From TRIPS to preferential trade agreements, including the Trans-Pacific Partnership Agreement and related trends in the European Union: Challenges for Emerging Countries

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Executive summary

The report addresses recent developments in the area of intellectual property rights (IPRs) since the adoption of the TRIPS Agreement (1994) with particular emphasis on trends in preferential trade agreements (PTAs) and plurilateral initiatives such as the Trans-Pacific Partnership Agreement (TPP), ACTA and the new agenda of the European Union (EU) on intellectual property.[1] The report is organized in five chapters.

Chapter I deals with new initiatives undertaken by developed countries to enlarge and strengthen the achievements attained during the Uruguay Round. It, thus, describes the evolution of the relationship between intellectual property (IP) and trade and the significance of the TRIPS Agreement not only as one of the pillars of the World Trade Organization (WTO) but also in altering the evolution of international IP law by introducing strong minimum standards of protection and enforcement. The proliferation of preferential trade agreements (PTAs) is further analysed in terms of its origin, principal actors, rationale and their TRIPS-plus character. TPAs are described as an important normative setting arena.

The latest trade agreement negotiated between the Republic of Korea and the US (KORUS) is the theme of Chapter II. It draws attention to the incremental nature of the IP provisions in PTAs –in terms of building new agreements on previous ones- as one important feature of arrangements negotiated with major trading partners. United States (US) officials and industry in general have characterized KORUS as: "a base line for the negotiations with our trade TPP partners". From this perspective, the outcome of subsequent agreements could not be less -from the US perspective- of what KORUS did achieve.

Chapter III reviews the Trans-Pacific Partnership (TPP) negotiations tracing its origins in the P.4 Group and the subsequent interest expressed by the US of joining and further leading the group with the view of expanding it to become a major trading block. The ambitious nature of the negotiations and the strong IP agenda is discussed. Pharmaceuticals and public health related questions and enforcement of intellectual property rights (IPRs), in general, but particularly in the digital environment are important features of this agenda. Public health related questions and enforcement issues are further analysed in Chapter V of the report. Emphasis is placed on the main features of the negotiations and the importance of a successful chapter on intellectual property to meet the expectations of IP sensitive industries where intellectual property categories such as patents, copyright, trademarks, trade secrets are important ingredients of their business models. Chapter III concludes with observations on the implementation process of PTAs in particular with reference to US law.

The 2004 European Strategy and the 2014 Strategy for the protection and enforcement of IPRs in third countries is the attention of chapter IV. The official European

[1] In assessing the merits of the report, particularly with respect to the TPP and its negotiating process, the reader should be cognizant of its ongoing character as well as to the absence of public available official texts.

Union (EU) documents describe and shape the activities of the EU aimed at ensuring the enforcement of IPRs in foreign economies. Both documents present in an organized and detailed manner norm-setting activities, control and surveillance, and soft policy actions undertaken by the EU to ensure the respect of European IP owner rights in foreign economies. While the comparison of both documents illustrates the important changes that have taken place in this field, they contribute also to a better understanding of the set of heterogeneous activities undertaken in this domain. The changes introduced in the 2014 Strategy represent a good assessment of the past ten years and the interests at stake. As we analyse further these changes, the reality may not necessarily correspond with the objectives and actions identified in the 2014 Strategy.

Finally, chapter V considers a number of interrelated questions some of them touched upon throughout the report. Here, attention is paid to the ongoing trade negotiations between the US and the EU under the Transatlantic Trade and Investment Partnership, TTIP; the relationship between foreign direct investment (FDI) and the PTAs IP chapters; the particular consequences of IP related provisions on public health and finally a review of the relevance of international norms on IP enforcement.

The chapter begins with tentative reflections on the ongoing negotiations on the TTIP claimed to be the "biggest bilateral trade deal in history" and with observations on what might be the IP issues focus of attention in that process. It follows with an overview of the nexus between IP and FDI in PTAs and issues that have arisen in recent years with respect to indirect expropriation and the recourse to investor-state dispute settlement in health related cases.

Subsequently, the chapter dwells into the controversial relationship between public health and intellectual property. Special attention is paid to the impact of TRIPS, an agreement that with the passage of time has been praised for its generally balanced content. Treaties concluded after TRIPS have strengthened the protection of pharmaceutical products by means of setting up or enhancing standards relating to patent protection, test data exclusivity, the linkage between patent protection and marketing authorization and the enactment of new enforcement related standards. Recent expressions of these trends are found in KORUS, and present in the TPP.

The final section of the chapter deals with the overarching issue of IPRs enforcement. Although TRIPS implications in relation to enforcement were significant, countries that promoted the adoption of TRIPS shortly afterwards underlined the need to enhance the international normative *acquis* on enforcement. PTAs and ACTA have been an important scenario for these developments. TPP has revived some of the concerns expressed during the ACTA negotiations. In fact, some of the TPP proposals go even beyond the final act of ACTA.

Obligations dealing with domestic enforcement have become a common feature of international agreements, changing the historical neglect of this area of regulation in such conventions. Since TRIPS was adopted, and particularly in the last decade, new bilateral and plurilateral treaties enshrine norms on civil, criminal, border and digital enforcement. This normative blooming has been accompanied by the creation of international bodies that oversee the implementation of international intellectual property commitments undertaken by states. Likewise, enforcement has become a political priority of both the United States

and the European Union, which have developed a clearly recognizable foreign intellectual property policy where enforcement occupies central place.

The conclusion of the Anti-Counterfeiting Trade Agreement (ACTA) was a major achievement in this context. ACTA is a plurilateral treaty on international and national enforcement negotiated between a closed group of nations, which is pending ratification. Even if ACTA never enters into force, this agreement is at the centre of ongoing enforcement-related initiatives. When compared to TRIPS, ACTA is more specific, creates new obligations and neglects procedural guarantees enshrined in TRIPS. Moreover, ACTA intends to create an autonomous governing structure, where the ACTA Committee occupies centre-place and has vast competences. ACTA represents a major systemic shift compared to TRIPS. While the latter represented a multilateral compromise subject to specific boundaries, ACTA resembles to a 'framework' agreement announcing the content of future intellectual property enforcement commitments.

Principal conclusions of the report:

- ➢ TRIPS has been a major stepping stone in the process of IP convergence paving the way for the proliferation of PTAs.
- ➢ The PTAs phenomenon initiated immediately after the adoption of the TRIPS Agreement has proliferated in recent years, with the participation of an increasing number of emerging economies, which sometimes also conclude PTAs with IP provisions between themselves.
- ➢ IP has been a controversial component of PTAs and an important bargaining chip used by advanced economies.
- ➢ PTAs are the principal arena of norm setting negotiations explained in part by the paralysis or inability of multilateral institutions to build new consensus. For some, the new generation of IP norms is bringing into being precisely at this level.
- ➢ The TPP is an ongoing process well advanced at the negotiating phase. KORUS is an important guide to judge the content and even the impact of the agreement. It is foreseeable that TPP would not be less demanding than KORUS.
- ➢ Generally, higher IP standards in the pharmaceutical sector have been adopted in exchange of improved market access to powerful economies. KORUS and the European PTA with South Korea set the bar for future initiatives, including the TPP.
- ➢ Among the areas attracting most of the attention and concern, public health stands out. New intellectual property rules have enhanced the position of pharmaceutical patents owners, particularly thanks to the conclusion of PTAs.
- ➢ In recent years the trend towards strengthening patent protection has converged with another trend consisting of the inclusion of technical and regulatory standards relating to pharmaceutical products, which also benefits the position of innovative companies.

- ➢ New enforcement rules have clarified and strengthened the enforcement related standards set forth in TRIPS Part III. In some cases, enforcement norms cover areas unregulated in TRIPS.

- ➢ New norms on enforcement raise questions because of the general inclination to- mostly or solely- reflect the interests of right holders. This unbalance generates tensions *vis a vis* the protection of priority legal interests (health, privacy, access to information) and the objectives of the multilateral trade system, fundamentally that of enhancing free trade.

- ➢ Following the failure of ACTA, PTAs remain the key instrument to increase the normative standards relating to IP enforcement. TPP will probably be not only TRIPS plus but also ACTA plus, as far as enforcement is concerned.

- ➢ New IP commitments based on the transplantation of foreign law raise important issues and risk to increase the judicialization of IP matters.

- ➢ Emerging economies participating in PTAs need to consider their medium and long term strategies and implement the new commitments without upsetting their policy space in sensible areas of development such as health, nutrition and education and preserve their initiatives to promote their scientific and technological development. Smart implementation of new commitments should be strategically considered from the outset of negotiations.

- ➢ According to informal sources, and at the time of writing, TPP negotiations are near completion. Technical work has been sealed and outstanding issues have been elevated to a political level. A US trade authority bill is under consideration in Congress with partial bipartisan backing. The stake of the TPP in US Congress is of paramount importance but one should not neglect the views and positions of civil society, media and parliaments in the other 11 countries negotiating the agreement.

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Chapter I
From the TRIPS Agreement to the most recent developments in the intellectual property world

The focus of Chapter I is on the evolution of the complex relationship between intellectual property and trade and the significance of the TRIPS Agreement not only as one of the pillars of the World Trade Organization but also in influencing the evolution of international intellectual property law by introducing a set of strong minimum standards of protection and enforcement. The proliferation of preferential trade agreements (TPAs) is further analysed in terms of its origin, principal actors, rationale and its TRIPS-plus character. TPAs are described as an important stage in norm setting in this area. The rationale behind TPAs including robust chapters on intellectual property, as part of the new agendas of most advanced countries, is further analysed here.

1. Introduction

The TRIPS Agreement commits member states to certain set of minimum standards on protection and enforcement of IPRs. The Agreement constitutes at the same time a major event in the evolution of the international system. It represents a shift in international policymaking from the bottom-up approach of the Paris Convention (the 1883 Convention for the Protection of Industrial Property) and the incorporation of IP into the international trading system, authorizing trade sanctions including cross retaliation in cases of noncompliance. In other words, TRIPS constitutes "a revolution in international intellectual property law."[2]

While the Paris Convention does contain some general obligations regarding international cooperation (national treatment with respect to foreign applicants[3]; the right of priority when filing patents in different countries[4], and the principle of independence with respect to patents for the same invention in different jurisdictions[5]), it does not encroach on the freedom of states to legislate. Thus, with probably few exceptions (the grant of

[2] J. Reichman, The TRIPS Agreement comes of Age: Conflict or Cooperation with the Developing Countries?, 32 *Case W. Res J Intment* 441, at p. 442 (2000).
[3] Paris Convention (1967), Art. 2.
[4] Ibid, Art. 4.
[5] Ibid, Art. 4 bis.

compulsory licenses (Art.5 A)), the Paris Convention was not invasive in terms of mandatory criteria for protection and enforcement of IPRs. (See Box I.1)

Box I.1: The Paris Convention and freedom to legislate

In the field of patents, for example, the Convention leaves the member States entirely free to establish the criteria for patentability, to decide whether patent application should or should not be examined in order to determine, before a patent is granted, whether these criteria have been met, whether the patent should be granted to the first applicant for a patent, or whether patents should be granted for products only, for processes only, or for both and which fields of industry and for what term.
Georg H. Bodenhausen, former Director-General of WIPO, in *Guide to the Application of the Paris Convention for the Protection of Industrial Property As Revised At Stockholm in 1967*, at p. 5, BIRPI, Geneva, 1968.

According to TRIPS minimum standards, countries are obliged to give effect to this principle in their national laws. Likewise, not being obliged to do so, countries may implement more extensive protection in their national laws provided they do not contravene the provisions of the Agreement. (See Box I.2).

Box I.2: The minimum standards in TRIPS (Art.1.1)
Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice

In brief, the principle of minimum standards in the TRIPS Agreement is comprehensive in terms of protection and enforcement of IPRs, reinforced by the WTO dispute settlement mechanism. This facet of the Agreement has had the most significant influence in the two decades following the establishment of TRIPS and explains in many respects the developments and trends analysed in this report.

2. TRIPS and the controversial relation between trade and intellectual property rights[6]

The adoption of TRIPS and its incorporation into the World Trade Organization (WTO) appears to have appeased the initial controversies on the compatibility between intellectual property and the international trade regime. Suffice to mention that GATT 1947 considers "the protection of patents, trademarks and copyrights" as a general exception to the free movement of goods.

In the 19th century, the Industrial Revolution in Europe and North America, and the growth of international trade, marked a critical moment in the history of IP. In 1873, at the world exhibition in Vienna, countries were invited to expose their technological and

[6] See for further details, P. Roffe and Gina Vea (2009), The WIPO Development Agenda in an Historical and Political Context, *The Development Agenda: Global Intellectual Property And Developing Countries*, Edited by Neil W. Netanel, Oxford University Press, pp.79-109

scientific achievements. Governments and potential exhibitors raised concerns over the possibility that visitors might copy some of the inventions. In response, the United States (US) invited governments to negotiate and adopt the first international treaty for the protection of industrial property. (See Box I.3)

Box I.3: Invitation to the first international treaty on industrial property (extracts)

We live no longer in the day of Industrial action, which is strictly confined and is removed from foreign competition, and where slow communication prevents or delays the utilization of inventions. We live at a time of liberal Customs policy; Steam and Electricity have newly united once isolated seats of industry in a way undreamt of; and the mutual exchange of goods shows today a magnitude which a generation ago one could not have imagined. Under such altered relations the Patent granted for an invention in one country becomes in fact a restriction, unprofitable and obstructive, if that invention without limitation or increase in price, becomes in an adjoining country common property.

Heinrich Kronstein and Irene Till, "Reevaluation of the International Patent Convention," 12(4) *Law and Contemporary Problems*, 768 (autumn 1947)

While the US viewed international patent protection as fundamental to international trade, others across the Atlantic regarded patents as a distortion to free trade. The anti-patent critics in Europe considered the patent mechanism to be one that restricts, rather than promotes, trade. They argued that it distorts the market by protecting certain economic interests over others.

In brief, patent advocates were interested in the geographic extension of the exclusive rights granted by patents, and thus in a system that would make it easier to secure patent protection in foreign markets. Those raising objections were interested in actual domestic production and opposed to a system that would favour importation, instead of local production.[7]

The European anti-patent movement "collapsed" after a persuasive campaign by the groups supporting patent protection.[8] It ended at the time of the negotiations of the Paris Convention in 1883, during which countries reached a strategic compromise around the working of a patented invention in the country of importation. This concept of "local working" evolved during the various revision conferences. In the same context, the instrument of "compulsory licensing" was later introduced in the Convention as one of the measures that countries could adopt to remedy possible abuses resulting from the exclusive rights conferred by patents, including, for example, failure to work. This strategic compromise was constructed around in what is today Article 5A of the Convention. In its present version, it views compulsory licenses as a possible remedy to prevent abuses of the patent monopoly

3. The emergence of TRIPS

[7] See Fritz Machlup, *An Economic Review of the Patent System* 17 (United States Government Printing Office, 1958).
[8] Ibid.

The origin of the clearer nexus between intellectual property and trade was pioneered by the US in different pieces of legislation particularly in the 1974 Trade Act and its further refinements. Failure in WIPO both to address a developing country initiative to revise the Paris Convention and the Treaty Supplementing the 1883 Convention gave further impetus to industry sectors in the US, Japan and the European Community to contemplate the incorporation of IPRs in the Uruguay Round Trade Negotiations launched in 1986. One key argument made by the supporters of a future TRIPS Agreement was the weaknesses of the existing international system to tackle major encroachments to IPR holders. (See further discussion in Chapter V-D, enforcement issues, infra)

In contrast to developing countries' activism in the period of reform to the Paris Convention, that preceded the negotiations of the TRIPS Agreement, the role of these countries in the drafting and negotiation of TRIPS was limited—and almost entirely defensive. For a long period, developing countries took the position that, except for counterfeiting and issues related to anticompetitive behaviour, the subject of IPRs was simply not appropriate for discussion within the General Agreement on Tariffs and Trade (GATT) system. To this end, they defended the exclusive role of WIPO to serve as the international specialized body to deal with IP issues. Developing countries finally accepted the TRIPS deal as part of the "single-undertaking" that prevailed in the Uruguay Round (a deal involving a package of issues on improved access to markets—in general, markets for agriculture and textile goods, services, and investment); in exchange, they received concessions in terms of flexibilities in the implementation of its provisions, including transitional periods for full convergence with the Agreement.

3.1 The Agreement

As highlighted, TRIPS is special in the evolution of international IP law for a number of considerations, primarily:

- For its quasi-exhaustive regime covering in a single instrument the core IP disciplines. Thus, contrary to early practice, the Agreement covers in one instrument: copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits, protection of undisclosed information and control of anti-competitive practices in contractual licences.
- Sanctions the principle of minimum standards of protection and enforcement of IPRs (see Box I.2, supra).
- Non-discrimination in patent protection in terms that "patents shall be available for any inventions, whether products or processes, in all fields of technology, … and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." (Art. 27.1).
- Existing obligations under the classical IP conventions (Paris Convention, Berne Convention) coexist with the Agreement.
- A set of detailed provisions, first time ever, on enforcement of IPRs.
- Compliance with the minimum standards is subject to the dispute settlement mechanism of the new WTO.

4. The post TRIPS scenario and the failure to advance normative agendas in WTO and WIPO

TRIPS and its minimum standards of protection and enforcement, signals the beginning of a new phase in the evolution of IP. Since the entry into force of TRIPS in 1995, significant changes have been introduced in the legal regimes of numerous countries particularly in middle-income economies obliged to initiate important reforms to become attuned with TRIPS. Developing countries and least developed countries as well as countries in transition to a market economy benefited from transitional arrangements to its full convergence to the Agreement. India was a country that made full use of these measures becoming fully convergent only in 2005.

The implementation of the Agreement and technical assistance to that effect was left under the responsibility of WTO and WIPO. At the same time and directly related to our narrative, the two organizations faced major hurdles in making progress in their respective normative agendas.

4. 1 The World Trade Organization

Once TRIPS entered into force, WTO emerged as the focus of the formation of new international IP standards. Shortly thereafter, however, its role contracted. Attempts to consolidate and make progress on matters vaguely drafted or left open for review met with major obstacles. Since the entry into force of TRIPS, the most prominent activity has been around the nexus between IP and public health and the flexibilities permitted by the Agreement that led to the final adoption of a Ministerial Declaration. This was achieved in the 2001 Doha Declaration,[9] which clarifies certain aspects of the Agreement and their congruence with the need to preserve flexibility in its implementation without being inconsistent with the authority of states to adopt measures necessary to protect public health. The Doha Declaration also initiated a revision of TRIPS, Article 31, on compulsory licensing, and the case of countries with weak local structures of production and their limited capacity to make use of the flexibilities of the Agreement. [10]

Issues that have also occupied the attention of WTO Members have been related, among others, to matters left in the Agreement for future reviews such as the protection of plants and animals, negotiations on indications of origin and the recourse in the dispute settlement mechanism to the so-called non-violation complaints. Some countries have also made a link to the extension of the special protection of wines and spirits in the case of indications of origin to other products and the disclosure of source or origin of genetic resources and or traditional knowledge in patents applications. On these matters as well as in others, PTAs discussed subsequently have advanced in different directions superseding or making partially obsolete -for the parties to these agreements- the discussions in WTO.

[9] Declaration on TRIPS and Public Health, WT / MIN (01) / DEC / 2, Adopted on November 14, 2001.
[10] Thus far, the revision of the Agreement has not entered into force See, *A Handbook on the WTO TRIPS Agreement (*2012), edited by Antony Taubman, Hannu Wager, Jayashree Watal, Cambridge University Press

The exceptional situation of the LDCs with respect to TRIPS -that due to the lack of a "sound and technological base" enjoy special treatment- has been an important aspect of the work of the Council for TRIPS. In this respect the implementation of Art. 66[11] has been the subject of major attention in two specific situations, i.e., the commitments made by developed countries to assist LDCs in the transfer of technology[12] and more generally on the application of the Agreement to those countries.

4.2 The World Intellectual Property Organization

WIPO, the IP specialized agency of the United Nations, suffered institutionally when governments focused their attention on the consolidation and implementation of the TRIPS Agreement and in the negotiations of PTAs and plurilateral agreements to cover gaps or advanced in the trade agenda in areas left vague or open in the Agreement.

Following the adoption of TRIPS, WIPO made important attempts to regain its leadership in IP norm setting. As a result, one important and fruitful initiative became enshrined in its Digital Agenda that led to subsequent negotiations and adoption of two important treaties, the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT) in 1996, known as the "Internet treaties". These treaties served to address an issue not directly accounted for in the TRIPS Agreement: "the profound impact of the development and convergence of information and communication technologies on the creation and use of literary and artistic works." [13]This is precisely an area where PTAs have made significant headways.

Parallel efforts were made under the guise of the so-framed Patent Agenda introduced by Director General at the 2001 WIPO General Assembly. (See box I.4) One of the objectives of the Patent Agenda was to advance in a Substantive Patent Law Treaty (SPLT). The initial intention was to address "issues of direct relevance to the grant of patents" in particular, the definition of prior art, novelty, inventive step/non-obviousness, industrial applicability/utility, the drafting and interpretation of claims, and the requirement of sufficient disclosure of the invention.[14] The initiative was perceived particularly by developing countries as an unbalanced attempt to intensify the process of convergence and

[11] Article 66: Least-Developed Country Members: "1.In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period. 2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."

[12] See Sueri Moon, *Does TRIPS ART. 66.2 Encourage Technology Transfer to Developing Countries? An Analysis of Country Submissions to the TRIPS Council (1999-2007)*, Policy Brief No.2, UNCTAD-ICTSD Project, Geneva, 2008 and *Meaningful Technology Transfer to the LDCs: A Proposal for a Monitoring Mechanism for TRIPS Art. 66.2*, Policy Brief 9, ICTSD, 2011.

[13] See Preamble, WCT.

[14] Ibid, para. 31

harmonization initiated with TRIPS. The SPLT discussions, in many respects, precipitated the launching in 2004 by a group of developing countries of a WIPO Development Agenda.[15]

In brief, the Patent Agenda and its SPLT component did not advance and both WIPO secretariat and governments continue as of today labouring to delineate and make progress on a future norm setting agenda.[16]

Box I.4

Increasingly, applicants are using patent rights strategically, engaging in international licensing and building intellectual property assets to support valuation and investment. But to remain effective, the patent system must continue to develop, with particular emphasis on improved ways of obtaining patent protection for inventions in a number of countries. Recent and present initiatives for harmonization of patent laws and for reform of the Patent Cooperation Treaty (PCT) need to be pursued in a coordinated fashion, and new initiatives need to be identified and developed.

Agenda for development of the international patent system (Memorandum of the Director General), A/36/14, August 2001, at http://www.wipo.int/edocs/mdocs/govbody/en/a_36/a_36_14.pdf (visited Apr-15)

Notwithstanding the initial difficulties and the obstacles faced in the area of patent harmonization, WIPO in recent years has successfully negotiated six international instruments adopted in the period 1996-2013 (See Box I.5).

