnote 15; United States–Chile free trade agreement (2003), Article 17.7(3), footnote 17; United States–Singapore free trade agreement (2003), Article 16.4(1), footnote 17.

61. See, for example, CAFTA–DR (2005), Article 15.5(4).

62. For an overview of the DMCA, see United States Copyright Office (1999). For in-depth discussion of this issue, see Roffe (2004), footnote 37, pp 64-68.

63. See EU–Chile association agreement (2002), Article 170, note 18.

64. See CAFTA–DR (2005), footnote 15, Article 15.2(2); United States–Chile free trade agreement (2003), footnote 17, Article 17.2(1); United States–Singapore free trade agreement (2003), footnote 17, Article 16.2(6); and United States–Morocco free trade agreement (2004), footnote 17, Article 15.2(3).

65. CAFTA–DR (2005), Article 15.2(5); United States–Chile free trade agreement (2003), Article 17.2(7 United States–Singapore free trade agreement (2003), Article 16.2(4); and United States–Morocco free trade agreement (2004), Article 15.2(6).

66. Roffe (2004), pp 17–18; see also Vivas-Eugui (2003).

67. Ibid.

68. European Commission (2006a), note 34.