Box I.5

Treaties adopted under WIPO after the entry into force of the TRIPS Agreement

Treaty	Year
Marrakech Treaty to Facilitate Access to Published Works for Persons who are Blind, Visually Impaired or otherwise Print Disabled.	2013
Beijing Treaty on Audiovisual Performances	2012
Patent Law Treaty	2000
Singapore Treaty on the Law of Trademarks	2006
WIPO Copyright Treaty (WCT)	1996

[15] See also, note 22, infra.

[16] On the present status of work under WIPO SCP, see information at http://www.wipo.int/policy/en/scp/ (visited 27/04/14).

WIPO Performances And Phonograms Treaty (WPPT)	1996

Source: information available at WIPO website

5. The PTA experience

5.1 Introduction

PTAs have become in recent years the principal venue of normative negotiations on IP law. From this perspective, PTAs include all trade agreements of a bilateral, regional or plurilateral nature that cover IP as a subject matter of the agreements. Generally they constitute a chapter of a broad arrangement that has been negotiated, as in the case of TRIPS, as part of a single undertaking covering broad trade issues.

Many PTAs include obligations going beyond the minimum standards of the Agreement, the so called TRIPS –plus and TRIPS-extra obligations. This is a process with both positive and negative connotations. Positive in the sense that for its advocates TRIPS-plus represent the natural evolution of the international IP system in the light of the minimum standards of protection and enforcement consecrated in TRIPS. Negative, for those that see this phenomenon as breaking with the fundamental objective of the Agreement of preserving a balance between the private and public interests inherent to the system and putting at risk the so-called flexibilities of the TRIPS Agreement (see e.g., Box V.4, infra).

With the view of explaining to non-specialists the meaning of TRIPS-plus or extra situations, see a simple explanatory note in Box I.6.

Box I.6

TRIPS minimum standards	**Pre-Trips**	**TRIPS plus or extra**
Patents in all technological fields	No obligation	Ratification of TRIPS and expansion to new areas
Minimum protection of patents for 20 years	No obligation	Compensation or restoration of duration in cases of administrative delays or sanitary permits
Patents on plants and animals might be excluded from protection	No obligation	Plants and animals, under some circumstances, shall be protected by patents

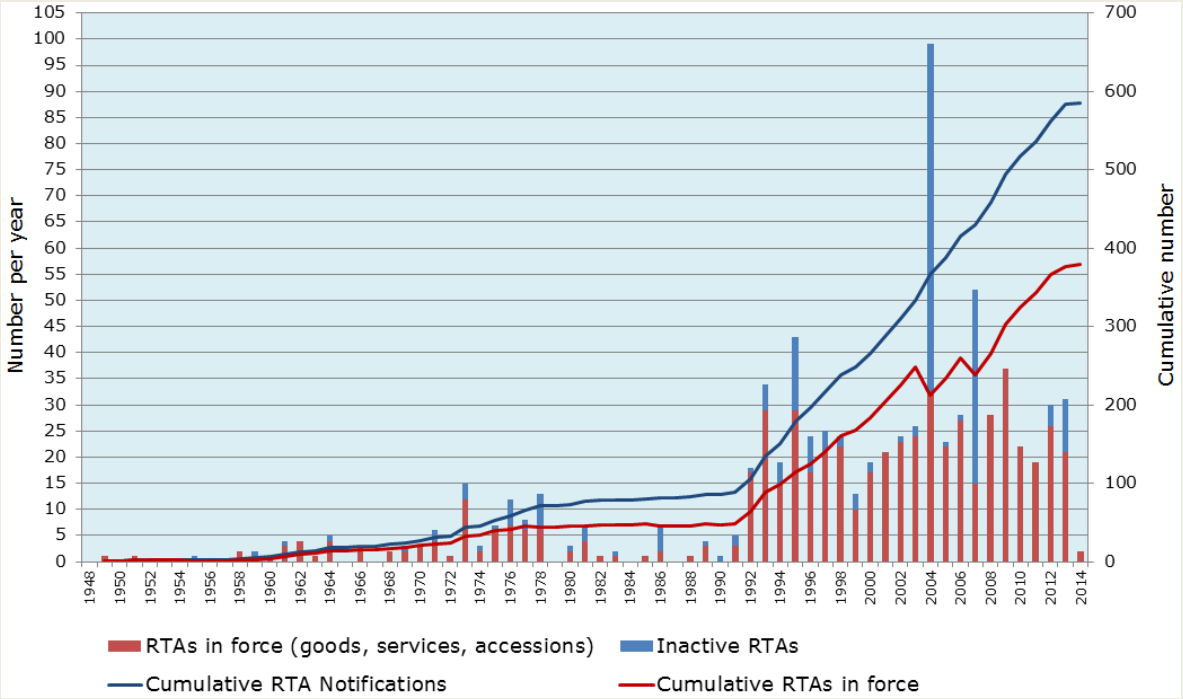
Undisclosed information – including data submitted for the marketing of pharmaceuticals- to be protected against unfair competition	No obligation	Exclusive protection for at least 5 years including a recent trend to expand exclusivity for new uses and protection of biologics Linkage between marketing approval and patent term
Copyright term of duration: 50 years for juridical persons	According to Berne Convention	Minimum duration of 70 years. Proposals in TPP up to 120 years
Copyright provisions did not include the digital environment	No obligation	Extensive protection including both traditional and digital forms of expression
Geographical indications: special protection in the case of wines and spirits	No particular obligation except in situations covered by Lisbon Treaty	Expansion of protection beyond wines and spirits
Comprehensive regime on enforcement of IPRs	No obligation	-Expansion of minimum standards by making mandatory provisions considered optional under TRIPS - Enlarged border enforcement -Expanding enforcement provisions to the digital environment. - Enlarged criminal enforcement
Moratorium on the application of the dispute settlement system to non-violation complaints	No obligation	Dispute settlement includes non-violation situations

5.2 The proliferation of PTAs

Immediately after the Uruguay Round was concluded, the North America Free Trade Agreement (NAFTA) between Canada, Mexico and the US entered into force. Next, an explosion of regional or bilateral trade agreements has followed. While during the period

1948-1994, the GATT received 124 notifications of so called Regional Trade Agreements (RTAs) relating to trade in goods, since 1995, more than 400 agreements have been notified by WTO members as shown Box I.7.

Box I.7
RTA notified to the WTO: 1948-2014[17]



Source: WTO: http://www.wto.org/english/tratop_e/region_e/rta_participation_map_e.htm.

With the view of understanding the magnitude of the PTAs, particularly those incorporating IP provisions, negotiated since 1994, a Table has been attached to the report (Annex A). The Annex, using diverse sources, lists the PTAs that have been signed by countries in transition, developing and emerging countries with major trading partners. In the latter category we include the US, the EU, the European Free Trade Association (EFTA), China, Canada, Republic of Korea, Japan, Taiwan, Australia and New Zealand and Singapore.

The list also includes relevant agreements under negotiations at the time of writing. The latter includes the Trans - Pacific Partnership Agreement (TPP) that has been characterized as the "gold standard" of trade agreements in the 21th century. Intellectual property related matters, for the advocates of such model, constitute a crucial decisive factor of success.[18] Part III of the report focuses on the TPP process.

[17] As clarified at the source, WTO statistics on RTAs are based on notification requirements rather than on physical numbers of RTAs. Thus, for an RTA that includes both goods and services, WTO counts two notifications (one for goods and the other services), even though it is physically one RTA.

[18] According to one source: "Our analysis demonstrates the importance of IP intensive industries to the United States and its TPP partner countries. The economic gains, job growth, and value added to these 12 economies

The list shows an impressive number of PTAs signed in the post TRIPS period. One scholar taking into account the WTO data has identified close to 150 agreements including IP matters.[19]

To fully understand the phenomenon it is important also to underline three facts. First, not all PTAs with IP chapters qualify under the characterization of TRIPS plus (see Box 1.6 supra). In this latter category we include all agreements principally negotiated with the US, EU and EFTA.

Second, while the list is impressive, counting economies from a large number of developing countries, it does not include BRICS countries or Indonesia[20] and neither least developed countries. In the case of agreements negotiated by China it should be noted that they generally take into account its own national interests but broadly they are within the boundaries of the TRIPS Agreement.

Finally, the proliferation of PTAs needs also to take into account the fact that same countries sign between them more than one PTA or double PTAs,[21] by enlarging their trade relations with a network of other countries. This phenomenon is clearly present in the case of the TPP where the core members have already signed bilateral agreements among themselves. (See Annex C for details)

5.3 The rationale behind the proliferation of TRIPS Plus obligations

As a backdrop to the proliferation of PTAs with TRIPS-plus provisions there are a number of considerations to borne in mind. The most relevant relate to the nature of the commitments made during the Uruguay Round negotiations to which we refer subsequently.

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are mainly the direct results of increased activity in IP-intensive industries, which are likely to thrive and spawn local benefits in an environment with strong IP protection. We estimate approximately two-thirds of the annual benefits come from IP-intensive industries. These economic gains will not be realized in the TPP, or infuture free trade agreements, without strong IP rights." Reports // ndp | analytics The Economic Benefits of Intellectual Property Rights in the Trans-Pacific Partnership February 2014 | Contributors: Nam D. Pham, Ph.D., Joseph Pelzman, Ph.D., Justin Badlam, and Anil Sarda available at http://www.ndpanalytics.com/economic-benefits-tpp (visited Ap-15).

[19] See X. Seuba, Intellectual Property in Preferential Trade Agreements: What Treaties, What Content*?, The Journal of World Intellectual Property* Vol. xxx, no. xxx, pp. 1–22 doi: 10.1002/jwip.12015, 2013.

[20] For broader geopolitical considerations on these trends see Peter Yu, TPP and Trans-Pacific Perplexities, *Fordham International Law Journal*, Vol. 37: 1129, 2014 and Heribert Dieter, *The Return of Geopolitics: Trade Policy in the Era of TTIP and TPP*, International Policy Analysis, Friedrich Ebert Stiftung, December 2014.

[21] See Joost Paulwelyn and Wolfgang Alschner, *Forget about the WTO: The network of relations between PATs and 'double PTAs',* Graduate Institute, Geneva, 2014, available http://graduateinstitute.ch/files/live/sites/iheid/files/sites/ctei/shared/CTEI/people/students/Wolfgang%20Alschner/Pauwelyn_Alschner-Relations%20between%20PTAs.pdf (visited Apr-15).

For the main advocates of the TRIPS Agreement its final conclusion was indeed at its time a major success but not the end of the story. At the same time, subsequent initiatives to deal with the "unfinished business" in TRIPS as well as with the pursuit of new initiatives particularly with respect to the digital environment in the case of copyright protection, in deepening the protection of pharmaceuticals and regulated products and in general with respect to enforcement of intellectual property rights were not making the desired progress. From this perspective, the multilateral system was failing to achieve this desired progress.

We have also analysed in this context the difficulties encountered both in WTO and WIPO by the main advocates of a more assertive and potent IP agenda. Developing countries on the other hand, hesitant at the time of the introduction of intellectual property in the trade agenda during the Uruguay Round, have consistently resisted moves to go beyond the boundaries of the TRIPS *aquis,* and, thus, becoming their zealous defenders. As also noted, a number of developing countries raised in WIPO the need to establish a development agenda under the rationale that: "Intellectual property protection cannot be seen as an end in itself, nor can the harmonization of intellectual property laws leading to higher protection standards in all countries, irrespective of their levels of development."[22]

At the same time two important consequences of the Uruguay Round, with clear side effects on PTAs are the application of the non-discrimination principles, and the fact that the TRIPS Agreement includes the commented set of extended minimum standards on the protection and enforcement of IPRs.

5.3.1 Non-discrimination under the WTO

One of the pillars of the GATT-1947 is the non-discrimination principle reflected in the two tenets of the international trading system: the national treatment and the most favoured nation (MFN) principles.

In the particular context of TRIPS (Art. 3), national treatment obliges Members to accord to foreigners a treatment that is "no less favorable than that it accords to its own nationals".

With respect to MFN, new in the context of international IP law, TRIPS prescribes that "any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country, shall be accorded immediately and unconditionally to the nationals of all other Members."

While in the case of trade in goods and trade in services these two principles admit important exceptions, the TRIPS Agreement incorporates the broadest non-discrimination principle, subject to limited exceptions, between nationals and foreigners and between nationals of Member States. This means, for the purpose of our analysis, that any matter affecting the availability, acquisition, use, scope, maintenance, and enforcement of IPRs

[22] Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO, Annex, at page 2, WIPO, WO/GA/31/11, August 27, 2004, available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=31737 (visited Apr-15) The initiative led finally to the adoption in 2007 of 45 recommendations under the WIPO Development Agenda, see WIPO http://www.wipo.int/ip-development/en/agenda/recommendations.html, (visited Apr-15)

specifically addressed in the Agreement and included in a trade agreement negotiated by any WTO Member, shall be extended to all other WTO Members.

5.3.2 TRIPS as a set of minimum standards

As highlighted earlier (see Box I.2), while WTO Members are bound by the minimum standards of the Agreement, including national treatment and MFN, that need to be reflected in their national laws, TRIPS allows, simultaneously, countries to adopt "more extensive" protection if they wish to do so. For example in *China tiIntellectual Property Rights*, the Panel took the view that the "The second sentence of Article 1.1 clarifies that the provisions of the Agreement are minimum standards only, in that it gives Members the freedom to implement a higher standard, subject to a condition."[23] The sole condition is that the more extensive protection shall not contravene the provisions of the Agreement.

It is subject of interpretation what could be the meaning of "more extensive protection" non-contravening the Agreement. It should be noted that scholars and governments have argued -the latter in the context of the Council for TRIPS-[24] that the Agreement incorporates also natural ceilings as "to ensure that measures and procedures to enforce IPRs do not themselves become barriers to legitimate trade" (TRIPS, Preamble). Thus, according to this view, the Agreement would have not only minimum but also maximum standards - from which countries should not deviate.[25]

5.4 An overview of the principal strategies followed in PTAs by major trading partners: US, EU, EFTA

Following the adoption of TRIPS, the proliferation of PTAs, particularly those negotiated with major trading partners, has been an important feature of recent developments in the IP world. Chapters III and IV deal in details with particular aspects of the trade agreements negotiated with the US and the EU.

5.4.1 PTAs negotiated with the US

Agreements to which the US is a Party have traditionally been ambitious in nature. Prior to the completion of the TRIPS Agreement, the US already concluded a bilateral agreement with Canada[26] in which IP features prominently.[27] Then, in NAFTA, the IP provisions became an important component of the treaty, exceeding the minimum standards of the TRIPS Agreement. Following NAFTA, the agreement with Jordan[28] anticipated the policy, which the US later adopted in the Trade Promotion Authority (TPA) of 2002. The latter

[23] See "WTO Analytical Index: TRIPS", available at http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_01_e.htm#p. , under Art. 1 of TRIPS.

[24] See Peter Yu, TRIPS Enforcement and Developing Countries, *American University International Law Review*, Vol. 26, Number 3 (2011), at p. 756, citing India in the TRIPS Council.

[25] See Annette Kur and Henning Grosse Ruse-Khan, Enough is enough –the notion of binding ceilings in international intellectual property protection, in *Intellectual Property Rights in a Fair World Trade System*, Edited by Annette Kur and Marianne Levin, Edward Elgar, 2011, at pp.359-407.

[26] The Canada – US Free Trade Agreement entered into force on January 1, 1989.

[27] The US had in that instance a particular concern regarding the liberal Canadian policies of allowing compulsory licensing in support of its pharmaceutical domestic generic industry. See Reichman & Hasenzahl (2003).

[28] The agreement was signed on October 24, 2000; http://www.ustr.gov/trade-agreements/free-trade-agreements/jordan-fta (3 May 2011).

sets general principles and objectives that guide the negotiations to the achievement of a number of goals, including the accelerated and full implementation of the TRIPS obligations and to "reflect a standard of protection similar to that found in US law" in the provisions of any trade agreement.[29] The subsequent agreements have followed this expansive and robust IP agenda.

As in the case of TRIPS, the breadth and scope of the agreements sponsored by the US relate to all major IP disciplines. While the structure and specific contents of these agreements may vary slightly in terminology, they generally follow a common comprehensive pattern with a robust emphasis on enforcement issues. (See chapter V-D, infra)

An interesting phase in the evolution of US policies constitutes the changes introduced in May 2007, after the expiration of the Trade Promotion Authority of 2002, as a result of a bipartisan understanding on the ratification of outstanding trade agreements.[30]

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[29] See for example, in the case of the ongoing discussions -at the of time writing- in the US Congress, the Bipartisan Congressional Trade Priorities and Accountability of 2015. Section 2 (5) of the Bill provides:
"INTELLECTUAL PROPERTY. The principal negotiating objectives of the United States regarding trade-related intellectual property are—
(A) to further promote adequate and effective protection of intellectual property rights, including through—
(i)(I) ensuring accelerated and full implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agrements Act (19 U.S.C. 3511(d)(15)), particularly with respect to meeting enforcement obligations under that agreement; and
(II) ensuring that the provisions of any trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law;
(ii) providing strong protection for new and emerging technologies and new methods of transmitting and distributing products embodying intellectual property, including in a manner that facilitates legitimate digital trade;
(iii) preventing or eliminating discrimination with respect to matters affecting the availability, acquisition, scope, maintenance, use, and enforcement of intellectual property rights;
(iv) ensuring that standards of protection and enforcement keep pace with technological developments, and in particular ensuring that rightholders have the legal and technological means to control the use of their works through the Internet and other global communication media, and to prevent the unauthorized use of their works;
(v) providing strong enforcement of intellectual property rights, including through accessible, expeditious, and effective civil, administrative, and criminal enforcement mechanisms; and
(vi) preventing or eliminating government involvement in the violation of intellectual property rights, including cybertheft and piracy;
(B) to secure fair, equitable, and non-discriminatory market access opportunities for
United States persons that rely upon intellectual property protection; and
(C) to respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001, and to ensure that trade agreements foster innovation and promote access to medicines." Bill to establish congressional trade negotiating objectives and enhanced consultation requirements for trade negotiations, to provide for consideration of trade agreements, and for other purposes, available athttp://www.finance.senate.gov/newsroom/chairman/release/?id=7701eb50-a0ef-4257-bfc1-b06efe725b8c (visited Apr-15)

[30] Congressional leaders reached a compromise with the Administration on issues related to IP, labor standards and the environment with respect to three of the PTAs pending for ratification by Congress (Colombia, Republic of Korea, Panama; see http://www.ustr.gov/trade-agreements/free-trade-agreements). The Peru Trade Promotion Agreement, by contrast, entered into force in February 2009. See

Amendments were thus introduced to the agreements signed with Colombia, Panama and Peru with respect to provisions dealing with pharmaceutical products, reflecting concerns voiced on the impact of those agreements on public health policies.[31] The changes relate to topics such as extensions of the patent term, data exclusivity, the patent-data protection, linkage and dealing in the proper agreement with the Doha Declaration on TRIPS and Health.

Recent agreements suggest that the US strategy has continued to expand, forsaking the cited trend in the case of Peru, Colombia and Panama. These features are present in KORUS and in the ongoing negotiations in the TPP. KORUS is discussed subsequently in Chapter II and the TPP is the subject of analysis in Chapter III.

5.4.2 PTAs negotiated with the EU and EFTA

The EU strategy, under the risk of not being at a disadvantage with the US, has evolved from the first generation of agreements that incorporated very general commitments on the implementation of TRIPS (see agreements negotiated with Chile and Mexico) and of endorsing its broad strategy on the protection of geographical indications (GIs). A shift began to emerge after 2004 when the European Commission announced its strategy on enforcement of IPRs in third countries. The strategy included the objective to revisit IP aspects in trade agreements.[32] Consequently, this strategy was reflected in the agreements negotiated with CARIFORUM, Peru, Colombia, Republic of Korea and Central America. All these agreements put greater emphasis on IP provisions particularly with respect to enforcement.

Prior to CARIFORUM, the most significant IP-related provisions in the EU agreements –beyond the obligation to accede, ratify or adhere to a number of WIPO administered treaties- included specific arrangements on the reciprocal protection of GIs related to wines and spirits, and the protection of traditional expressions. Recent agreements provide further strengthening of the provisions on GIs in a clear and determined way of aligning parties[33] to the position sustained by the EU in multilateral discussions and deliberations regarding an international registry for wines and spirits and the expansion of the protection afforded to wines and spirits to all other products.[34]

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http://www.ustr.gov/trade-agreements/free-trade-agreements/peru-tpa and OAS-SICE (.http://www.sice.oas.org/Trade/PER_US/PER_US_s/Index_s.asp (1 May 2011).

[31] See for example US Government Accountability Office, GAO (2007).

[32] See C. Fink, op. cit. and Xavier Seuba, *La Nueva Política de la Comunidad Europea sobre Propiedad Intelectual en Terceros Estados*, Revista RUE, Aranzadi, Año XXXIV, No. 6, Junio 2008.

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

[34] On the latest status of the negotiations at the World Trade Organization, see Issues Related To The Extension of the Protection of Geographical Indications Provided for in Article 23 of the TRIPS Agreement to Products other than Wines and Spirits and Those Related to the Relationship Between The Trips Agreement And the Convention on Biological Diversity, Report by the Director-General, WT/GC/W/633, TN/C/W/61, 21 April 2011 and World Trade Organization, Multilateral System Of Notification And Registration Of Geographical Indications For Wines And Spirits, Report By The Chairman, Ambassador Darlington Mwape (Zambia) to the Trade Negotiations Committee, TN/IP/21, 21 April 2011.

Chapter IV, infra, provides further reflections on the EU strategy in the negotiations of PTAs with third countries.

EFTA model has followed closely the EU approach,[35] but from the outset included specific protection of data provided to national authorities on the safety and efficacy of pharmaceutical and agro-chemical products. While all EFTA trade agreements contain references to treaties that parties should adhere to -as in the case of the EU- they follow various schemes to achieve the same objective.[36]

[35] Roffe & Santa Cruz (2006).

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

Chapter II
KORUS as a prelude to the TPP negotiations

The incremental nature of the intellectual property provisions in PTAs –in terms of building new agreements on the basis of previous ones- has been an important feature of treaties negotiated with major trading partners. KORUS represents the latest PTA concluded by the United States. It has been characterized, by US officials and industry in general, as the model to follow in the future: "a base line for the negotiations with our trade TPP partners". One can predict that outcomes of subsequent agreements would not be less of what KORUS has achieved.

1. Introduction

One important feature in the evolution of PTAs is the incremental nature of its intellectual property provisions. If one takes, for example, NAFTA, negotiated at the time of TRIPS, it is easily a discernible trait of making the IP chapter sharper, more ambitious and reflecting in many respects the law prevailing in the US. Some scholars have suggested that the trend in some instances goes beyond US law.[37] In this particular context, the trade agreement negotiated with the Republic of Korea (KORUS) is the latest, representing the model of future agreements sponsored by the US.

In this regard, the US Congress in 2011 requested President Obama to include in the TPP negotiations the high standards of protection for IP incorporated under KORUS and to use it as "a base line for the negotiations with our trade TPP partners and to table such text in the next TPP round of negotiations … based upon the high IP standards embodied in KORUS".[38] A coalition of important US business, addressed to the USTR a similar request in 2012.[39]

As it will be discussed in chapter III infra, TPP draws on KORUS but goes beyond it in some areas of the negotiations and in particular with respect to its IP proposals.

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[37] See Frederick Abbott, UNCTAD - ICTSD Project on IPRs and Sustainable Development Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law, ICTSD-UNCTAD, Issue Paper 12, February 2006.

[38] See http://infojustice.org/wp-content/uploads/2011/07/22-Representatives-July-2011.pdf.

[39] The letter, which is additionally signed by the American Council of Life Insurers; American Insurance Association; American Legislative Exchange Council; Coalition of Service Industries; Emergency Committee for American Trade; Express Association of America; International Association of Drilling Contractors; Motion Picture Association of America; National Foreign Trade Council; National Retail Federation; Retail Industry Leaders Association Securities Industry and Financial Markets Association; Software & Information Industry Association; TechAmerica; The Council of Insurance Agents & Brokers; U.S. Chamber of Commerce; U.S. National Center for APEC; United States Association of Importers of Textiles and Apparel; United States Council for International Business; United States-New Zealand Council; and the Washington Council on International Trade, can be found at: http://servicescoalition.org/images/files/press-releases/Business%20Community%20TPP%20Services%20Letter%20final062912.pdf.

The KORUS, negotiated and signed in 2007 did not enter into force until March 2012.[40] Differences in sectors such as automobiles and beef explain this important delay.[41] The debate over the ratification of the agreement, as has been reported, was contentious and divisive.[42]

2. KORUS and related intellectual property issues

KORUS, in general, but particularly the IP chapter has been seen by US industry sources as the strongest ever agreed treaty. In fact, the Chairman of the Advisory Committee for Trade Policy and Negotiations (ACTPN) highlighted the significance of the provisions on intellectual property "as one of the most important parts of any trade agreement. The ACTPN applauds and endorses the state-of-the-art IPR provisions in the agreement." Box II.1 reviews some of the aspects of KORUS seen by industry as essential: enforcement of IPRs, trademarks, copyright and health care.

Box II.1: Excerpts from views of the Advisory Committee for Trade Policy and Negotiations on KORUS, intellectual property chapter

"…. The members of the ACTPN commend the U.S. negotiators for obtaining what appears to be the strongest ever bilateral protections for intellectual property in large part because they tackle in a meaningful way the problems associated with Korea's lack of certain effective enforcement mechanisms. We view this as an extremely important outcome and a very strong part of the agreement. It should serve as the model from here on out."

"The ACTPN also commends the strong IPR enforcement mechanisms and penalty provisions, particularly the criminalization of end-user piracy and counterfeiting and Korea's guarantees of authority to seize and destroy not only counterfeit goods but also the equipment used to produce them."

"…. Important achievements in the trademark area are the provisions stipulating that trademark recordal is not required for any purpose, including the assertion of any rights, and a requirement to accede to the Trademark Law Treaty by 2008.

"Copyright protection is also greatly improved under the agreement. KORUS provides for extended terms of protection for copyrighted works and establishes anti-circumvention provisions to prohibit removing codes or other devices designed to prevent piracy.

[40] President Obama signed KORUS implementing legislation in October 21, 2011 (Public Law 112-41), using expeditious procedure in the US Congress thanks to the Trade Promotion Authority, and the Korean National Assembly passed the agreement on November 22, 2011. Information available at: http://www.ustr.gov/about-us/press-office/press-releases/2012/march/us-korea-trade-agreement-enters-force-march-15-2012.

[41] The delay was due to differences between President George W. Bush and the Democrat leader concerning several issues (autos and beef among them). It was not until December 3, 2010, after further negotiations, that President Obama and South Korean President Lee reached an agreement by exchange of letters signed on February 10, 2011 regarding the outstanding issues. As a result of this the implementing legislation modified certain provisions of the 2007 agreement. The US Congress then approved the agreement on October 12, 2011, and the Korea's National Assembly approved it on November 22, 2011. Both parties completed their review of the adopted implementing measures of the agreement and exchanged diplomatic notes on February 21, 2012.

[42] Brock R. Williams, Mark E. Manyin, Remy Jurenas, Michaela D. Platzer, Congressional Research Service, "The U.S.-South Korea Free Trade Agreement (KORUS FTA): Provisions and Implementation" September 16, 2014, p. 5, available at: https://www.fas.org/sgp/crs/row/RL34330.pdf.

Government agencies are required to use only legitimate computer software, setting a positive example for private users.

"The agreement is also notable for its intellectual property provisions that will facilitate high- quality health care, including through continued access to innovative products by ensuring fair, transparent, and non-discriminatory treatment for U.S. pharmaceutical products and medical devices."

https://ustr.gov/sites/default/files/uploads/Countries%20Regions/africa/agreements/korus/Advisory%20Committee%20for%20Trade%20Policy%20Negotiations.pdf (visited 3/16/2015)

KORUS meant for the Republic of Korea the introduction of important changes in its IP related legislation, which was not the case for the US: "No statutory or administrative changes will be required to implement Chapter Eighteen."[43]

We examine briefly selected aspects of KORUS as a guide to understand why the agreement constitutes a base line for the TPP negotiations and also as a reflection of why KORUS has been characterized as "the strongest ever bilateral protections for intellectual property". A further important component of KORUS relates to the provisions on patents and pharmaceuticals that are discussed separately in chapter V of the report.

2.1 Copyright issues and the digital environment

Copyright extension

According to KORUS (article 18.4.4(a)) and following the practice of earlier PTAs negotiated by the US, the term of protection of a work (including a photographic work), performance, or phonogram is to be calculated on the basis of the life of the author, the term shall be not less than the life of the author plus 70 years after his/her death. Korea provided for a protection of 50 years before KORUS entered into force.

Extended right of reproduction

KORUS (Article 18.4.1), provides that authors, performers, and producers of phonograms have the right to authorize or prohibit all reproductions of their works, performances, and phonograms, in any manner or form, permanent or temporary including temporary storage in electronic form. Korea amended its law to make it compatible with KORUS particularly on the temporary storage, unless it was necessary for information processing.

Fair use

KORUS (Footnote 11, Art. 18.4.) introduces a fair use provision in the case of copyright (provided also in the case of trade marks under Art. 18.2.5) in order to allow for the reproduction of copyrighted works without the necessary permission of the copyright holder, when such reproduction does not conflict with the normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the copyright holder.

Strengthened technological protection measures

[38] The United States – Korea Free Trade Agreement Implementation Act, Statement of Administrative Action, at ebcache.googleusercontent.com/search?q=cache:vDqgXiq49noJ:www.finance.senate.gov/legislation/download/%3Fid%3Dddceb252-a7be-4449-b761-a6f09b094288+&cd=1&hl=en&ct=clnk&gl=ch (visited 3/16/2015)
.

KORUS (Article 18.4.7) provides for a strengthened set of provisions, compared to earlier PTAs to avoid the circumvention of technological protection measures (TPM) that authors, performers, and producers of phonograms may use in connection with the exercise of their rights in order to protect the unauthorized use of their works.

3. Enforcement

KORUS, again, provides here a revised model on enforcement issues covering broadly civil, administrative procedures and remedies, alternative dispute resolution, provisional measures, special requirements related to border measures and criminal procedures and remedies. For example, on the latter, wilful copyright or related rights piracy on a commercial scale is defined as covering significant wilful copyright or related rights infringements "that have no direct or indirect motivation of financial gain".

It also includes stringent criminal procedures to be applied against persons, without authorization of the holder of copyright or related rights in a motion picture or other audiovisual work, "knowingly uses or attempts to use an audiovisual recording device to transmit or make a copy of the motion picture or other audiovisual work, or any part thereof, from a performance of the motion picture or other audiovisual work in a public motion picture exhibition facility."

KORUS, as in earlier PTAs, provides detailed provisions on liability for Internet service providers and limitations including incentives to cooperate with copyright owners in deterring any unauthorized storage and transmission of copyrighted materials. It also limits the scope of remedies that may be available against on-line service providers for copyright infringements that they do not control and take place through systems or networks controlled or operated by services providers. The amended Korean laws in this regard have introduced several exceptions to the limitation of liability of on-line services providers by means of its categorization, defining the terms of the exemption and providing conditions for the liability exemption (Act No. 10807).

Chapter III
The Trans-Pacific Partnership Agreement

The TPP negotiations have their origins in the P.4 trading group (Brunei Darussalam, Chile, Singapore and New Zealand) that attracted the interest of the US that later joined the group and since then has played a crucial role towards its expansion with the view of becoming a major trading block. The ambitious nature of the negotiations and the strong intellectual property agenda is highlighted here. Emphasis is given to the main features of the negotiations and the importance of a successful chapter on IP to meet the expectations of IP sensitive industries particularly with respect to the protection of undisclosed information, biological products, effective duration of patents, trade secrets and in general with respect to the enforcement of IPRs particularly in the digital environment. Additional information is provided on the current practice of the implementation process in the case of US law.

1. Introduction: the leadership played by the US

The Trans-Pacific Partnership Agreement (TPP) is probably the most ambitious mega regional trade agreement currently under negotiations due to its trade inclusiveness and ambitious intellectual property agenda. It has been characterized as the "21st century agreement." TPP has today twelve negotiating partners (Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam). The strength of the twelve countries as a group, in terms of aggregated GDP, population and world trade is illustrated in Box III.1.

Box III.1
TPP economic snapshot

GDP: US$27,750.0 billion (2013)
GDP per capita: US$34,752 (2013)
Population: 798.5 million (2013)
TPP % of world GDP: 37.5% (2013)
TPP % of world population: 11.2% (2013)
TPP % of world trade: 25.0% (2013)

Source: http://www.dfat.gov.au/fta/tpp/ (visited 16/03/2015

If successful, the agreement would deepen not only trade related issues but other economic and financial economic ties among its members in the case of market access, rules of origin, technical barriers to trade, sanitary and phytosanitary measures, competition, public procurement, trade in services, investment, electronic commerce, telecommunications, temporary entry, financial services, intellectual property, environment, labour and cooperation. Additionally, new and crosscutting issues have been included in the negotiations, such as regulatory coherence, competitiveness, development, state-owned enterprises, and small and medium size enterprises.

Although the origins of the TPP could be traced to 2003 with the so-called P3 group (Chile, New Zealand and Singapore), which afterwards became the P4 with the inclusion of Brunei Darussalam, in late 2009 the United States decided to be part of this negotiating group in an expanded fashion. (See also Box III.3, infra) Since then the TPP negotiations have naturally been led by the US. The agreement may become the largest plurilateral trade pact for the US by trade value. In fact, it is more than twice as large as any other TPP country in terms of its economy and population,[44] followed by Japan. (See Box III.2 infra on US trade balance with respect to its TPP partners).

The TPP Trade Ministers (2011) "identified five defining key features that will make TPP a landmark, 21st-century trade agreement, setting a new standard for global trade and incorporating next-generation issues that will boost the competitiveness of TPP countries in the global economy": its comprehensive market access, a fully regional agreement, the crosscutting nature of trade issues, the new trade challenges (to promote trade and investment in innovative products and services, including related to the digital economy and green technologies), and to ensure a competitive business environment across the TPP region) and a living agreement in terms of updating it to address emerging new issues. [45]

The TPP is also seen as "the platform for a broader Asia-Pacific free trade area, an area that it may encompasses 40% of the world's population and over half of global production."[46] Several countries have been mentioned as potential TPP partners including China, Republic of Korea, India, Costa Rica, Thailand, and Colombia.

According to the number of Regional Trade Agreements notified to the World Trade Organization all TPP countries (see chapter I, *supra*) have a large experience in negotiating PTAs with their TPP partners (see details in Annex D) as well as with other trading partners[47] (for details see Annex C). Chile is the TPP country with the largest number of signed trade agreements and it is the only TPP negotiating party that has already a free trade agreement concluded with the other eleven partners. The US has PTAs

[44] Brock R. Williams, Congressional Research Service, "Trans-Pacific Partnership (TPP) Countries: Comparative Trade and Economic Analysis", June 10, 2013, available at https://www.fas.org/sgp/crs/row/R42344.pdf .
[45] The whole statement is available at: https://www.dfat.gov.au/fta/tpp/111112-tpp-broad-outlines.html.
[46] Brock R. Williams, Congressional Research Service, "Trans-Pacific Partnership (TPP) Countries: Comparative Trade and Economic Analysis", Op. cit., p. 26.
[47] *Ibid* pp. 27-30.

currently in force with six of the TPP countries (Australia, Canada, Chile, Mexico, Peru, and Singapore).

Box III.2
US trade balance with TPP members[48]

Trans-Pacific Partnership Countries

	U.S. FTA	Population (millions)	GDP ($billions)	U.S. Imports ($billions)	U.S. Exports ($billions)	Trade Balance ($billions)
Australia	✓	22.8	1,542	9.5	31.2	21.7
Brunei		0.4	17	0.1	0.2	0.1
Canada	✓	34.8	1,819	324.2	291.8	-32.5
Chile	✓	17.4	268	9.4	18.9	9.5
Japan		127.6	5,964	*146.4*	*70.0*	*-76.3*
Malaysia		29.5	304	25.9	12.9	-13.1
Mexico	✓	114.9	1,177	277.7	216.3	-61.3
New Zealand		4.4	170	3.4	3.2	-0.2
Peru	✓	30.5	199	6.4	9.4	2.9
Singapore	✓	5.4	277	20.2	30.6	10.3
Vietnam		90.4	138	20.3	4.6	-15.6
United States		314.2	15,685	Total U.S. Imports from TPP Countries **$843.6**	Total U.S. Exports to TPP Countries **$689.0**	Total U.S. Trade Balance with TPP Countries **-$154.6**

$U.S. dollars

[48] Ian F. Fergusson, Coordinator, Mark A. Mc Minimy, Brock R. Williams, Congressional Research Service, "Trans-Pacific Partnership (TPP) Countries: Comparative Trade and Economic Analysis", November 19, 2014, p. 2. Figures are shown from the US perspective, available at https://www.fas.org/sgp/crs/row/R42344.pdf. It should be noted that the Congressional Research Service (CRS), is a non-partisan US governmental body that provides policy and legal analysis for all members and committees of the Congress.

The current TPP negotiating partners include 4 (out of ten) members of the Association of Southeast Asian Nations (ASEAN), namely Brunei, Malaysia, Singapore, and Vietnam. Additionally, the Regional Comprehensive Economic Partnership (RCEP) initiative that would join ASEAN with Australia, China, India, Japan, New Zealand, and the Republic of Korea will incorporate 7 of the 12 TPP members, namely Australia, Brunei, Japan, Malaysia, New Zealand, Singapore, and Vietnam. Finally, all TPP negotiating partners are also members of the 21-member Asia-Pacific Economic Cooperation (APEC) forum.

The leadership played by the US in the TPP negotiations is explicit in President's Obama statements and argumentations that are consistent with his "Made in America Trade Agenda" and "more jobs for Americans", which is not only critical for the US economy but also for the its leadership *vis à vis* China in the Asia-Pacific Region. Furthermore, as reiterated by the United States Trade Representative:

> TPP is as important strategically as it is economically. Economically, TPP would bind together a group that represents 40 percent of global GDP and about a third of world trade. Strategically, TPP is the avenue through which the United States, working with nearly a dozen other countries (and another half dozen waiting in the wings), is playing a leading role in writing the [trade] rules of the road for a critical region in flux.[49]

In a way, as KORUS did, TPP offers the US the possibility for economic rebalancing its strategic position in the Asia-Pacific Region because of the constant rise of the Chinese economy:

> The centerpiece of our economic rebalancing is the Trans-Pacific Partnership (TPP)-a high standard agreement the United States is crafting with Asia-Pacific economies from Chile and Peru to New Zealand and Singapore.[...] We always envisioned the TPP as a growing platform for regional economic integration.[50]

A group of US Congressmen addressed (2011) a letter to the President highlighting the importance of the TPP for industry and particularly targeting the need for appropriate IP protection and the opportunity that the ongoing negotiations offer:

> The United States is the most innovative, creative, and IP-dependent economy in the world. Our IP-intensive industries employed more than 19 million Americans, create high paying jobs, and account for approximately 60 per cent of U.S. exports. As such the United States has the most to lose from weak IP standards in foreign markets. Inadequate protection of U.S. intellectual property around the world could impair future investment in research and development and discourage the capital investments critical to developing new technologies that can save or enhance lives and create jobs for millions of Americans. In order to protect

[49] Remarks by Ambassador Michael Froman at the Council on Foreign Relations **"***The Strategic Logic of Trade", statement made in New York in June 16, 2014 and available at:* https://ustr.gov/about-us/policy-offices/press-office/speeches/transcripts/2014/June/Remarks-USTR-Froman-at-Council-Foreign-Relations-Strategic-Logic-of-Trade.

[50] US National Security Adviser, Thomas Donilon, 11 March 2013. See Ian F. Fergusson, Coordinator, Mark A. McMinimy, Brock R. Williams, Congressional Research Service, op. cit., p.7.

existing U.S. jobs and to create new jobs in the United States, it is essential that the United States press the TPP negotiating parties for the highest IP standards and that those standards apply to all TPP participants without exception.[51]

In brief, it has been argued that IP in the TPP negotiations is crucial and essential for competitiveness and job creation and -as in the case of previous PTAs- to reinforce its innovation-based sector by means of exporting a number of aspects of the US IP system. For example in the case of patents and pharmaceuticals emphasis has been placed on patent term adjustment and patent term extension; provisions regarding the protection of undisclosed information for pharmaceuticals including biologics; additional protection for the data regarding new clinical information of known products; patent linkage; indirect reliance[52]; patent protection for the new uses of known products; longer grace periods for patent novelty.

2. Brief negotiating history

The TPP, as mentioned earlier, emerges as an ambitious integration project in the Asia Pacific region following the review clause of the P4 agreement.[53] Effectively, this agreement was opened to attract new members in the region. (See Box III.3 for a brief account of the P4 Agreement).

Box III.3
The P4 agreement in brief

During the APEC summit of the Asia-Pacific Economic Cooperation Forum (APEC) held in 2002 in Los Cabos (Mexico), Chile, New Zealand and Singapore started negotiations for what initially was known as the Pacific Three Closer Economic Partnership (P3-CEP). Subsequently, Brunei for the first time participated in the fifth round of such negotiations in April 2005, and finally joined the Trans-Pacific Strategic Partnership Agreement, also known as P4, which was signed in June 3, 2005 and entered into force in January 1, 2006, between Chile, Brunei Darussalam, New Zealand and Singapore. It was the first plurilateral trade agreement ever signed by countries across the Pacific, which aimed to eliminate 90% of tariffs among member countries in January 1, 2006, and completely eliminate them in 2015.

[51] Letter dated July 13, 2011 addressed to the U.S. President and signed by Christopher S. Murphy; Howard Coble; Mary Bono Mack; Marsha Blackburn; John R. Carter; Ted Deutch; David Dreier; Blake Farenthold; Tim Griffin; Brett Guthrie; Richard Hanna; Tim Huelskamp; Lynn Jenkins; Bill Johnson; Hank C. Johnson; Adam Kinzinger; Leonard Lance; Rick Larsen; Jeff B. Miller; Donald A. Manxullo; Edolphus Twons and Jim Cooper, can be seen at: http://infojustice.org/wp-content/uploads/2011/07/22-Representatives-July-2011.pdf.

[52] Indirect reliance is a marketing approval granted by a country for a new pharmaceutical product based on the evidence of a marketing approval of that product in a third country, in which case the country granting the marketing approval shall not permit third persons to market the same product for at least five years from the date of the marketing approval of the new pharmaceutical product.

[53] Article 12.9 of the P4 agreement reads as follows: "Review. The Parties shall consult within two years of entry into force of this Agreement and at least every three years thereafter, or as otherwise agreed, to review the implementation of this chapter and consider other trade in services issues of mutual interest, with a view to the progressive liberalization of the trade in services among them on a mutually advantageous basis."

The P4 was built, as an open pact as provided under Article 20.6, which gives the possibility to other APEC economies or other states, become a party to the Agreement, on the terms agreed by the parties. This provision allowed Australia, Peru and Vietnam to join the TPP group in 2008, while Mexico and Canada did it in 2013 and Japan in 2014.[54]

When P4 negotiations regarding financial services and investment started in March 2008, the US decided to join the group "with the goal of shaping a regional agreement that will have broad-based membership and the high standards worthy of a 21st century trade agreement"[55] and in September 2008 Australia, Peru, and Vietnam joined the negotiations. Malaysia did it in 2010 and Canada and Mexico followed suit in 2013. Japan joined in 2014.[56] A detail of this process is described in Box III.4.

Box III.4
TPP negotiations

Country	**Joined the negotiations in**	**First TPP meeting to assist**
Originals P4 members: Brunei Darussalam, Chile Singapore and New Zealand	May 26, 2006	1st Melbourne
Australia	November 20, 2008	1st Melbourne
United States	February 2008	1st Melbourne
Peru	November 2008	1st Melbourne
Vietnam	November 2008	1st Melbourne
Malaysia	October 2010	3rd Bandar Seri Begawan

[54] Article 20.6 on accession of the P4 Agreement provides:
"1. This Agreement is open to accession on terms to be agreed among the Parties, by any APEC Economy or other State. The terms of such accession shall take into account the circumstances of that APEC Economy or other State, in particular with respect to timetables for liberalization.
2. The agreement on the terms of accession shall enter into force 30 days following the date of deposit with the depositary of an Instrument of Accession which indicates acceptance or approval of such terms".
The complete text of the P4 Agreement can be found at:
http://www.sice.oas.org/Trade/CHL_Asia_e/TransPacific_text_e.asp#a206.

[55] Announcement made by President Barack Obama, in November 14, 2009 in Tokyo, Japan, available at http://www.usnzcouncil.org/brief-overview/.

[56] The broad outlines of an ambitious TPP agreement was launched at the APEC Leaders' Meeting held in Honolulu, on November 2011, by the Leaders of Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, Vietnam, and the US. The stamen made by Leaders is available at http://beehive.govt.nz/sites/all/files/TPP_Leaders_Statement.pdf.

Canada	June 2012	15th Auckland
Mexico	June 2012	15th Auckland
Japan	May 2013	18th Kota Kinabalu

Source: Several domestic relevant sources.

According to information provided under different official websites of the negotiating countries, until late April 2015 the TPP negotiators have held 27 rounds of negotiations and several inter-sessional meetings, being the latest the round held in Hawaii in February 2015. At the time of writing, negotiations at the "technical group" level have been completed and political discussions will continue at a higher level on outstanding matters. A final Ministerial Meeting is expected to take place in the first semester of 2015.[57]

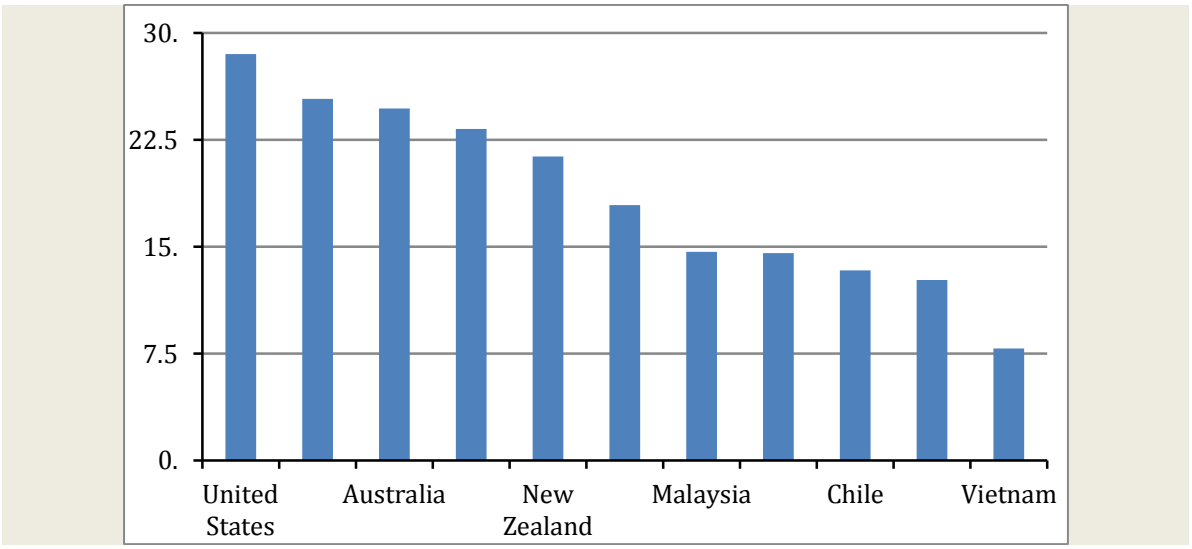
3. Intellectual property in the negotiations

Although there are deep differences between the levels of IP standards in TPP countries (see Annex B for further details), it is inconceivable to envisage a PTA led by the US without strong IP related provisions. The US Chamber of Commerce elaborates regularly an international IP index measured according to a number of criteria considered by the Chamber to rank countries according to the perceived strength of their IP system. Box III.5 portrays eleven TPP economies under this ranking. These differences in levels of protection, enforcement and in general sophistication of their respective IP regimes explain the problems reportedly encountered in this area of the TPP negotiations.

Box III.5[58]
International IP Index: Overall economy score of TPP countries

[57] At the time of writing, the bilateral negotiations between the US and Japan regarding market access (mainly on rice and automobiles) were still going on and a meeting between President Obama and Prime Minister Abe was scheduled for end April 2015.

[58] 2015 Index according to the U.S. Chamber of Commerce's Global Intellectual Property Center, elaborated under the basis of 30 countries (there is no available information for Brunei Darussalam), measured according to 30 different criteria. See the GIPC International IP Index, Third Edition, February 2015, available at http://www.theglobalipcenter.com/up-unlimited-potential-the-gipc-international-ip-index-3rd-edition/.



One main concern of TPP countries, other than the US and probably Japan, relates to patents and pharmaceutical products, including the protection of biologics, data protection for new uses of known products, patent protection for known products, indirect reliance, linkage, and transparency rules regarding the procurement of medicines under public health programs, all issues included in the US TPP original proposals. Patents and regulated products have not been the only areas of disagreement in the negotiating process (see Box III.6 infra).

As reiterated, the reinforcement of IP protection worldwide has been a traditional tenet of US trade policy and the country has played the leading role in achieving its strong and effective IP agenda. In this respect and according to the USTR,[59] the US objectives in the TPP negotiations have been:

- Strong protections for patents, trademarks, copyrights, and trade secrets, including safeguards against cyber theft of trade secrets;
- Commitments that obligate countries to seek to achieve balance in their copyright systems by means of, among other approaches, limitations or exceptions that allow for the use of copyrighted works for purposes such as criticism, comment, news reporting, teaching, scholarship, and research;
- Pharmaceutical IP provisions that promote innovation and the development of new, lifesaving medicines, create opportunities for robust generic drug competition, and ensure affordable access to medicines, taking into account levels of development among the TPP countries and their existing laws and international commitments;
- New rules that promote transparency and due process with respect to trademarks and geographical indications;

[59] See https://ustr.gov/tpp/Summary-of-US-objectives, visited 11/03/2015.

- Strong and fair enforcement rules to protect against trademark counterfeiting and copyright piracy, including rules allowing increased penalties in cases where counterfeit or pirated goods threaten consumer health or safety; and
- Internet service provider "safe harbor" provisions, as well as strong and balanced provisions regarding technological protection measures to foster new business models and legitimate commerce in the digital environment.

The reported, non-written history of the negotiations, point to the fact that IP, as in previous PTAs, has been one of the most controversial issues and it has been an arduous process for the US to prevail in this area. As shown in the leaked documentation, an important number of TPP members have resisted the original maximalist US viewpoints. Reports suggest, however, that the IP outstanding issues in recent formal and informal rounds have been reduced in number because positions of different negotiating partners have been reconciled. The US, again, has played a major role in this process by holding bilateral informal encounters with the eleven other negotiating partners with the view of reducing gaps in their respective positions.[60]

With the goal of providing an overview on the most controversial issues in the IP negotiations, Box III.6 presents the principal contentious questions in the leaked known document. It should be reiterated that in the light of the absence of official documentation of the negotiations the comments are of a preliminary nature and relate to positions taken by some countries at the time the text was leaked to the public or information otherwise available to the authors. Among the most elusive issues are those related to patents and pharmaceuticals, copyright and enforcement. In general and as described in chapter 2 supra, the intellectual property provisions in the TPP take as an important source the latest successful PTA negotiated by the US under KORUS. The information contained in the Box is based on the leaked version of the TPP negotiating document.[61] Chapter V of this report considers further the public health and enforcement related questions in the TPP.

Box III.6: Main IP related controversial provisions (in parenthesis reference to provision as identified in leaked version of the TPP)

IPR Chapter	Controversial issue

[60] According to informal information and with the view of making progress in the finalization of the TPP, it appears that the US has "softened" some of its original proposals on issues such as plants protection and patentability of second uses of known products, in view of large resistance from TPP partners.

[61] This document was leaked by WikiLeaks by mid-October last year and it corresponds to the negotiating text resulted after the 21st round of negotiations held in Ho Chi Minh from May 12 to 17, 2014. The leaked text also reflects the negotiation position of each party to the negotiations. The leaked document at the time of writing is still publicly available at: http://wikileaks.org/tpp-ip2/.

Objectives and Principles of the TPP agreement	- The link between the TPP objectives and those provided under articles 7 and 8 of the TRIPS Agreement have been controversial, mainly on each Party's right to protect public health and access to affordable medicines (QQ.A.2 *bis*), including the appropriate reference to be made to the Doha Declaration on TRIPS and Public Health and related WTO documents. (QQ.A.6) - Scope and limitation of National Treatment (QQ.A.9) - Transparency on laws and IPRs related matters. (QQ.A.10) - Exhaustion of IPRs particularly in the case of copyright. (QQ.A.11)
Trademarks	- Different types of protectable trademarks not limited to a visually perceptible sign, such as sounds and/or scents. Several countries have opposed the protection of scents as trademark. (QQ.C.1) - Ways of using the so-called common names. (QQ.C.2)
Geographical indications[62]	- The possibility to protect or recognize geographical indications through an agreement between the TPP party and another government or governmental entity. (QQ.D.3) - Grounds for opposition and cancellation procedures for geographical indications regarding wines and spirits recognized under an agreement with a government or governmental entity. Controversial has been the issue of refusing or affording a geographical indication when it was likely to cause confusion with a trademark or a geographical indication subject to pre-existing good faith pending application or with a pre-existing trademark or geographical indication already protected according to the Party´s law . (QQ.D.4) - Applicable rules for geographical indications already protected or recognized under an existing agreement with a government or governmental entity. (QQ.D.5) - Protection for homonymous geographical indications, an issue of concern mainly to Chile and Peru. (QQ.D.12) - Inclusion of lists of protectable geographical indications belonging to each Party (QQ.D.12)

[62] One of the main problems has been the discussion if geographical indications recognized under a treaty should or should not be subject to the provisions of this section. This has been particularly important for countries that have already signed an agreement with the European Union.

Patents	- Patentability of plant related inventions and new uses or new method of using known products. (QQ.E.1) - Blocking the possibility of adopting in national laws provisions based on Section 3(d) of the Indian Patents Act (See further discussion in Chapter 5, infra) (QQ.E.1, paragraph 2). - Grounds for the cancellation of a patent limited only to grounds that would have justified a refusal to grant de patent. (QQ.E.3) - Scope of the Bolar exception. Countries disagreement focused on whether the exception is limited to "generate information" to support a marketing approval including export of the product.(QQ.E.13) - Publication of the patent application and exceptions to it. (QQ.E.11) - Patent term adjustment in case of unreasonable delays in a Party's issuance of patents to compensate such delays and its conditions thereof. (QQ.E.12) - Prohibition to use undisclosed information or test data to ground authorization of an agricultural chemical product to someone different from who provided such information or data. (QQ.E.13) - Protection of traditional knowledge, genetics resources and cultural expressions. (Proposal made by Peru) (QQ.E.23)
Pharmaceuticals	- Patent term extension to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of delays in the marketing approval process. (QQ.E.14) - Protection of undisclosed information and test data from using the information or data without the consent of the owner. (QQ.E.16 in Addendum I) - Patent linkage. (QQ.E.17 in Addendum I) - Definition of biologic products (QQ.E.20 in Addendum I) - Extended protection for data protection regarding biological products (0, 5, 8, 12 years). (QQ.E.20 in Addendum I)
Copyrights and related rights	- Scope of protection of related rights. (QQ.G.14) - Copyright term of protection (50, 70, 75, 95 years from the end of the calendar year of the first authorized publication of the work). (QQ.G.6) - Retransmission of television signals (whether terrestrial, cable, or satellite) on the Internet. (QQ.G.ZZ) - Scope of the Technological Protection Measures (TPMs) and Right Management Information (RMIs). (QQG.10; QQ.G.13)
Enforcement	- Enforcement procedures for trademarks and copyrights in the digital environment. (QQ.H.1) - Abuse of enforcement procedures to be addressed by judicial authorities (QQ.H.4) - Special requirements related to border enforcement measures. (QQ.H.6). - Availability of criminal procedures, penalties, and remedies.

	(QQ.H.7) - Protection of Encrypted Program-Carrying Satellite and Cable Signals through criminal procedures and penalties. (QQ.H.9)
Internet service providers	- Level of liability of Internet Service Providers (Addendum III)
Entry into force of the agreement	- Rules regarding the transitional arrangements to the entry into force of the agreement. (QQ.J.X; Annex A; Addendum II)

4. The process of TPP entry into force and transitional arrangements

TPP members have discussed several options for the entry into force of the agreement. Informal sources suggest that discussions focus on a proposal that the agreement should enter into force after the date on which at least certain number of signatories (two or three members) accounting for at least certain percentage of the combined GDP of the signatories (50%-75%), having each notified the Depositary of the completion of their applicable legal procedures.

For any other signatory, the agreement shall enter into force within a certain period of time after the signatory and the Parties have jointly notified the Depositary that the signatory concerned has completed its applicable legal procedures for the agreement to enter into force. The Depositary shall be one of the TPP members.

A further thorny issue has been around transitional arrangements, with respect to: i) which provisions of the agreement would be subject to a transitional period; ii) how long the transitional periods would last; and iii) which country may avail itself of transitional arrangements.

Regarding the first question, it seems that there is a degree of consensus that transitional measures should be available for certain provisions concerning pharmaceutical products such as patent term adjustment, patent term extension, patent linkage, data protection, indirect reliance and data protection for biologics.

With respect to the extension of the transitional measures, they will depend on the particular subject matter. For instance, the issues listed in the previous paragraph, might be subject to different arrangements.

For determining the countries that may avail themselves for transitional arrangements, TPP members would be divided into three main categories: Category A composed at least of the United States, Japan, Singapore and other countries to be

confirmed; Category B headed at least by Mexico, Brunei and other countries to be confirmed, and Category C by Peru and Vietnam.

5. Other related issues on the entry into force of the TPP

There have been positive signs in recent months that an agreement might emerge among the TPP partners. Progress have been reported on legal, institutional, textiles, rules of origin, state-owned enterprises, environment, goods market access, technical barriers to trade, and e-commerce and, as have been pointed out, gaps have been bridged in the contested IP chapter. Optimism prevails at the executive and technical level but resistance to the TPP persist among dissident stakeholders. Any scenario is foreseeable on the future of the TPP including a rejoicing conclusion or an ACTA-like situation.

In the case of the US there are still important hurdles to be overcome including the Trade Promotion Authority, TPA, (also known in as fast track); a US statutory mechanism being used since 1974 under which an authorization is given to the US President by Congress to negotiate and conclude international agreements with third parties, subject to the conditions and requirements listed by Congress, which then shall be approved or rejected normally without any modification and in a fast track procedure.[63] If an agreement has been negotiated and concluded by the US President without a TPA, then Congress is allowed to request amendments to the agreement before the required Congressional approval, as it has happened in the past with the conclusion of some PTAs between the US and Latin American countries.

According to practice, a TPA would include the following:

(1) TPA outlines Congressional guidance to the President on trade policy priorities and negotiating objectives.

(2) TPA establishes Congressional requirements for the Administration to notify and consult with Congress, with the private sector and other stakeholders and with the public during the negotiations of trade agreements.

(3) TPA defines the terms, conditions and procedures under which Congress allows the Administration to enter into trade agreements, and sets the procedures for Congressional consideration of bills to implement the agreements.[64]

Discussions on the granting of a trade authority in the form of a Trade Priorities and Accountability Act 2015 (TPA) appear to make progress in Congress according to available information at the time of writing.[65] Section 7 of the draft bill[66] contains special provisions

[63] It should be noted that even with a TPA granted, a majority of the US Congress may insist with the President to introduce changes in a signed and concluded agreement, as it was the case in KORUS.
[64] Trade Promotion Authority, USTR: www.ustr.gov/trade-topics/trade-promotion-authority.
[65] See reporting in the New York Times, Deal Reached on Fast-Track Authority for Obama on Trade Accord, http://www.nytimes.com/2015/04/17/business/obama-trade-legislation-fast-track-authority-trans-pacific-partnership.html?hp&action=click&pgtype=Homepage&module=first-column-region&region=top-news&WT.nav=top-news&_r=2. See also UD Trade Debate Kicks into High Gear as Congress Debates TPA

regarding the treatment of certain trade agreements for which negotiations have already begun, including TPP and TTIP, among others.

Another important aspect of US law regarding the implementation of free trade agreements refers to the certification practice discussed in the following paragraphs.

The certification process –first used in the Canada – United States Free Trade Agreement in 1998- is an US internal mechanism, which has been included in US legislation to implement trade agreements. Under this piece of legislation the US President certifies that the domestic legislation of a country with which the US has already signed a trade agreement, satisfies "the US expectations of what is needed to comply with the free trade agreement (FTA)."[67]

In latest agreements signed by the US, the language of the certification clause included in its domestic legislation stated:

> At such time as the President determines that countries listed in subsection (a)(1) have taken measures necessary to comply with the provisions of the Agreement that are to take effect on the date on which the Agreement enters into force, the President is authorized to provide for the Agreement to enter into force with respect to those countries that provide for the Agreement to enter into force for them.[68]

This text is similar in the case of the PTAs signed with Chile,[69] Australia,[70] and the Republic of Korea.[71]

Bill, ICTSD Bridges, http://www.ictsd.org/bridges-news/bridges/news/us-trade-debate-kicks-into-high-gear-as-congress-debates-tpa-bill (Apr-15)

[66] The text of the bill is available at: http://www.finance.senate.gov/newsroom/chairman/release/?id=7701eb50-a0ef-4257-bfc1-b06efe725b8c See also note 29, supra

[67] Jane Kelsey, "Q&A on the US legal requirement for "certification" of trade partners´ compliance before an agreement like the TPP goes into effect", Third World Network, August 2014, available at: http://tppnocertification.org/wp-content/uploads/2014/08/Certification-memorandum.pdf.

[68] Paragraph included under 19 U.S. Code § 4011 - Approval and entry into force of the Agreement of the Dominican Republic-Central America-United States Free Trade Agreement (b) (2), available at: http://www.law.cornell.edu/uscode/text/19/4011.

[69] See https://books.google.cl/books?id=ekD_DwwaixcC&pg=PA1165&lpg=PA1165&dq=conditions+for+entry+into+force+of+the+agreement+US+Chile&source=bl&ots=XjpwByG9cK&sig=VbApyNXQ_E9VJAgdD6xPKXHs58c&hl=es-419&sa=X&ei=bLumVIWdMsehyASB84GoAw&ved=0CBwQ6AEwAA#v=onepage&q=conditions%20for%20entry%20into%20force%20of%20the%20agreement%20US%20Chile&f=false.

[70] See https://books.google.cl/books?id=PFQN67pcXo8C&pg=PA449&lpg=PA449&dq=conditions+for+entry+into+force+of+the+agreement+US+australia&source=bl&ots=kH0G1kkoMu&sig=ydBWbaaoYVZIMS2KRmfYlELH-KM&hl=es-419&sa=X&ei=LLymVJs-1p3KBN6UgZAD&ved=0CDsQ6AEwBA#v=onepage&q=conditions%20for%20entry%20into%20force%20of%20the%20agreement%20US%20australia&f=false.

[71] See https://books.google.cl/books?id=ekD_DwwaixcC&pg=PA1423&lpg=PA1423&dq=conditions+for+entry+in

In other words and according to this US legislative practice, a trade agreement signed by a third party with the US does not enter into force neither on the date it is signed by the US President nor on the date it is approved by Congress, but on the date when the US President determines that the trading partner has taken all domestic measures necessary to comply with the provisions of the agreement.

The certification process has provided the opportunity to amend laws or draft laws for its partners, when the United States considers that those pieces of legislation do not fully comply with the provisions of the agreement.[72]

It should be noted that the certification process is an obligation imposed by Congress to the President, which has been incorporated in the enacting acts passed on the approval of US PTAs, since 1988, whether the negotiations of the agreement has taken place with or without a TPA.

The certification process has been applied to bilateral trade agreements and regional trade agreements as well, as it occurred in the US-DR-Central America PTA, in which case the certification was done individually to each country.

It should be noted also another important feature of US Congressional practice that may affect the implementation of a PTA. This refers to the relationship of the PTA with US law. This practice, adopted already in the Canada-US trade agreement consist that in case of conflict between the agreement and US domestic legislation, the latter shall prevail, unless otherwise provided in the implementing legislation. Additionally, nothing in the act approving the agreement shall be construed to amend or modify any law of the United States or limit any authority conferred under any law of the US.[73] Similar provisions have

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to+force+of+the+agreement+US+Korea&source=bl&ots=XjpwByGagJ&sig=X8HukTVyFrMB8xK08o4GUZjy-pc&hl=es-419&sa=X&ei=-LumVIT8A5egyATC5YKwAw&ved=0CC0Q6AEwAg#v=onepage&q=conditions%20for%20entry%20into%20force%20of%20the%20agreement%20US%20Korea&f=false.

[72] This situation has been faced, with different degree of intensity and demand, at least by Chile, RD-CAFTA, Peru, Colombia, Australia and Korea in the approval process of their respective free trade agreements with the US. In the case of Latin American countries, see Pedro Roffe & Mariano Genovesi (2011), *Implementación y Administración de los Capítulos de Propiedad Intelectual en los Acuerdos de Libre Comercio con los Estados Unidos: La Experiencia de Cuatro Países de América Latina*, Banco Interamericano de Desarrollo, Vicepresidencia de Sectores y Conocimiento Sector de Integración y Comercio, Inter-American Development Bank, Sector of Integration and Trade, POLICY BRIEF (No. IDB-PB-129)

[73] 19 U.S. Code § 3312 - Relationship of Agreement to United States and State law (regarding the US-Canada FTA) states as follows:

"(a) Relationship of Agreement to United States law

(1) United States law to prevail in conflict

No provision of the Agreement, nor the application of any such provision to any person or circumstance, which is inconsistent with any law of the United States shall have effect.

(2) Construction

Nothing in this Act shall be construed—

(A) to amend or modify any law of the United States, including any law regarding—

(i) the protection of human, animal, or plant life or health,

been included in the implementing legislation that has approved all PTAs concluded recently by the United States. In the present 2015 trade authority draft bill under consideration in Congress, the same type of provision on US sovereignty is part of the Bill.[74]

In view of this Congressional practice for almost the last three decades, there are no reasons to think that the TPP –if successful- would be in this area an exception. In the context of the TPP, however, questions have been raised regarding the international law implications of the above discussed US legislative practices.

Similar doubts have been raised on the implications of side letters between different TPP members recognizing reciprocal bilateral prerogatives and rights under previous bilateral agreements or special understandings between the parties privy to these side letters and their effects *vis à vis* the other members of the Agreement.

In a recent article published by Ip-Watch it is reported that according to information in Inside US Trade, the US has proposed a side letter to Chile which purpose would be to "enable the US-Chile Free Trade Agreement (FTA) provisions to prevail over those contained in the TPP with regard to the implementation of a patent linkage system."[75]

Side letters have been used often in trade agreements to which the US is a party. They frequently reflect a particular understanding with respect to a specific issue where doubts have emerged in the negotiating process. For example, reference to the Ministerial Doha Declaration on Health of 2001 was the subject of side letters in the case of the RD-CAFTA Agreement with the USA. This precise practice was abandoned as a result of the 2007 bipartisan agreement discussed supra where decision was taken to include reference to the Doha Declaration in the main text of the treaty. (See Chapter I)

(ii) the protection of the environment, or
(iii) motor carrier or worker safety; or
(B) to limit any authority conferred under any law of the United States, including section 2411 of this title; unless specifically provided for in this Act."

[74] See note 29, supra.

[75] Burcu Lilic & Pablo Bioller, Divide and Conquer: The New US Strategy to Disentangle the TPP Negotiations, *Intellectual Property Watch*, 23/04/2004, available http://www.ip-watch.org/2015/04/23/divide-and-conquer-the-new-us-strategy-to-disentangle-the-tpp-negotiations/?utm_source=IP-Watch+Subscribers&utm_campaign=9b36f2170d-DAILY_SUMMARY&utm_medium=email&utm_term=0_b78685696b-9b36f2170d-352127785#bio (visited (Apr-15)

Chapter IV
The European Strategy for the enforcement of intellectual property rights in third countries

The 2004 European Strategy for the enforcement of IPR and the 2014 Strategy for the protection and enforcement of intellectual property rights in third countries depict and shape the activities of the EU aimed at ensuring the enforcement of IPRs in foreign economies. Both documents present in an organized and detailed manner norm-setting activities, control and surveillance, and soft policy actions undertaken by the EU to ensure the respect of the rights of European IP owners in foreign economies. While the comparison of both documents illustrates many of the main changes that have taken place in the last ten years in the IPRs field, the description and comparison of the two documents permits understanding the set of heterogeneous activities undertaken in this domain. The changes introduced in the 2014 imply a good assessment of the past ten years and the interests at stake. However, as we analyse in this chapter, the reality may not coincide with the objectives and actions identified in the 2014 Strategy.

1 Introduction

For economies with IPRs intensive industries, enforcement of IP has both an internal and external dimension.[76] Consistently, IP-intensive economies envisage and implement a number of actions having per objective ensuring the respect of IP abroad. While traditionally the United States has been more active in this field, in the last decade the European Union has not lagged behind.

Two policy documents depict and shape the activities of the EU aimed at ensuring the enforcement of IP rights in foreign economies: the 2004 *Strategy for the enforcement of IPR in third countries* (the 2004 Strategy, hereinafter),[77] and the 2014 *Strategy for the protection and enforcement of intellectual property rights in third countries*.[78] Both documents present in an organized and detailed fashion the aims and actions of the EU to ensure the respect of the rights of European IP owners in foreign economies. The tone of the documents is more conciliatory than respective expressions emanating from US sources. However, probably with the exception of the process of adoption of the USTR 301 reports and the concomitant actions, as well as the use of the WTO dispute settlement procedure,[79] the EU activity is in no way of less significance or softer than that of the US.

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[76] This is particularly the case of United States, EFTA economies and the European Union. *See* the Global Competitiveness rankings in the *Global Competitiveness Report 2014-2015*, http://reports.weforum.org/global-competitiveness-report-2014-2015/report-highlights/ (accessed February 2015).

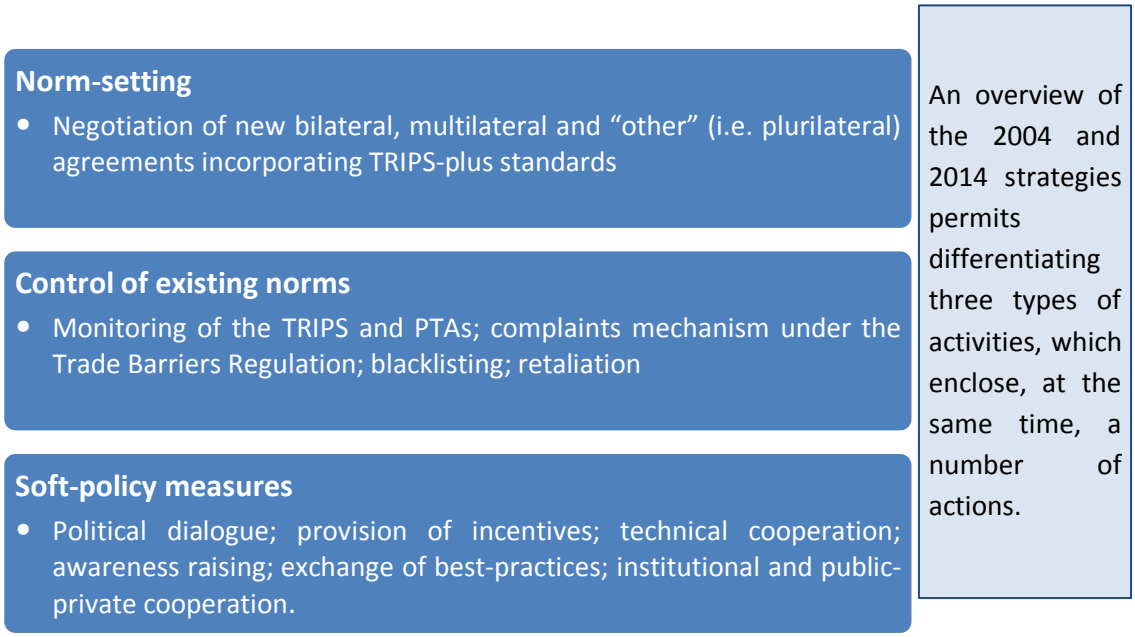
[77] *Strategy for the enforcement of intellectual property rights in third countries*, 2005/C29/03, OJ C129, 26.5.2005.

[78] *Trade, growth and intellectual property - Strategy for the protection and enforcement of intellectual property rights in third countries*, Strasbourg, 1.7.2014 COM(2014) 389 final

[79] Until October 31 2014, the DS Body of the WTO had received 484 cases, where only 34 cases were related to IP. Eighteen of them (53%) have been presented by the US and only 6 (8%) by the EU. This relates to the fifth line of action of the 2004 Strategy

The description and comparison of the 2004 and 2014 documents is a telling exercise. On the one hand, the sections describing the actions to be taken permit understanding in a fairly systematized manner the entire set of heterogeneous activities undertaken in this particular field (See Box IV.1). On the other hand, the comparison of both documents illustrates many of the main changes that have taken place in the last ten years in the IPRs field. Indeed, while a number of actions that both Strategies envisage is coincidental, there are relevant differences in the respective analysis of the underlying situation, the emphasis put in some or some other situations and actions, and the concomitant areas of action.

Box IV.1: Graph of Activities identified in the 2004 and 2014 Strategies



What follows next is an introduction of the content of both documents and, in particular, an assessment of the main changes in the tone of the European approach to the enforcement of IPRs in third countries. We hold that, while the changes introduced in the 2014 Strategy are welcomed, since they represent a good assessment of the past ten years and the interests at stake, the EU action in practice may not be fully in line with the objectives and actions identified in the 2014 Strategy.

2. The 2004 Strategy for the enforcement of intellectual property rights in third countries

2.1 Overview of the 2004 Strategy

TRIPS meant a major event in the international codification of IP enforcement.[80] Pursuant to TRIPS, WTO Members had to implement in their national legal orders a fairly complete

[80] See also discussion in Chapter V Section (D).

set of enforcement related standards. However, even if most of the WTO members fulfilled their TRIPS commitments, the EU held that violations of IPRs continued to increase.[81] With the objective of enhancing the implementation of the enforcement legislation, the EU adopted the 2004 Strategy, presented as an effort to remedy the lack of correlation between the international normative progress and the reality of enforcement within national borders.

The 2004 Strategy was an instrument fundamentally targeting the Commission and right holders. With respect to the Commission, the 2004 Strategy provided a long-term line of action and identified the mechanisms available to it.[82] With respect to right holders and other interested actors, the Strategy informed about the means and actions available and promoted enhanced cooperation with right holders and other private entities.[83] While the 2004 Strategy affirmed that it did not try to impose one-size-fits-all solutions, the need to differentiate countries depending on their level of economic development would only be emphasized ten years later, in the 2014 Strategy. In comparison, the 2004 Strategy pays little attention to the broader societal context.

2.2 The objectives and actions envisaged in the 2004 Strategy

In a clear and concise manner, the 2004 Strategy enumerated the envisaged actions on the part of the European institutions and other relevant stakeholders.

First, the Strategy put in place a mechanism to periodically *monitor* the enforcement of IPRs in third countries. This mechanism was based on the collaboration of public and private entities,[84] and resulted in the adoption and updating of the list of the priority countries for the subsequent period. Reminiscent of the USTR 301 reports, the European mechanism was however described as a soft and rather cooperative tool.

Second, in the field of *international norm-setting and monitoring*, the Strategy underlined the relevance of multilateral norms and mechanisms, and the need to deploy a continued effort in the monitoring of TRIPS compliance. It stated, however, that bilateral treaties should be reinforced and enforcement provisions set forth therein should be made more operational. In relation to both multilateral and bilateral obligations, the 2004 Strategy pledged to raise more systematically enforcement concerns at political meetings and in the councils and committees created in the framework of these bilateral agreements.

A third line of action was *political dialogue*. It was stated that, while the Commission would insist both in bilateral and multilateral fora that it was ready to assist States to improve enforcement, it would not refrain from using the instruments at its disposal when deficient enforcement harmed European right holders. Specific actions of

[81] *2014 Enforcement Strategy*, op. cit., p. 4.

[82] More precisely, the Strategy intended to "i) provide a long-term line of action for the Commission; ii) Describe, prioritise and co-ordinate the mechanisms available to the Commission services for achieving their goal".

[83] In the Strategy it was announced the commitment to "iii) Inform right holders and other entities concerned of the means and actions already available and to be implemented; iv) Enhance co-operation with right holders and other private entities concerned, by seeking their input on the identification of priorities and establishing public-private partnerships in fields like technical assistance, information to the public, etc."

[84] Among others, Commission delegations, embassies of Member States, right holders and associations and chambers of commerce.

cooperation were envisaged, including the provision of training to officials in priority European delegations so that they could offer relevant information to entities with enforcement-related problems.

A fourth line of action was *technical cooperation*. In that context, a flexible approach was suggested, taking into account the recipient country's needs, level of development, membership to the WTO, and main problems in terms of enforcement. It had also an internal aspect, since the Strategy plead for better coordination between European agencies and more time before expecting the results of technical cooperation.[85]

Fifth, *dispute settlement and sanctions* were also mentioned in the 2004 Strategy. It was announced that countries where violations are systematic and no government action is taken would be publicly identified. Next, dispute settlement mechanisms provided for in multilateral and bilateral agreements would be used more intensively. Moreover, the Strategy proposed right holders the use of the Trade Barriers Regulation mechanism, which permits launching particular cases through the mobilization of DG Trade.

Sixth, the 2004 Strategy also promoted the creation of *public-private partnerships*. The Strategy identified companies as source of information and key partners for awareness raising initiatives. An enhanced use should be made of existing public-private partnerships linked with enforcement, among others IPR Helpdesk and Innovation Relay Centers. In that very same context it was also envisaged supporting the creation of local IP networks involving companies, associations and chambers of commerce.

Seventh, the Strategy also had per objective providing better *information to the public*. This implied raising the awareness of consumers in third countries about both the benefits of IP and the problems of not respecting intellectual property rights. Awareness-raising concerned as well IP owners, who should be informed about the risks existing in some countries and the need to use the means available domestically to enforce their rights.

Eight, better *coordination* at the Commission was also identified as a priority target. For that purpose, inter-service meetings should be regularly organized and webpage information should be improved.

3. The 2014 Strategy for the protection and enforcement of intellectual property rights in third countries

3.1 The analysis provided by the 2014 Strategy of the present context and the past ten years

The 2014 Strategy is not only an interesting document for clarifying what can be expected from the EU in the field of IP enforcement, but also an insightful text to examine many of the capital changes that took place in the policy and normative IP world between 2004 and 2013.

The introductory part of the 2014 Strategy touches upon a number of contemporary areas of debate and provides a detailed analysis of the broader social context. In fact, many

[85] More specifically, it claimed that trade-related technical assistance programs with respect priority countries should include IP (in particular to Latin America), that in production countries that strategy should move from legislation to more specific enforcement-oriented strategy and actions.

of the issues mentioned in that introduction are only partially related to IP enforcement *per se*, and concern, by contrast, the broader IP policy and normative spheres. This is indeed the case of the section devoted to the relationship between public health and IP, as well as the section on the relationship between environment and IP law and those devoted to research and innovation, and information and communications technologies. In fact, the introduction also depicts areas such as the contribution of IP to development. Overall, this approach represents a major change with respect the 2004 Strategy which was primarily devoted to IP enforcement as such.

The drafters of the 2014 Strategy changed the straightforward messages of the 2004 Strategy for another, more contextualized and conciliatory, language.[86] The new document pays a great deal of attention to the social perception of IPRs and frequently insists in the links between IP and human rights, in the need to preserve the balance between the right holder's rights and the rights of other interested parties, and the need to treat countries differently in accordance to their level of development. The major technological developments experienced in the last decade –with particular reference to the digital environment- and the changing nature and scope of the challenges and risks to European companies are invoked in the Strategy to justify the need for a new document.[87] Interestingly, the 2014 Strategy draws a distinction between developing economies and emerging economies, suggesting that a tougher line should be implemented with respect to the latter.[88] This differentiation is indeed a major advancement. The EU, however, considers harmonization in emerging economies a priority. According to the EU, these countries have become IP-intensive goods exporters and benefit, thus, from higher standards of protection. However, the absence of a level playing field enables IP infringers to exploit the existing differences.[89] Concerning less developed economies, the differentiation proposed by the EU permits drawing a parallel with the US Congress 2007 Bipartisan Agreement, which introduced certain flexibilities in the IP field in benefit of developing countries.[90] Indeed, among the issues to follow in forthcoming European agreements and actions there is the fulfilment of this proclaimed differentiation.

As the 2004 Strategy did before, the 2014 Strategy emphasizes that there is a great gap between enforcement regulation and the practice of enforcement. Changes introduced by TRIPS in terms of enforcement legislation are not corresponded with comparable efforts in the practical aspects of enforcement. The Strategy takes a very broad perspective and

[86] Several examples will be pointed out next. Take for instance the control of goods in transit. While the 2004 document suggested that TRIPS take cognizance of this issue, the 2014 document does not refer to the issue directly.
[87] 2014 Strategy.
[88] When it comes to *emerging economies*, the discourse of the Commission is less condescending. According to the Strategy, some emerging economies have engaged in aggressive policies that seek to appropriate foreign technology and to boost national champions, in particular in sectors considered strategic, e.g. through 'forced technology transfer', local content requirements, and domestic innovation policies aimed at 'leapfrogging.
[89] 2014 Strategy, p. 7.
[90] As discussed in chapter I, the difference is that the 2007 agreement has not been followed in subsequent negotiations, while in the case of the EU it remains as integral part of the Strategy.

links substantive IP standards with intellectual property enforcement. For the Strategy, substantive standards should be clear and proportionate.

One of the most interesting aspects of the 2014 Strategy relates to the recognition of the influence of social perceptions and attitudes around IP. The Strategy establishes a clear link between the challenges for enforcement and the social debates surrounding the protection of IP. It states that the derailment of some initiatives aimed at enforcement of IP responds to concerns driven by a combination of societal factors: the perception of overreach by right holders, the perception that counterfeiting and piracy are victimless crimes, and a lack of awareness on the rationale and economics and the wider effects of intellectual property.

The drafters seem to make a clear diagnostics: balance within the IP system cannot only be in writing, it must also be perceived. "Balance", the much used word on the part of the academy, consumers and numerous countries, becomes a key word. Pursuant to the 2014 Strategy, "reasonable balance must be maintained between (1) the need to improve access to goods and services protected by IPRs and (2) the need to incentivize right holders to continue to invest in innovation, and (3) the need to balance different fundamental rights".[91] The Commission proposes therefore a more open framework, where the pursuit of balanced norms is expressly recognized as a fundamental objective while at the same time consumers are better informed about the importance of IPRs in different socioeconomic contexts.

The Strategy also pays attention to the important relationship between IP and development. In a message addressed to developing and emerging economies, the Strategy states that effective IPRs protection results in a number of benefits, especially when complemented by improvements in the investment and business climate and the capacity to absorb technology. According to the 2014 Strategy, emerging economies are increasingly becoming exporters of IP-intensive goods, and benefit therefore from stronger IP regimes. In this line, the Strategy recalls that the EU is cognizant of a differentiation that takes into account the level of development and the institutional capacity in developing countries.

The Strategy devotes special attention to the digital environment. In particular, it considers IP enforcement in the Internet an area of priority action, especially with respect to Internet service providers. The Commission suggests that legislative action is needed – although it does not specify the nature of the instruments that should be adopted, *i.e.* plurilaterals, bilaterals?-, and that certain alliances should be promoted. In this respect, it states that creators and intermediaries need to cooperate in taking operational initiatives. This can be done through soft law measures that complement legal frameworks, for example initiatives on a voluntary basis establishing a code of practice.

3.2 Action points of the 2014 Strategy

The actions identified in the 2014 Strategy can also be grouped into three different categories: activities relating to norm-setting, activities relating to the control of existing norms and soft-policy measures.[92] While many topics are coincidental in both strategies,

[91] 2014 Strategy, op. cit., p. 14.
[92] See above Box IV.1, *Graph of Activities identified in the 2004 and 2014 Strategies.*

there are also two notorious changes. One relates to the introduction of new areas of concern, the other relates to the emphasis put on some specific aspects.

An example of a new area of concern is the commitment to enhance data collection relating to the economics of enforcement, so as to improve the understanding of the role of IP infringement and its impact. Certainly, awareness-raising was tangentially mentioned in the 2004 Strategy, but the presence of this aspect in both strategies is so different that it can be considered a new area of concern.

Regarding a change on the emphasis in the activities that coincide in both strategies, this is notorious in the case of normative activities. While in 2004 it was announced that the approach with respect to bilateral treaties would change in order to clarify and strengthen enforcement clauses, the 2014 directly presents bilateral agreements as the best instrument to continue the development of IP enforcement norms.

The 2014 Strategy announces that the Commission will take up numerous action points. First, given that one of the main current problems is the negative reaction to IP policy initiatives on the part of a broad range of stakeholders, the Commission announces that it will regularly interact with all stakeholders with the objective of raising awareness and guide policy.

Second, another perceived problem is the alleged lack of understanding of the role of IPRs, and the resulting deleterious impact of infringement. In order to address this concern, it is announced that data collection and reporting will be enhanced, and regular surveys in order to maintain a list of "priority countries" for focused efforts will be conducted.

Third, normative action is also among the priorities. More specifically, it is announced that efforts to strengthen the international intellectual property normative framework will be deployed. This includes actions at different levels, namely the promotion of the ratification of existing treaties both on the part of EU Members and third economies, and the enhancement of IP chapters in bilateral trade agreements. In this last regard, it is stated that PTAs should offer adequate and efficient protection for right holders and address key weaknesses in partner countries' IP systems, while calibrating commitments to the countries' level of development.

In relation to international legal instruments, the Commission recalls that it can have resource to dispute settlement mechanisms or other remedies where European rights under international agreements are infringed.

The 2014 Strategy also envisages the promotion of international cooperation mechanisms. In this regard, it announces the continuation of intellectual property dialogues with key third countries, either in parallel or as an alternative to high-level trade and political dialogues. Also in the context of international cooperation, the Strategy states that technical cooperation programs are to be promoted, both those implemented by the EU itself and those other run by other international organizations.

The Strategy makes a number of references to *actions that the EU can adopt at the internal level*. It affirms that it is necessary to establish a stronger relationship between the

Commission, States and European business to directly support economic operators in overcoming concrete difficulties on IP issues, as well as to enhance networking and coordination of actions between the Union and Member States representations in third countries.

Whereas the Strategy does not allude to international sanctions, it foresees the deployment of *retaliatory measures*, in particular the possibility of restricting participation or funding in European programs in "sufficiently serious and clearly targeted cases". In this regard, it aims at enhancing coherence between IP and other policies, and to improve consistency between the Commission and Member States in third countries in this goal.

Finally, both the assistance to right holders through projects such as *IPR Helpdesk*, and the strengthening of the EU action in the field, by means of the further posting of IP experts to key European delegations, are also among the possible initiatives to be deployed.

4. Are the present EU initiatives in harmony with the goals envisaged in the 2014 Strategy?

4.1 Norm setting in the bilateral context that takes into account the different realities, balance of interests and fundamental rights

Several characteristics make the 2014 Strategy a more modern text in terms of the contextualization of the interests at stake and the attention paid to a number of relevant factors. One of the specific features of the 2014 Strategy is the emphasis put on the contribution of IP enforcement to development. It is in that context that special mention is made to the need of differentiating countries depending on their level of development. Similarly, in the 2014 Strategy it is also apparent the emphasis made to the need to preserve a balance between the rights of title holders and the rights of the alleged infringers and other interested parties. Additionally, and in a related fashion, several references are also made to the need of ensuring the protection of fundamental rights, such as freedom of expression, protection of personal data, and due process.

In consequence with the stated goals, it seems logic to infer that treaties negotiated by the DG Trade should reflect such a balance of interests, respect of fundamental rights and a different level of intensity, in accordance to the distinct level of development of the contracting parties. In order to assess the accuracy of this assumption, we present first a general outline of the features of the enforcement related provisions in treaties concluded by the EU between 2004 and 2013, and subsequently an analysis of similar provisions in the treaties concluded in 2014.

Intellectual property chapters enshrined in European PTAs experienced –as noted in chapter I- a remarkable change since 2004. From the relatively vague and flexible provisions of previous treaties, and in keeping with the spirit of the 2004 Strategy, the content of IP chapters became more precise and the standards set forth therein more demanding. This has implied that the differences that were very clear with respect to the negotiation position of the US have almost disappeared. Indeed, while some years ago IP negotiations with Europe were, in general, straightforward, now the European position has become stricter and expectations higher.

This has also been the case of the enforcement related provisions of the PTAs concluded between 2004 and 2013, namely with Central America (Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama), Peru, Colombia, Cariforum and South Korea. Recently in 2014 new agreements with Ukraine, Georgia, Moldova, Singapore and Canada were concluded.

The features of the IP enforcement provisions set forth in the agreements concluded between 2004 and 2013 are presented in the following table (See Box IV.2) Our intention is of comparing them with the features of the five agreements concluded in 2014 and with the further goal of assessing whether the changes and objectives identified in the 2014 Strategy have been achieved.

Box IV.2: Features of enforcement provisions in 2004-2013 EU PTAs

Phenomenon	**Examples**
Expand the scope of TRIPS enforcement regime	New areas, new topics: digital enforcement, more IP categories covered in the enforcement section (supplementary protection certificates, plant variety rights…)
Clarify and expand ambiguous TRIPS enforcement provisions	Border enforcement provisions become much more specific: i.e. the case of the provisions on transit control
Increase of the level of exigency of enforcement compromises	*i)* Options become obligations*; ii)* more requirements to public authorities are set up; *iii)* more rights for right holders; *iv)* new situations become the object of criminal sanctions
Unbalanced transplant of EU enforcement regulation	Partial transplantation of texts such as *i)* Directive 2004/48; *ii)* Regulation 1383/2003; *iii)* Infosoc directive
Do not differentiate the level of exigency depending on the level of development	Provisions are even more demanding in the case of developing economies than developed economies

After a close examination of the enforcement-related provisions of the agreements concluded in 2014, it can be stated that these features remain unchanged. (See table in following Box IV.3) Thus, the objectives announced and set forth in the 2014 Strategy in terms of differentiation, balance and respect of a number of procedural rights have not been met.

Box IV.3 Features of enforcement provisions in 2014 EU PTAs

Phenomenon	Cases	Details
Transplantation of provisions favouring one of the parties	Ukraine, Moldova and Georgia	• Absence of guarantees with respect to: measures for the preservation of evidence; provisional measures; corrective measures • No compensation for unduly adopted measures • No demand for proportionality
No differentiation between developed and developing countries	Ukraine, Moldova and Georgia PTAs are in fact stricter that Singapore and Canada	• Broader scope (more topics and IP categories covered) • Expanded border measures (all IP categories *vs* counterfeit and pirate goods) • General safeguards and references to resources limitations are absent
Respect to human rights	Ukraine, Moldova and Georgia	• Disregard to procedural rights permits questioning the respect of due process principles

5. Provision of economic data to raise awareness of the consequences of infringement

The 2014 Strategy text contextualizes enforcement in the broader framework of the relevance of IP for innovation, competitiveness and European economy, and by recalling the 2013 study of the EPO and OHIM on the contribution of IP to economic performance

and employment. In that study it is affirmed that IPR-intensive sectors account for around 39% of European GDP (worth some EUR 4.7 trillion annually) and, taking indirect jobs into account, up to 35% of all jobs[93]. The 2014 Strategy also quotes data on enforcement provided by two other studies prepared by private sources.[94] In our view, these references, used to justify the relevance of the Strategy, are in conflict with the objective of providing economic assessments that permit raising awareness of the relevance of IP protection.

The three studies quoted by the 2014 Strategy address either the scale or the impact of IP infringements and, in the case of the OHIM/EPO study, the relation of IP with employment and GDP. The *scale* of infringement alludes to the magnitude of infringement in terms of quantity, while the *impact* of infringement tries to capture its socioeconomic relevance. A large number of studies have tried to estimate the number of infringing products, the value of those products, and the socioeconomic effects of infringement of IP per se. However, the reliability of numerous studies is controversial, which is also the case of the estimates quoted in the 2014 Strategy. Some of the difficulties are inherent to the object of the research. Like other illicit activities, some infringements are furtively performed and therefore remain unreported. Other difficulties relate to the studies themselves, and concern the sometimes debatable methodologies adopted and the conflicts of interest of the authors and funders of the studies.

Until recently, public institutions were not involved in the estimation of the global extent and relevance of infringement, and data collection on illicit activities was mostly carried out by private actors. Private stakeholders who often have a direct interest in the object of analysis have elaborated estimates concerning the scale of infringement, the value of IP, or the impact of intellectual property infringement. In fact, even figures quoted by public sources to describe the magnitude of the problem, or to justify the action of public authorities, have been frequently produced by private stakeholders. This is indeed the case of some of the estimates quoted in the 2014 Strategy (ICC, CEBR, commissioned by the Global Anti-Counterfeiting Group).

Concerning the 2013 OHIM/EPO report, it has been considered "a tale without a message", due to the impossibility to establish evidence regarding the causal link between IP and the economic data provided.[95] In our view, however, the OHIM/EPO study also has a number of methodological biases. Just to mention one, in the case of patents the study considers a proxy for innovation patents that have only been filed, instead of those effectively granted.[96] Counting filed patents does not reflect any objective level of

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[93] *Intellectual property rights intensive industries: contribution to economic performance and employment in the European Union*, Industry-Level Analysis Report, Joint project between the European Patent Office and the Office for Harmonisation in the Internal Market, Munich and Alicante, 2013.

[94] CEBR, *The impact of counterfeiting on four main sectors in the European Union*, Centre for Economic and Business Research, London, 2000 and Global impacts study. *A new study, conducted by Frontier Economics examines the global economic and social impacts of counterfeiting and piracy*, ICC, February 2011. available at http://www.iccwbo.org/Advocacy-Codes-and-Rules/BASCAP/BASCAP-Research/Economic-impact/Global-Impacts-Study/ .

[95] A. Kur, D. Harhoff, "Great data, nice tale, but what's the message? The OHIM/EPO study in the economic relevance of IP-intensive industries in the EU", *IIC*, vol. 45, 2014, p.618.

[96] A similar argument can be made in relation to trademarks, where the European study counts the registered trademarks, when the majority of trademarks are not exploited.

innovation. First, numerous patent applications are rejected. In addition, when patents are granted, defendants in law suits usually argue that the allegedly infringed patent is invalid, an argument that happens to be successful in roughly half of the cases.[97] In fact, as the United States Supreme Court has noted, patent litigation frequently arises because of "the notorious difference between standards applied by the Patent Office and by courts."[98] So, there is an important gap between patent filing and a valid patent.

The studies quoted in the 2014 Strategy reflect as well a number of criticisms made to economic assessments produced so far. Among these criticisms:

- Studies do not recognize relevant economic variables, such as the investment needed to set up the intellectual property system[99] and the impact of some intellectual property commitments on welfare.
- Estimates use fragile methodologies relating the scale of infringement, such as the use of indirect measures that approximate or represent the real phenomena[100].
- Estimates use debatable assumptions relating to the impact of infringement, in particular an unrealistic 1 to 1 substitution rate.[101]
- Studies do not take into consideration economic outputs –legally unacceptable but neutral from the economic point of view- generated by infringement. This result from reference made to consumer surplus,[102] lowering of prices,[103] access to

[97] A study conducted by Allison and Lemley found that, from 1989 to 1996, 46 percent of patents were invalidated in final written decisions on validity. J. R. Allison, M. Lemley, 1998.
[98] *Graham v John Deere Co.* 383 U.S. 1, 18 (1966).
[99] Intellectual property enforcement requires public investment. The State will still need to invest in a meaningful manner. Hiring personnel, setting up institutional infrastructures, restructuring existing agencies and acquiring the necessary means for implementing enforcement activities are just the first steps. Afterwards, the state will have to assume the running costs of the system. In order to assess the investment required, it is necessary to identify the activities falling within the enforcement domain, and the investment items related to them. Among such activities are i) identification of the infringement, ii) storage of allegedly infringing goods, iii) adjudication of controversies, iv) disposal and destruction of infringing goods, and v) imprisonment of those responsible for criminal infringement. This raises several questions, including: what should be the optimal level of public investment in IP enforcement; should the investment change depending on the level of development of the country concerned; and what does this investment tell about intellectual property rights as "private" rights. Given that ensuring IP enforcement is an investment, from the purely economic point of view the question that needs to be posed is which is the adequate level of investment. There are indeed optimum levels of investment on enforcement: the benefit arising from law enforcement must be at least equivalent to its cost. This means, in effect, that there are rational levels of intellectual property infringement or, put in economic terms, investments not worth making.
[100] These proxy indicators commonly stem from the activity of custom authorities (i.e. seizures) and surveys conducted among consumers or producers.
[101] In estimating the impact of infringement, a common practice consists of relating the scale of infringement with consumers' desire to substitute legitimate goods for counterfeits. The so-called "substitution rate" is therefore a crucial part of the equation. Despite this importance, the rate at which the consumer is willing to switch from purchasing a fake good to paying for the genuine article is highly controversial. It varies from sector-to-sector, across intellectual property categories, and even with respect to the same product depending on the price. These are some of the reasons behind the general rejection of one-to-one substitution and the search of more sophisticated approaches to capture consumers' attitudes.
[102] Consumers may purchase infringing products purposely, since these may be cheaper than genuine goods.
[103] Which may enable access to products that otherwise would have not been bought.

products otherwise unavailable in the market, [104]network externalities or demand-side economies of scale,[105] and the fact that some economic activity may also improve as a consequence of infringement.[106]

- Economic studies do not consider the anticompetitive impact of some enforcement measures.[107] For instance, some intellectual property enforcement norms may provoke over deterrence and discourage legal activities in fear of the consequences of eventual law suits and the costs of litigation. Injunctions, damages and criminal sanctions are particularly telling.
- Studies relating to the economics of enforcement are unavailable, so far, to assess the economic significance of civil, border and criminal enforcement mechanisms considered independently. Indeed, the very same institution can be implemented in different manners, and "enforcement" is the result of a complex mechanism and variable processes. Most of the attention has been traditionally directed to rules of substantive law, while important civil, border and criminal enforcement norms have largely been ignored.

[104] Price set aside, intellectual property-infringing goods may also be the only source for accessing products. not available in the market, sometimes of similar, or even equal, quality to the original.
[105] The valuation of products may increase with the number of consumers who own the same product.
[106] Beneficiaries may be directly related to the infringement, but may also be unrelated third parties or even the rightholder. The positive output of intellectual property- intensive industries in terms of creation and quality of employment is frequently highlighted. However, "employment effects are unclear, because employment may decline in certain industries or rise in other industries as workers are hired to produce counterfeits.". Similarly, industrial activity and manufacturing capacities may also benefit from infringement.
[107] Strengthening right holders' position to the detriment of their competitors' procedural rights may deter legal competition and restrict access to legal products. Moreover, new norms on enforcement may expand their impact to third countries and jurisdictions.

Chapter V
Interrelated questions

Chapter V takes on board, in some depth, issues not discussed in the report as well as others that have been touched upon earlier. We pay attention to four questions: the ongoing trade negotiations between the US and the EU under the Transatlantic Trade and Investment Partnership, TTIP; the relationship between foreign direct investment (FDI) and the intellectual property chapters of PTAs; the particular consequences of IP related provisions on public health and finally, a review of the relevance of international norms on IP enforcement.

A. Considerations on the on-going trade negotiations between the EU and the US: the Transatlantic Trade and Investment Partnership (TTIP)

The TTIP has been claimed to be the "biggest bilateral trade deal in history". A brief analysis of this negotiating process is in order to understand what the two major trading blocs might negotiate in areas such as intellectual property focus of this report. The US and EU, as examined throughout the report, have played, with different degree of intensity, a major role in the evolution of intellectual property normative standards since the adoption of TRIPS, being important actors in the negotiations of PTAs with strong IP provisions. What these two blocks would achieve in a future TTIP on intellectual property is an important question to consider.

1. Brief history of the negotiations

In June 2013 the EU Council of Ministers agreed in a mandate for transatlantic negotiations with the exclusion of the audiovisual content sector, being a sensitive issue especially for France. During the G-8 countries 2013 Summit held in Northern Ireland both President Obama and President Barroso, announced that formal negotiations for a US –EU free trade agreement has been launched, referred to as the "Transatlantic Trade and Investment Partnership Agreement" (TTIP or T-TIP).

In case a deal is reached, this bilateral agreement would be considered the "biggest bilateral trade deal in history" and "once in-a-generation prize" because it is claimed[108] it would be able to add £100 billion to the EU economy, £80 billion to the US economy and £85 billion to the rest of the world.[109] Additional figures suggest that the agreement could generate annually USD 159 billion for the EU and USD 127 for the US and may positively impact the global economy by USD 134 billion.[110]

Early negotiations for an agreement between the two parties started in late 2011 when the leaders of both sides met in the EU –US Summit of that year. In that opportunity the USTR and the EU Trade Commissioner established a High-Level Working Group in order "to identify policies and measures to increase EU-US trade and investment to support

[108] Speech of the British Prime Minister David Cameron during the announcement ceremony. See BBC News Business, available at: http://www.bbc.com/news/business-22943170.

[109] For a complete economic assessment of TIIP see Joseph Francois (project leader), Centre for Economic Policy Research, London, "Reducing Transatlantic Barriers to Trade and Investment: An Economic Assessment", Prepared under implementing Framework Contract TRADE10/A2/A16, March 2013 and its Annex, both available at http://trade.ec.europa.eu/doclib/html/150737.htm and http://trade.ec.europa.eu/doclib/html/150738.htm, respectively. For a brief of the study see a Memo of the European Commission entitled "Independent Study outlines benefits of the EU – US agreement, dated 12 March 2013, available at http://europa.eu/rapid/press-release_MEMO-13-211_en.htm.

[110] Daniel Hamilton, "TTIP: What are the implications for emerging powers and the international order?" 1 December 2014, citing an independent study prepared by the Centre for Economic Policy Research. The article is available at: http://www.ictsd.org/bridges-news/bridges-africa/news/ttip-what-are-the-implications-for-emerging-powers-and-the international order

mutually beneficial job creation, economic growth, and international competitiveness. Leaders asked the Working Group to work closely with all public and private sector stakeholder groups, and to draw on existing dialogues and mechanisms, as appropriate."[111] The Working Group in its final Report concluded "(…) that a comprehensive agreement that addresses a broad range of bilateral trade and investment issues, including regulatory issues, and contributes to the development of global rules, would provide the most significant mutual benefit of the various options we have considered."[112]

Many important differences have appeared during the seven rounds of negotiations, in areas and topics such as Internet Service Providers´ liability, geographical indications, copyrights, audiovisuals, biotechnology, enforcement, safe standards on health and genetic modified organisms (GMOs), public procurement, investment approach, and agriculture.

2. The negotiating objectives of both parties

According to the letter that the USTR sent to the US Congress in March 20, 2013 notifying the President´s intention to enter into negotiation with the EU, the US objectives were to include several sectors such as trade in goods and services, electronic commerce and information and communication technology services, investment, customs and trade facilitation, government procurement, labour, environment, intellectual property, state-owned enterprises, small- and medium-sized enterprises, transparency, anticorruption and competition, and dispute settlement.

In the specific context of IPRs, the letter addressed to Congress stated that on the IP field the US would seek to achieve the two following specific objectives:

> (…)to obtain, consistent with U.S. priorities and objectives, appropriate commitments that reflect the shared U.S.-EU objective of high-level IPR protection and enforcement, and to sustain and enhance joint leadership on IPR issues."
>
> "Seek new opportunities to advance and defend the interests of U.S. creators, innovators, businesses, farmers, and workers with respect to strong protection and effective enforcement of intellectual property rights, including their ability to compete on foreign markets.[113]

[111] See "The EU – US High Level Working Group on Jobs and Growth", available at: http://ec.europa.eu/enterprise/policies/international/cooperating-governments/usa/jobs-growth/index_en.htm. Additional information on the mandate of the High Level Working Group may be found in the Memo 11-843 issued in Washington on November 28, 2011, available at: http://europa.eu/rapid/press-release_MEMO-11-843_en.htm.

[112] "Final Report. High Level Working Group on Jobs and Growth", dated 19 June 2012, p. 1, and available at: http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf, p. 1.

[113] Letter of the Acting USTR, Ambassador Demetrios Marantis to the Honorable Joe Boehner, Speaker of the US House of Representatives, March 20, 2013, available at: http://www.ustr.gov/sites/default/files/03202013%20TTIP%20Notification%20Letter.PDF.

For the EU[114], the agreement should integrate three components: market access, regulatory issues and non-tariffs barriers and rules, all of them to be part of a single undertaking. [115]

The declassified mandate contains three paragraphs regarding IP related objectives, which differs with the proposal initially made by the EU Commission:

> 28. The Agreement shall cover issues related to intellectual property rights. The Agreement will reflect the high value placed by both Parties on intellectual property protection and build on the existing EU-US dialogue in this sphere.
>
> 29. Negotiations should, in particular, address areas most relevant for fostering the exchange of goods and services with IP content, with a view to supporting innovation. The negotiations shall aim to provide for enhanced protection and recognition of EU Geographical Indications through the Agreement, in a manner that complements and builds upon the TRIPS, also addressing the relationship with their prior use on the US market with the aim of solving existing conflicts in a satisfactory manner. After prior consultation with the Trade Policy Committee, additional IPR issues shall be considered in the negotiations.
>
> 30. The Agreement shall not include provisions on criminal sanctions.[116]

During the discussions on the scope of the mandate to be given to the EU Commission several issues were raised by EU member states, among them, the need of a more precise language on the objectives regarding geographical indications as it was finally introduced. The EU, as noted in Chapter I, is traditionally seeking stronger protection for its GIs and the negotiations with the US would not be an exception. However, no specificity was added to the mandate. [117]

As reported by TransAtlantic Consumer Dialogue (TACD) (May 2013) on a stakeholder meeting on TTIP and Intellectual Property Rights, led by the official in charge

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[114] See intellectual property and geographical indications in TTIP factsheet at: http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153020.7%20IPR,%20GIs.pdf.

[115] See paragraphs 2 and 4 of the declassified document regarding the "Directive for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America", Brussels, 9 October 2014, document 11103/13 DCL 1, of the Council of the European Union, available at: http://data.consilium.europa.eu/doc/document/ST-11103-2013-DCL-1/en/pdf .

[116] See the Council of the European document Nr. 11103/13 dated June 17, 2013, restricted document, which has been "officially declassified" as agreed by all EU members' states on October 9, 2013, (it was leaked in June 2013), and available at: http://data.consilium.europa.eu/doc/document/ST-11103-2013-DCL-1/en/pdf.

[117] The EU and the US maintain different approach to the protection of geographical indications and each expects something different in the negotiations. While the EU has a strong *sui generis* protection system, the US protects geographical indications through the trademarks. As many well-known European geographical indications have become the name of many products (champagne, parmesan, etc.) what the US call "generic names", this country wants to continue to sell its products abroad with its "generic names" to which the EU opposes. For additional information on this matter, see William New in Intellectual Property Watch, "Stakeholders Give Opposing Views On GIs In EU-US Trade Agreementough the tradema http://www.ip-watch.org/2015/02/12/stakeholders-give-opposing-views-on-gis-in-eu-us-trade-agreement/?utm_source=IP-Watch+Subscribers&utm_campaign=5ee21e87de-DAILY_SUMMARY&utm_medium=email&utm_term=0_b78685696b-5ee21e87de-352142353.

of IPRs for the Directorate General of Trade of the European Commission, the following points were highlighted at the meeting:

- For the EU the aim of the negotiations is not to harmonize IP legislation, so the IPR chapter should be a short one, including only issues of common interest;
- The IP chapter it is not expected to be a comprehensive one but rather limited to a number of significant IPR issues of interest for both sides including the handling of trade secrets, questions of upstream systems of trademark and patent systems (databases and the like), cooperation and also enforcement;[118]
- The issue on geographical indications relating to food products can be compensated through further openness of the EU market to US agricultural products;
- EU access to trademark and patent offices in the US should be improved, in order to reduce costs for greater protection;
- Protection of trade secrets should also be improved on both sides;
- Cooperation on enforcement matters should be improved in order to fight against IPRs infringement globally, although copyright related rights are protected differently in the EU and the US;
- Possibility of a greater protection (secrecy) for clinical trial data on medicines should be explored.

Although the interim and final report of the High Level Working Group highlighted the fact that IPRs might need to be left aside of the agreement, because "it would not be feasible in negotiations to seek to reconcile across the board differences in the IPR obligations that each typically includes in its comprehensive trade agreements". The final report of the Working Group recommended, however, its inclusion due to strong requests from some private stakeholders.[119]

Out of all the issues that could cover an agreement on IP, geographical indications stand as one of the most controversial matters in the negotiations. While the EU and stakeholders concerned are trying to ascertain traditional EU names for certain agricultural products, the US see them as common or generic names that should not constitute barriers to their exports.

3. Ongoing negotiations

At the time of writing, eight rounds of negotiations have taken place. The first round was held in Washington DC in July, 2014. The negotiators have set up 24 working groups (one

[118] Similar ideas were expressed by Rupert Schlegelmilch, director of DG Trade at the European Commission on this issue. See excerpts of his declaration in Monika Ermert IPWatch post entitled "IPR Lists For Trans-Atlantic Trade Deal Still Growing; Risk Of Locking In Old IPR Regimes?" published on May 15, 2013, available at: http://www.ip-watch.org/2013/05/15/ipr-lists-for-ttip-still-growing-risk-of-locking-in-old-ipr-regimes/?utm_source=post&utm_medium=email&utm_campaign=alerts.
[119] See the letter at: http://infojustice.org/archives/28254.

on IP), which have proceeded so far on their own negotiation speed,[120] grouped in three major areas: market access, regulatory cooperation and rules. Already at the first meeting there was a special emphasis on transparency and the participation of stakeholders.[121]

In late March 2014, two-page EU document was leaked to the public. It portrays the state of play and the positions of the parties on IP questions. According to the document, the future architecture of the intellectual property chapter would consist of four sections: list of international agreements to be part of; general principles stressing the importance of IP as a tool for growth, jobs, and innovation; binding commitments on a limited number of significant IP issues, and cooperation on matters of common interest. Box V.1 transcribes the full information as leaked by a blog.

Box V.1

Leaked document on the EU IPR position in the TTIP negotiations

(…) The main achievement of the fourth round is the agreement of both sides to continue further work on the basis of a US proposal for the architecture of the IPR chapter. It is important to highlight that the US proposal is along the lines of EU's initial idea to have a chapter addressing a limited number of issue of interest to both parties. The idea is to have 4 sections: 1) list of international agreements; 2) general principles stressing the importance of IP as a tool for growth, jobs, and innovation, 3) binding commitments on a limited number of significant IP issues, and 4) cooperation on issues of common interest. Further work will be required in the next rounds as regards the exact placement of above mentioned issues structure defined for the architecture. The detailed discussion held so far have helped both sides to identify those issues raised by stakeholders that would not be adequately addressed in TTIP.

Exploratory discussions included the following:

Patents: continued discussion of technicalities on grace periods and a possible "package" approach (with other issues, such as 18 months publication), with the general (global) streaming goal in mind; the US is keen on a variety of improved international cooperation aspect. EU was clear about the challenges arising from the specificities of the European patent "systems" (unitary patent, EPO system, national patents).

Design: US lukewarm to the idea of unregistered design protection for apparel, since several similar so-called "fashion bills" have been unsuccessful in the past.

[120] According to a US press release, these groups are: market access for agricultural and industrial goods, government procurement, investment, energy and raw materials, regulatory issues, sanitary and phytosanitary measures, services, intellectual property rights, sustainable development, small- and medium-sized enterprises, dispute settlement, competition, customs/trade facilitation, and state-owned enterprises. The press release is available at: http://trade.ec.europa.eu/doclib/press/index.cfm?id=941.

[121] It seems that the transparency issue is taken seriously by the parties. After the first negotiating meeting Monika Ermert for Intellectual Property Watch reported that several negotiating documents were leaked, indicating the initial position of some sectors within the EU. The article may be seen in the IP Watch webpage at: http://www.ip-watch.org/2013/07/16/eu-commission-prefers-its-own-leaks-on-fta/?utm_source=post&utm_medium=email&utm_campaign=alerts. By January 7, 2015, eight texts were leaked on competition, food safety and animal and plant health, customs issues, technical barriers to trade, and small and medium-sized enterprises. Government-to-government dispute settlement was also included. See http://www.euractiv.com/sections/trade-society/ttip-papers-published-eu-ombudsman-demands-more-transparency-311088.

Plant varieties: while the protection systems are fragmented, the protection afforded appears to be fairly similar in both EU and US.

Regulatory test data: the US continues to convey the concerns of some stakeholders regarding the treatment of undisclosed (pharmaceutical) test data; US insistent on clarifying safeguards regarding TRIPS compliance issues and potential negative consequences in the 3rd countries.

Copyright: both sides gave updates on the respective ongoing review processes. Positive news is that the copyright related issues identified by EU stakeholders as relevant (broadcasters rights, public performance and resale rights) are part of the US debate and supported by relevant sectors of the administration.

Trademarks: US indicated a clear interest in combating bad faith applications, possible need from cooperation from OHIM on "soft measure", depending on the mandate in the new Trademark package. US perceives very different treatment of TMs and GIs.

Third country and multilateral cooperation: further in-depth discussion on how both parties could potentially coordinate and collaborate on the initiatives that are already in place (country reports on enforcement of IPR, economic studies, IPR awareness campaigns, MoUs).

Trade Secrets: TS is a clear priority for the US, they have a variety of detailed legislative acts on trade secrets in preparation. US interested in the new TS proposal in the EU and the importance of coherent approaches on the two sides.

Enforcement: US interested in the functioning of enforcement in the EU in general and mutual recognition of court decision in MS, considerable curiosity about the functioning and effects of Unitary patent; promising discussion on customs IPR enforcement (TAXUD) cooperation and agreement to exchange 3-4 identified priority areas at the next round

Voluntary best practices: agreement to build upon the work/discussion in the Transatlantic working group. Agreement to identify some priority areas/concrete ideas for the next round.

Source: http://keionline.org/node/1984 (visited Ap-15)

Although, initially, it was perceived that the negotiations would be finished within a short period of time expectations today are to attempt to close negotiations by 2017, before the President Obama leaves office.[122]

The initial optimism about speedy results is now fading due to difficulties encountered in the rounds of discussions. Problems are mainly related to complex issues, both technically and politically, where different visions persist such as in the case of genetically modified organisms, geographical indications, cultural exemption, internet services providers' liability, health and safety standards.

[122] See Sylvia Amaro, "Deadline to Conclude EU-US TTIP Negotiations Pushed Back", 2014, available at https://euro-insight.com/posts/deadline-to-conclude-eu-us-ttip-negotiations-pushed-back-6938.

B. Intellectual property rights covered by the definition of investment and the issue of expropriation

> *When analysing the impact of PTAs an important facet to bear in mind relates to the relationship of the provisions on intellectual property and other chapters of the trade agreement. In this context of particular relevance are the provisions on foreign direct investment (FDI). The nexus between IP and FDI in the proper context of PTAs have in recent years raised problematic issues with respect to expropriation and the recourse to investor-state dispute settlement. Some cases have been brought to the attention of international courts with respect to health related cases.*

1. Introduction

As a general practice, investment is broadly defined in PTAs, including among others, assets such as IPRs. In fact in the case of KORUS, discussed in chapter II and described as the baseline for negotiations on the TPP, the respective chapter includes in its large definition of investment:

> every asset that an investor owns or controls, directly or indirectly, that has the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk. Forms that an investment may take include:
> (f) intellectual property rights

In light of our characterization of PTAs as a powerful instrument for the protection and enforcement of IPRs, the relationship with investment acquires particular relevance. This is the case especially of the provisions related to expropriation. Expropriation in the PTAs includes not only the traditional transfer or plain seizure of property but also its broad reference to direct or indirect expropriation.

Indirect expropriation might include a number of situations that in one way or the other might frustrate the original expectations of an investor when a decision was taken to invest in a particular country. In other words, they might refer to measures taken by the State that have similar effects to a classical nationalisation. PTAs or investment treaties refer to them as indirect expropriation but in general the literature mentions "regulatory", "creeping" or in general to measures tantamount to actual expropriation.[123] Indirect expropriation might include environmental regulations or administrative decisions that might affect the economic value of the investment.

[123] See, OECD Working Papers on International Investment, "Indirect Expropriation and the Right to Regulate in International Investment Law, OECD, 2004/04, available http://www.oecd.org/daf/inv/investment-policy/WP-2004_4.pdf, (accessed 22/02/2015).

KORUS, as in the case of previous PTAs, includes the concept that "neither Party may expropriate or nationalize a covered investment either directly or indirectly through measures equivalent to expropriation or nationalization". It should be noted that as a general rule, PTAs provide for a general exception to expropriation in the case of compulsory licenses granted in relation to IPRs in accordance with the TRIPS Agreement.

2. The recourse to investor-state disputes

A further important component of the investment chapters is the recourse to investor-state dispute settlement (ISDS) that allows the investor to present a claim under different mechanisms for final adjudication, such as: (a) under the ICSID Convention and the ICSID Rules of Procedure for Arbitration Proceedings; (b) under the ICSID Additional Facility Rules; (c) under the UNCITRAL Arbitration Rules; or (d) if the claimant and respondent agree, to any other arbitration institution or under any other arbitration rules.

ISDS have come to be seen as a controversial component of PTAs particularly in situations that might clash with the sovereign right of governments to regulate in areas of public interest. Recent cases have surfaced in the IP arena that by nature are controversial. Need to note in this context that Art. 8.1 of the TRIPS Agreement acknowledges that

> Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Notable cases in this respect have been those related to particular measures adopted by States to combat addiction to tobacco where private investors have resorted to ISDS mechanisms to claim indirect expropriation. This is the case of the latest arbitration disputes brought against Australia and Uruguay that have implemented special regulations on the labelling and packaging of tobacco related products.

Philip Morris brought the case for arbitration against Uruguay in February 2010 with the International Centre for Settlement of Investment Disputes (ICSID). Philip Morris alleges that recent tobacco regulations enacted by Uruguay violate several provisions of the Switzerland-Uruguay bilateral investment treaty (BIT). Specifically, Philip Morris is challenging three provisions of Uruguay's tobacco regulations: (1) a "single presentation" requirement that prohibits marketing more than one tobacco product under each brand, (2) a requirement that tobacco packages include "requirement with graphic images of the health consequences of smoking (such as cancerous lungs), and (3) a mandate that health warnings cover 80% of the front and back of cigarette packages.[124]

[124] See Philip Morris v. Uruguay: Will investor-State arbitration send restrictions on tobacco marketing up in smoke?
MATTHEW C. PORTERFIELD & CHRISTOPHER R. BYRNES – July 12, 2011, iicd
http://www.iisd.org/itn/2011/07/12/philip-morris-v-uruguay-will-investor-state-arbitration-send-restrictions-on-tobacco-marketing-up-in-smoke/ (visited 22/2/2015).

In the situation of Australia, several cases have been also brought under the WTO state-state dispute settlement system for apparent inconsistency, among others, with the TRIPS Agreement particularly with respect to the regime governing the use of trademarks.[125]

3. The case Ely Lily Company against Canada

One paradigmatic situation is the case brought under the NAFTA agreement against Canada by Ely Lily for the retroactive revocation of patents on several products notably Strattera (a medicine to treat attention deficit hyperactivity (AHP)) and Zyprexa (a treatment for schizophrenia and related psychotic disorders). The dispute has arisen largely because the company try to evergreen prior patents by claiming that a small selection of a number of previously patented compounds provides a ‘‘substantial advantage’’ that merits new patent protection. The administration decision was based on the ‘‘promise of the patent’’ doctrine that seeks to ensure that firms do not obtain a legal monopoly on the basis of speculative claims about increased utility—especially claims about therapeutic efficacy—that were unsubstantiated at the time of filing.[126]

The revocation of the patents was brought finally to the consideration of the Supreme Court of Canada that dismissed the case in 2013.

Ely Lily, under the NAFTA provisions –direct and indirect expropriation- brought in September 2013 a case before ICSID claiming "damages for the full measure of direct losses and consequential damages sustained as a consequence of Canada's breach of its obligations under NAFTA Chapter 11, estimated in an amount not less than CDN $500 million plus any payments Lilly or its enterprise is required to make arising from the improvident loss of its Zyprexa and Strattera patents or its inability to enforce its Zyprexa and Strattera patents".[127] The decisions taken by Canada triggered the arrival of cheaper generics in Canada, leading to what Lilly claims were significant sales and job losses.

Lilly argues that the courts relied on a government doctrine –promise of the patent- that produced "absurd" results and accuses Canada of expropriating its patents. As reported by the Wall Street Journal, Lilly circulated a new report on intellectual property issued in February 2015 by the US Chamber of Commerce. The report criticized Canada for "onerous patentability requirements" that "discriminate against pharmaceutical patents" and court rulings that differ from principles found in trade treaties. For its part, Lilly maintains that the report describes Canada as being "among the outliers related to intellectual

[125] Latest case brought by Indonesia (DISPUTE DS467, Consultations received: 20 September 2013) on Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging.

[126] See Jerome Reichman, Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection, Publiched in the 2014 issue of the Proceedings of the 108th Annual Meeting of the American Society of International Law, Available at: http://scholarship.law.duke.edu/faculty_scholarship/3377 (visited Ap-15).

[127] See http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/eli-03.pdf, (consulted Ap-15)

property protection," although the report does not use that word to describe Canada, but does so for several other countries.[128]

4. KORUS and the nexus intellectual property-expropriation investment issues

As noted, PTAs exclude as a case of expropriation the legitimate granting of compulsory licensing in accordance with the TRIPS Agreement. KORUS, further, provides that expropriation could not include cases of "revocation, limitation, or creation of IPRs, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter Eighteen (Intellectual Property Rights)." (Art. 11.6.5)

KORUS appears to have taken into consideration some of the problems that have recently arisen and described above on measures adopted by countries with respect to so called indirect expropriation that calls for "a case-by-case, fact-based inquiry that considers all relevant factors relating to the investment". KORUS appears also to be attentive to situations that have created serious differences in other PTAs. As noted in Box V.2, a number of situations are excluded from the concept of indirect expropriation.

Box V.2: KORUS ANNEX 11-B EXPROPRIATION

The Parties confirm their shared understanding that:

1. An action or a series of actions by a Party cannot constitute an expropriation unless it interferes with a tangible or intangible property right in an investment.

2. Article 11.6.1 addresses two situations. The first is direct expropriation, where an investment is nationalized or otherwise directly expropriated through formal transfer of title or outright seizure.

3. The second situation addressed by Article 11.6.1 is indirect expropriation, where an action or a series of actions by a Party has an effect equivalent to direct expropriation without formal transfer of title or outright seizure.

(a) The determination of whether an action or a series of actions by a Party, in a specific fact situation, constitutes an indirect expropriation, requires a case-by-case, fact-based inquiry that considers all relevant factors relating to the investment, including:

(i) the economic impact of the government action, although the fact that an action or a series of actions by a Party has an adverse effect on the economic value of an investment, standing alone, does not establish that an indirect expropriation has occurred;

(ii) the extent to which the government action interferes with distinct, reasonable investment-backed expectations; and

(iii) the character of the government action, including its objectives and context. Relevant considerations could include whether the government action imposes a special sacrifice on the particular investor or investment that exceeds what the investor or investment should be expected to endure for the public interest.

(b) Except in rare circumstances, such as, for example, when an action or a series of actions is extremely severe or disproportionate in light of its purpose or effect, non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety, the environment, and real estate price

[128] See WSJ, February 13, 2015, Canada Slams Lilly for 'Scattershot' Patent Filings in a Long-Running Dispute, Ed Silverman, http://blogs.wsj.com/pharmalot/2015/02/13/canada-slams-lilly-for-scattershot-patent-filings-in-a-long-running-dispute/ (visited Apr-15).

> stabilization (through, for example, measures to improve the housing conditions for low-income households), do not constitute indirect expropriations.

Seemingly, in the case of KORUS situations like the Eli Lily vs. Canada case might be mitigated under some of the considerations stated in the quoted Annex 11 B of the agreement, that recognizes that situations such as the following do not constitute indirect expropriations: actions designed and applied to protect legitimate public welfare objectives, such as public health, safety, the environment, and real estate price stabilization (through, for example, measures to improve the housing conditions for low-income households).

Provisions alike those of KORUS on the revocation of patents and expropriation are also present in the Comprehensive Trade and Economic Agreement (CETA) between Canada and the EU:

> For greater certainty, the revocation, limitation or creation of intellectual property rights to the extent that these measures are consistent with TRIPS and Chapter X (Intellectual Property) of this Agreement, do not constitute expropriation. Moreover, a determination that these actions are inconsistent with the TRIPS Agreement or Chapter X (Intellectual Property) of this Agreement does not establish that there has been an expropriation. (Article X.11.6)[129]

The TPP, Chapter on Investment, according to a recent media leakage[130] includes a provision resembling that of KORUS:

> The Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter QQ._ (Intellectual Property Rights) and the TRIPS Agreement. (Art. 11.7.5: Expropriation and Compensation)[131]

According to one commentator, the reference in the quoted provisions to the consistency with the intellectual property chapters raises important consequences including the ISDS "to be used by private companies to challenge the revocation, limitation or creation of intellectual property rights as inconsistent with the intellectual property chapter. Which is exactly what Eli Lilly did."[132]

It is expected that in the case of future PTAs negotiating parties draw lessons from recent controversial cases and adopt measures to safeguard the regulatory role of the State among others to "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development" as stated in the cited principles of TRIPS.

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[129] CETA, available at http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf (Ap-15)
[130] See Wikileaks, https://wikileaks.org/tpp-investment/WikiLeaks-TPP-Investment-Chapter.pdf (Ap-15)
[131] A footnote to the provision adds: For greater certainty, the Parties recognize that, for the purposes of this Article, the term "revocation" of intellectual property rights includes the cancellation or nullification of such rights, and the term "limitation" of intellectual property rights includes exceptions to such rights.
[132] Sean Flynn, How the Leaked TPP ISDS Chapter Threatens Intellectual Property Limitations and Exceptions, infojustice.org, March 26, 2015, http://infojustice.org/archives/34189 (visited Ap-15)

C. PTAs and the case of public health

The controversial relationship between public health and intellectual property has occupied an important place in the evolution of international IP law. The impact of the TRIPS Agreement on health acquired prominence in the early years of its implementation but with the passage of time it has been praised for its generally balanced content. TPAs concluded after TRIPS have strengthened the protection of pharmaceutical patents accompanied by obligations relating to regulatory aspects of pharmaceutical products. Particular concern has been voiced in relation to new norms relating to patent protection, test data exclusivity, the linkage between patent protection and marketing authorization and the enactment of new enforcement related standards impacting on public health. Recent expressions of these trends are found in KORUS and their reflection in the TPP negotiations.

1. Introduction

TRIPS, as analysed in chapter I, was a milestone in international IP law. While it left an important margin of manoeuvre to adjust IP regulation in accordance to national needs, it also triggered legislative harmonization in an unprecedented manner. The "minimum standards" set forth in TRIPS became, in fact, a sort homogeneous international IP regime. In several areas the concomitant harmonization was not, by any means, trivial. The list would be long, but TRIPS implied a major transformation of international and national substantive IP standards, enforcement and dispute settlement norms. Among the controversies arising from the rules found in TRIPS, that concerning the interface between intellectual property protection and public health has attracted most of attention and concern.

The principle of differential treatment, cross-cutting the WTO regime, was largely left aside in TRIPS. Transitional periods and some vague references to technology transfer in favour of least-developed countries were the sole specific translations of this general principle. Changes were particularly relevant in the area of public health. In this context, it has been rightly noted that the obligation to grant patents for products and processes in all areas of technology was probably the most important concession made by developing countries in the Uruguay Round.[133] In fact, this was a very relevant provision even for a number of developed countries, since product patents for medicines were excluded also in developed countries just before TRIPS was adopted.[134]

While TRIPS has become, with the passage of the time, an agreement praised for its generally balanced content, the decade that followed its entry into force was marked by a very critical message with respect to the impact of the Agreement on the protection of

[133] C. Correa, usti Uruguay Round and Drugs', *in* F. Lobo y G. VelLobo y (eds.), *Medicines and the New Economic Environment*, Madrid, Civitas, 1998, p. 50.

[134] On the litigation in Spain arising from the TRIPS obligation to grant product patents for pharmaceuticals, *see* CEFI-IDEI, *Una década del Acuerdo ADPIC. Avances en la protección de la innovación*, Madrid,CEFI-IDEI, 2006; C. Lema Devesa, A. Tato Plaza, *Patentes farmacéuticas y el Acuerdo ADPIC*, Granada, Comares, 2007; X. Seuba (Ed.), *Salud Pública y Patentes Farmacéuticas*, Barcelona, Librería Bosch, 2008.

public health. In a nutshell, it was widely held that the conditions established in TRIPS restricted the capacity of states to implement intellectual property and pharmaceutical policies adjusted to public health needs and national economic particularities.

Summarizing normative, jurisprudential and doctrinal development in the area of IP and public health in the post TRIPS period is a challenging endeavour. Such a summary is difficult because, succinctly, everything has changed. The levels of protection have drastically increased and the overall tendency to enhance IP protection has been largely successful. This section of the report introduces what TRIPS implied and what has come afterwards, fundamentally by means of the conclusion of PTAs. Three milestones can be underlined.

First, TRIPS implied drastic changes relating to the patentability of medicines and set forth the basic conditions for the management of pro-competition tools. Second, agreements concluded later on have strengthened the protection of pharmaceutical patents, fundamentally but not only by restricting the tools that foster competition. Third, IP provisions have been accompanied by obligations relating to regulatory aspects of pharmaceutical products, also enhancing the power of intellectual property rights holders, which frequently happen to coincide with the originator of the data relating to safety and efficacy of the products or with the company commercializing the medicines.

2. The relevance of TRIPS for public health

TRIPS has been rightly considered a 'distal' determinant of health,[135] in the sense that, together with social, biological and economic determinants of health (the so-called 'proximal' determinants of health), TRIPS impacts on health and human well-being by conditioning the availability of and accessibility to health products.

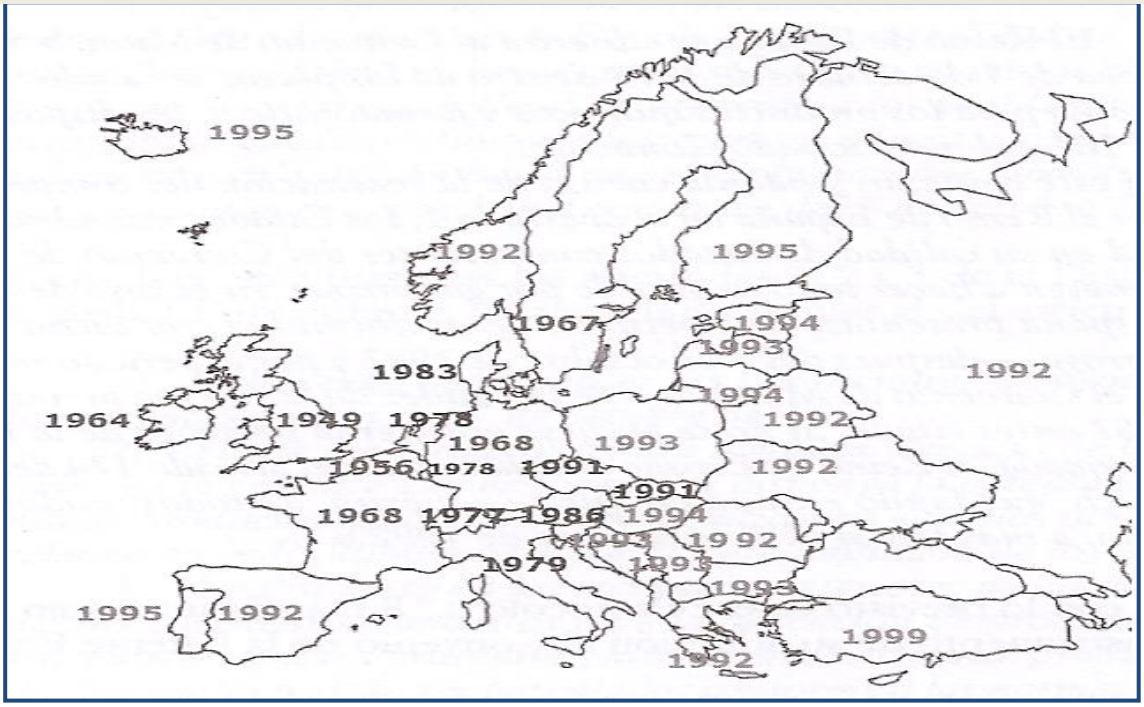
In the years that followed the adoption of TRIPS, a number of studies tried to ascertain the precise impact of the agreement on the price of pharmaceutical products.[136] While the results of those studies can hardly be considered conclusive, since local and product-related specificities give place to different results, it is clear that TRIPS expanded the patentability and restricted the tools available to foster competition.

One of the most important provisions in TRIPS is Article 27, which identifies the patentable subject matter and clarifies that it includes both products and processes in all fields of technology. It forbids therefore the once classic patentability exclusion of food products and medicines. As noted, this is indeed the most important change *vis à vis* the previously existing situation, even for developed countries, among other a relevant number of European countries. (See Box V.III)

[135] On international trade law, and intellectual property norms, as distal determinants of health, D. W. Bettcher, *et al.*, "Global trade and health: key linkages and future challenges", *Bulletin of the World Health Organization,* 2000, vol. 78, nº 4, p. 523.

[136] J. Dumolin, "Patents and the price of drugs", *Revue Internationale de Droit Economique,* Special Edition, 2001, pp. 49-72; J. Watal, "Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India under WTO TRIPs Agreement", *The World Economy,* vol. 23, nº5, 2000, p. 735.

Box V.III: Year of introduction of pharmaceutical product patents in Europe



TRIPS also enshrined for the first time in a multilateral treaty the classic *patentability criteria*: novelty, inventive step (non-obviousness) and industrial application (utility). The references to *patent exclusions* –i.e. the possibility to exclude some inventions from patentability invoking health, morals or public security grounds-, *patent exceptions* –uses that the right holder cannot impede because broader socioeconomic interests justify them-, *compulsory licenses* –licenses without the authorization of the right holder, necessary to counter anticompetitive practices or to respond to social or urgent needs-, and *exhaustion of rights* –the moment when the right holder will not be able to control any longer the commercial activity with patented products- conform the TRIPS 'patent regime'.

The TRIPS 'patent regime' needs to be read in light of the Doha Declaration on the TRIPS Agreement and Public Health. This important WTO ministerial declaration added nothing to the substantive content of TRIPS, but was of great hermeneutic importance. Indeed, it prescribes the general mandate to interpret TRIPS in a way favourable to public health protection. A mandate that, in light of the numerous ambiguous provisions set forth in TRIPS has become of great practical relevance.

Pharmaceutical products are also related with another important provision found in TRIPS, concerning the protection of undisclosed information. Pharmaceutical regulations make the award of marketing authorization conditional on the presentation of scientific, technical and health-related information. This data certifies the efficacy and safety of the medicine, and its adequacy to fulfil the goals and indications announced by the manufacturer. Pursuant to Article 39.3 of the TRIPS and Article 10 of the Paris Convention pharmaceutical test data must be protected against unfair competition. The prevailing view, both in the doctrine and in comparative law, is that TRIPS Article 39.3 main purpose is to

prevent the use of such data by competitors, but not governments.[137] Accordingly, most of the governments have understood that they honoured their international obligations while relying on the data presented by the originator to approve subsequent marketing applications.

3. TRIPS flexibilities

Following the adoption of TRIPS, a number of controversies affecting emerging economies were settled in the WTO Dispute Settlement System. This was the case of controversy relating to the transitional mailbox applications system implemented by India; the controversy concerning the Brazilian requirement of local production of patented products; and the case affecting Argentina and the provisions in force on injunctive measures. Other controversies targeted developed economies and were particularly relevant from the point of view of public health protection. This was the case of the dispute affecting Canada and relating to the Bolar exception. The initial use of the WTO dispute settlement system created the impression that TRIPS would be used in an aggressive fashion to limit the policy space of WTO Members to tailor intellectual property law in accordance to local needs. Additionally, unilateral actions on the part of the US against developing countries that made use of some TRIPS-compatible options increased the perception that public health became secondary to IP protection. This was particularly the case of the suspension of trade benefits and development aid to South Africa, in reaction to the regime of parallel importation implemented in the first African economy, devastated by the impact of HIV/AIDS in the late 1990s.

In response to the perceived threats, the margin of manoeuvre afforded by TRIPS began to be explored in greater depth, with the objective of clarifying to what extent TRIPS allowed making use of measures that enhanced competition and access. By the end of the 1990s, the so-called TRIPS flexibilities started to find its way in the academic literature and were, later on, incorporated into the public policy discourse. Some years later, also local courts started to make use of this popular terminology. In fact, according to WIPO "Some experts believe that the foundation of the available flexibilities are to be found in the negotiation process of the TRIPS Agreement, where policy autonomy for implementation was agreed by Members, as trade negotiators favoured an agreement with a great degree of built-in flexibility."

In the area of patents and health, TRIPS flexibilities have been categorized in many different ways. One of them consists in grouping the flexibilities depending on whether they operate before or after the granting of a patent. This classification has led to distinguish between *pre* and *post* grant flexibilities. Another terminology, leading to the same groupings, is that distinguishing between 'preventive' and 'remedial' flexibilities. Each flexibility has its particular characteristics, and all of them have been thoroughly studied elsewhere. It is important, however, to classify, enumerate and briefly introduce

[137] C. Correa, *Trade related aspects of intellectual property rights*, Oxford: Oxford University Press, 2007, p. 391; Commission on Intellectual Property Rights, Innovation and Public Health, *Public Health, Innovation and Intellectual Property Rights*, Geneva: WHO, 2006, p. 124; M. Perez Pugatch, "Intellectual Property, Data Exclusivity and Market Access", in P. Roffe, G. Tansey, D. Vivas-Eugui (Eds.), *Negotiating Health. Intellectual property and access to medicines*, London: Earthscan arICTSD, 2006, pp. 101-110.

these flexibilities, since this will permit presenting with greater detail the so-called TRIPS *plus* and TRIPS *extra* provisions. (See Box V.4)

Box V.4: Flexibilities in the TRIPS context

Pre-grant flexibilities / preventive flexibilities

Exclusion from patentability	TRIPS Art. 27	• Always that it is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, but not if the product is going to be commercialized • Therapeutic, diagnostic, surgical methods can be excluded • It is possible to exclude the patentability of plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes
Strict patentability criteria	TRIPS Art. 27	• With regards to the novelty: – On among other options is to combine several sources to check whether there is novelty. – Another option is to accept non-scientific publications to destroy novelty. – New uses may be excluded • There are many ways to influence on the inventive step or non-obviousness criteria – Enhancing the level of knowledge of the PHOSITA – Excluding metabolites, prodrugs, polymorphs, substances existing in nature – Excluding products that do not enhance the efficacy with respect other existing products • Industrial application – The possibility to repeat the product and technical effect are key – It requires more that utility – Key in the area of biotech

Patent oppositions	National legislation	Pre-grant and post-grant can contribute to the quality of patents
Transitional periods	TRIPS Arts. 65, 66 and paragraph 7 of the Doha Declaration	A transition period of ten years for developing countries that did not grant patents for pharmaceutical products and processes before January 1995; LDCs had until 2016, but this period will probably be extended until 2021.

Post-grant flexibilities / remedial flexibilities

Parallel imports /exhaustion of rights	Article 6	• The rightholder can decide where, when and at what price marketing the protected product, but when introduced in the market the rightholder exhausts his right to control the trade with such a product. • Exhaustion can be – national / regional /international • TRIPS excludes exhaustion of rights from the WTO dispute settlement system and Doha Declaration confirms the freedom to choose the exhaustion regime
Exceptions to patent rights	Article 30	• Conditions – limited – not unreasonably conflict with a normal exploitation of the patent – do not unreasonably prejudice the legitimate interests of the patent owner taking into account the interests of third parties • Examples – Acts done with private purposes – Educational or experimental use – Preparation of individual recipes – Award of marketing authorization – Use of the invention by a third party in good faith

Compulsory licenses	Article 31	– Grounds (for instance): public non-commercial use, urgency, dependency of patents and reaction to anti-competitive practices – Operational aspects • Previous contacts in case of dependency of patents • It cannot be exclusive • Evaluated case by case • Accompanied by adequate remuneration • Duration needed to achieve intended goal • End when circumstances that motivated its granting cease to exist • Product predominantly for the supply of the domestic market

4. International intellectual property regulation and public health after TRIPS

TRIPS standards were initially found problematic for developing countries and access to public goods. This is precisely the reason why the abovementioned flexibilities were emphasized and became a rich area of research and policy action. However, as described in chapter I, shortly after TRIPS was concluded a new wave of trade agreements included new standards of protection enhancing the levels of IP protection set forth in TRIPS. In the case of pharmaceutical products, these standards concern patent protection, test data protection, regulatory issues relating to the link between patent protection and the award of marketing authorization, the abandonment of transitional periods, and the enactment of new enforcement related standards, particularly those relating to trademarks and border enforcement.

A general overview of these provisions permits summarizing them by saying that some agreements oblige to: *i)* satisfy TRIPS sooner than required by TRIPS transitional periods; *ii)* resort to the technique of 'legislation by reference' and incorporate IP obligations found in other treaties; iii) nullify or restrict flexibilities foreseen in TRIPS by providing more stringent norms, which either strengthen obligations already found in TRIPS or create new obligations not foreseen in TRIPS.

A general description of each of the TRIPS *plus* and *extra* measures is provided next, while greater detail on many of them is provided when commenting on the specific regulation of TRIPS *plus* and *extra* measures, of relevance for public health, in recent negotiations such as KORUS and TTP.

Concerning patents, one of the notorious measures to strengthen patent protection is that relating to the extension of the patent term. In several trade agreements it is in effect foreseen that delays occurred during regulatory and patent approval processes will entitle

right holders to claim compensation by means of the extension of the actual term of patent protection, up to five years. While many of the agreements concluded by the US foresee the patent extension for delays caused in the context of both regulatory and patent approval process, treaties negotiated by the EU limit the extension to cases of regulatory delays. As noted before, though, and by virtue of the WTO non-discrimination principle, European right holders are indeed benefited by the protection enacted in US agreements.

Another provision found in some agreements concluded after TRIPS entered into force is that of restricting the margin of manoeuvre with respect to patent exclusions. As abovementioned (Box V.4), TRIPS allows to exclude patents for new uses of known products, that is, second-use patents. By contrast, new agreements concluded by the US oblige to grant patent protection to new uses of products already commercialized. This is a particularly important change with respect to pharmaceutical patents, since in the medicines' context it is not infrequent to discover that medicines have multiple indications. In this context- patent exclusions- it is often found in PTAs the explicit obligation to provide patent protection for plants and animals, as is also the case with original proposals made in the TPP negotiations.

One of the most popular TRIPS flexibilities, compulsory licenses, has also been severely curtailed in some new trade agreements. In these agreements the grounds of granting compulsory licenses have been reduced to national emergencies, antitrust remedy and public non-commercial use. Moreover, the condition imposed therein to enable the patent holder to control the marketing authorization during the patent term makes it difficult, if not impossible, the award of compulsory licenses. In effect, pursuant to new PTAs the patent owner must be notified when marketing approval is sought during the patent term, and has the power to oppose to the actual granting of such an authorization.

In addition to the protection against unfair competition and disclosure, some legal orders -and trade agreements- require the granting of periods of temporal exclusivity with respect to the use of this data, a type of exclusivity which has given rise to controversies as to the nature of the protection awarded. During this period, health authorities are not allowed to use the pharmaceutical information provided by the originator when analysing subsequent applications. In fact, health authorities may be even prohibited from taking into consideration the existence of this information. If this is the case, proof of bioequivalence between the two products will not suffice to obtain marketing authorization and competitors willing to market their product should in principle produce their own data. Naturally, this is not economically or ethically viable; hence the practical impact of this type of protection is to consolidate the monopoly power of the originator for a period of, normally, five years.

5. The PTA between the United States and Republic of Korea as an example of maximalist protection on health related issues

We examine below the principal aspects of KORUS, discussed more generally in chapter II, that touch upon patents and pharmaceuticals

Patent term adjustment

In meeting the requirements in KORUS, the Republic of Korea had to amend its patent law in order to adjust the term of a patent to compensate for unreasonable delays that occur in

the granting of a patent. In earlier PTAs negotiated by the US, a delay was considered unreasonable if the granting took place more than five years after the filing of the patent application or four years after a request made for examination of the application. In KORUS and as reflected in the proposals under consideration in the TPP, these delays are reduced, respectively, to four and three years.[138]

Extension of the patent term for delays in the marketing approval of the product

The amended Korean law introduced the obligation in KORUS (see Box V.5) to extend the patent term beyond 20 years and up to five years according to the enacting legislation, to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.

Box V.5: KORUS provision on compensation of patent term as a result of the marketing approval process

With respect to patents covering a new pharmaceutical product that is approved for marketing in the territory of the Party and methods of making or using a new pharmaceutical product that is approved for marketing in the territory of the Party, each Party, at the request of the patent owner, shall make available an adjustment of the patent term or the term of the patent rights of a patent covering a new pharmaceutical product, its approved method of use, or a method of making the product to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial use of that pharmaceutical product in the territory of that Party. Any adjustment under this subparagraph shall confer all of the exclusive rights, subject to the same limitations and exceptions, of the patent claims of the product, its method of use, or its method of manufacture in the originally issued patent as applicable to the product and the approved method of use of the product. (Art. 18.8.6(b)

Patent linkage

Korea was under the obligation to establish the patent linkage system for the marketing approval of generic drugs as provided under KORUS (See Box V.6), allowing Korea for a three-year transitional period for the implementation of this obligation, expiring on March 15, 2015.[139]

Box V.6: Linkage under KORUS

Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence of safety or efficacy information of a product that was previously approved, such as

[138] KORUS, Art. 18.8.6(a).

[139] See the exchange of letters between the Minister of Trade of Korea and the USTR dated February 2, 2011, p. 4, available at: http://www.ustr.gov/webfm_send/2557 .

evidence of prior marketing approval in the territory of the Party or in another territory, that Party shall:
(a) provide that the patent owner shall be notified of the identity of any such other person that requests marketing approval to enter the market during the term of a patent notified to the approving authority as covering that product or its approved method of use; and
(b) implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of a patent notified to the approving authority as covering that product or its approved method of use. (Art. 18.9.5)

A question that has arisen in the implementation of KORUS' patent linkage is its coverage of biologics. The US government has taken the firm view that the patent linkage extends to biologics. It is reported that civil societies, activists including patent attorneys and industries supporting KORUS, oppose the inclusion of biologics. In a letter (February 2015) by the US Ambassador to the government of Japan, he calls the attention that legislation to implement the agreement "would carve out biologics from Korea's patent linkage requirement." The Ambassador recalls "that is critical that Korea adopt a patent system that covers all pharmaceutical products, in line with KORUS." It is also noted in the letter that the US is seeking similar protections in the TPP negotiations.[140]

Protection of new clinical information

KORUS innovates with respect to earlier PTAs negotiated by the US by introducing new exclusive protection for a period of three years concerning new clinical information for a product that was previously approved. (See Box V.7) The same protection is extended to the submission of evidence concerning new clinical information for a product that was previously approved based on that new clinical information in another territory. The protection in this case is for at least three years from the date of marketing approval based on the new clinical information in the territory of the Party. (KORUS, Art. 18.9.2, b) These innovative trends are also reflected in the proposals under negotiations in the TPP.

Box V.7: Korus and the protection new clinical information

If a Party requires or permits, as a condition of granting marketing approval for a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information that is essential to the approval of the pharmaceutical product containing the previously approved chemical entity, other than information related to bioequivalency, the Party shall not, without the consent of a person that previously submitted such new clinical information to

[140] US Ambassador confirmed patent linkage under FTA include biologics, Haesob's IP blog, March 11, 2015, http://hurips.blogspot.kr/2015/03/us-ambassador-confirmed-patent-linkage.html (visited 3/12/2015).

obtain marketing approval in the territory of the Party, authorize another to market a same or a similar product based on:
(i) the new clinical information submitted in support of the marketing approval; or
(ii) evidence of the marketing approval based on the new clinical information,
for at least three years from the date of marketing approval in the territory of the Party. (Art. 18.9.2, a)

Transparency in pharmaceutical products and medical devices

Following what was introduced for the first time in the PTA between Australia and the US, [141] KORUS includes provisions regarding pharmaceutical products and medical devices and health reimbursement programs, "in order to promote the development of and the facilitation of access to high-quality patented and generic pharmaceutical products and medical devices." [142] These provisions may impact on the domestic management of healthcare programs at the national or central level of government regarding the coverage and reimbursement of pharmaceuticals and medical devices. Similar proposals are under discussion in the TPP negotiations.

KORUS provides that when a Party´s central level of government[143] health care program operates through listing pharmaceutical products (including biologics), medical devices (including diagnostic products), or indications for reimbursement or setting the amount of reimbursement for those products, the reimbursement should be based on competitive market-derived prices and its applicable procedures, rules, criteria and guidelines shall be fair, reasonable and non-discriminatory.

If reimbursement determination is not based on competitive market-derived prices, then it must be calculated in a way that the value of the patented pharmaceutical product will be recognized and must permit manufacturers to apply –based on evidence of safety or efficacy- for increased the reimbursement over that provided comparator products. A procedure should also be available to appeal the reimbursement decision.

KORUS also refers to transparency obligations regarding laws, regulations and procedures of general applications on any matter related to pricing, reimbursement, or regulation of pharmaceutical products or medical devices. The provisions of the chapter are subject to the monitoring of a Medicines and Medical Devices Committee.

At least three important US health care programs, according to sources in the US, would not comply with the provisions of KORUS Chapter 5, namely: Medicaid, which is

[141] In the Australia-US FTA this matter is regulated under a two-page Annex 2-C "Pharmaceuticals" to Article 2 of the agreement while in the case of Korea, the matter is under the six-page Chapter Five "Pharmaceuticals Products and Medical Devices" of the agreement.
[142] See KORUS, Chapter 5 dealing with Pharmaceutical Products and Medical Devices (Art. 5.2).
[143] It should be noted that as the US Medicaid being a regional level of government healthcare program, it is not subject to the provisions of the chapter.

not a federal healthcare program; 340B Drug Pricing Program, and Medicare Part B because the reimbursement for pharmaceutical products and medical devices seems not to be competitive market-derived nor do they appropriately value patented drugs as requested under KORUS.[144]

6. Intellectual property and heath related provisions in the TPP

As stressed in this report, KORUS constitutes the source of most of the proposals under negotiations in the TPP with the intention in some quarters to sharpen them and make them more precise. Naturally and as discussed in chapter III, the relationship between IP protection and public health has been a matter of concern in the context of the TPP. With the view of recapitulating, among the main proposals -beyond those already in KORUS- found in the negotiating texts, the following deserve further consideration:

- Enhanced efficacy requirement: in the patentable subject matter it is expressly prohibited the rejection of patents on the basis that the product did not result in enhanced efficacy of the known product when the applicant has set forth distinguishing features establishing that the invention is new, involves an inventive step, and is capable of industrial application. This provision seems to have been drafted in response to legislative efforts to combat evergreening by means of requiring enhanced efficacy with respect to previous products in order to grant patents. Naturally, the Indian Patent Act section 3(d) and the Novartis-Imatinib case are readily identifiable as a source of this concern.
- Patentability of second uses: in the latest known version of the TPP it is proposed introducing patent protection for new uses or new methods of using a known product. In our opinion, however, the proposal also found in the text mentions "any new use, or new method of using a known product that *is not otherwise excluded from patentability by the Party*". This would allow parties to adjust the acceptability of patents on secondary uses. Mention must also be made of the fact that, although it is not yet entirely clear, the obligation to patent diagnostic, therapeutic and surgical methods has been removed from the latest text.
- Grace periods: If approved, as it seems that it would be the case, the provision relating to grace periods enshrines long periods for public disclosure made by or originating from the patent applicant.
- Regulatory or Bolar exception: The proposals relating to the Bolar exception are very relevant, since the exception has not been regulated, in detail, in some earlier PTAs. Products' coverage, acts falling under the scope of the exception and geographical extension are the topics addressed in this long proposal. Relating to products, parties disagree with respect to the coverage: for some, it would only

[144] For further details on the consistency of the US law with KORUS regarding these healthcare programs, see Krista Maier, "Are the U.S. Health Care Programs Drug Prices Based on "Competitive Market-Derived Prices?", June 29, 2011, available at http://infojustice.org/archives/4058. Regarding consistency of the US law with KORUS on the copyright side, see Sean Flynn, "Consistency of the Korea-US Free Trade Agreement Copyright Right Provisions with the U.S. Law", posted on December 19, 2001 at: http://infojustice.org/archives/6640.

include pharma products, while others, in line with national regulations, would embrace as well agrochemical products. It is interesting to note that relatively broad sample of acts that could be inferred from this provision (those relating to generating information to meet requirements for marketing approval) and the fact that, as has already happened in some Latin American countries, it would cover exportation as well.

- Utility requirement: The proposal relating to the utility criteria contributes at blurring the differentiation between industrial application and utility, something that has already generated concern –and judicial processes condemning this practice- in some countries, including some TPP countries. Promoting the 'utility' standard, by assimilating the 'industrial applicability' standard to that of 'utility', gives place to a more flexible 'industrial application' requirement. This relaxation not only conflicts with the content of the legal order of many states, but also with previous international obligations. The demand for an object to be used in any type of industry limits the spectrum of patentability that would result from merely requiring utility. For instance, patent applications for inventions for merely personal use, or inventions in the biotechnological field, may be rejected pursuant to the industrial application criteria, while this would not be possible according to the utility criteria.
- Patent term extension: As in KORUS, the patent owner might be compensated for unreasonable curtailment of the effective patent term as a result of delays in the marketing approval process. It must be noted that not all TPP negotiating states enshrine this possibility nowadays. This is at least appears to be the case of Japan, Australia, New Zealand, Malaysia, Vietnam, Canada, and Mexico.
- The protection of undisclosed information and test data for a number of years of exclusivity: This is a long and detailed proposal. It must be at least underlined that: i) it impedes direct and indirect reliance on test data; ii) there is an interesting but hardly feasible proposal to take into consideration the date of first approval wherever in the world when counting the years of test data protection; iii) it includes a prohibition to rely on foreign marketing authorization permits for the same period of time of local test data protection.

D. Enforcement as a cross-cutting area affecting all IP-related industries

Intellectual property rights enforcement has been an overarching concern in the post TRIPS period. Although TRIPS implications in relation to enforcement were significant, countries that have been behind an accelerated implementation of TRIPS have reiterated the need for the enhancement of the international normative acquis on enforcement. PTAs and ACTA have been an important scenario for these developments. ACTA tried to introduce a major systemic shift. Negotiated among a closed group of nations, it is the only international treaty ever adopted with an exclusive focus on enforcement. The Trans-Pacific Partnership has revived some of the concerns expressed during the ACTA negotiations. In fact, some of the TPP proposals go even beyond the final act of ACTA.

1. Enforcement relevance

Norms on enforcement have a capital importance in any legal system. From the practical point of view, enforcement rules determine the effectiveness of the system, thus transforming rights and obligations of substantive content into tangible entitlements. While traditionally overlooked when analysing developments in international IP law, enforcement rules are key to understand the significance and real value of any intellectual property institution.

A central element of IPRs is the faculty of preventing others from undertaking activities that fall within the object of protection. The majority of IP enforcement institutions are tributary to this right to exclude and have been built around this primary entitlement, a feature that can be observed in civil, criminal and border enforcement. For IP owners and their competitors, enforcement related institutions such as injunctions, damages, provisions relating to evidence or border measures are the most visible aspect of intellectual property law.

2. The pre-TRIPS world

States have traditionally retained the power over the concrete implementation of IPRs. Their will to preserve the control of IP enforcement norms and mechanisms was evident in the classical IP conventions. The Paris and Berne conventions contain few minimum standards on enforcement beyond national treatment and certain provisions,[145] most of the times optional without providing governments with much guidance concerning appropriate and modern enforcement standards. The provisions enshrined in the classical treaties are very limited, afford states a great margin of discretion, and have had a limited impact.[146] Unsurprisingly, right holders found little relief in these treaties.

[145] Panel Report, *China- Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R, 26 January 2009, par. 7.241(hereinafter *China–Intellectual Property Rights*).

[146] P.K. Yu, "Shaping Chinese criminal enforcement norms through the TRIPS Agreement", in C. Geiger (Ed.), *Criminal Enforcement of Intellectual Property. A Handbook of Contemporary Research*, Cheltenham: Edward Elgar, 2012, p. 287.

In the late 1970s and early 1980s developed nations manifested their discontent with respect to the lack of effective enforcement within some countries, and the concomitant problems their industries faced. These countries sustained that inadequate enforcement was a trade barrier, since their exports were being substituted by locally manufactured infringing products.[147] Counterfeiting was considered a central issue during the 1973-1979 GATT Tokyo Round, although the practical effects in terms of normative changes were meagre.

3. From Punta del Este to TRIPS

The Uruguay Round provided an excellent occasion to strengthen the IP enforcement normative framework. Intellectual property domestic enforcement was at the heart of the negotiations just from the beginning. Developed nations already had a fairly clear agenda in mind: the enhancement of domestic remedies, international cooperation, border enforcement and institutional aspects were their key objectives.

TRIPS negotiators did not attempt to achieve full harmonization with respect to enforcement-related norms, but to establish general standards to be implemented according to national preferences. At the time of the adoption of TRIPS, national differences were significant, which made it impracticable to adopt a uniform set of rules, or the universal recognition and execution of national rulings.[148] Instead, the goal was to agree on the first international and comprehensive set of norms on enforcement,[149] which is precisely what can be found in TRIPS Part III, indeed a major achievement of the Agreement.[150]

4. The disenchantment with TRIPS

Although the practical consequences of TRIPS enforcement provisions were enormous for WTO Members, right holders and competitors, approximately a decade after TRIPS entered into force, IP enforcement returned to the forefront of international norm making. Countries that had promoted the adoption of TRIPS underlined the need to enhance the international normative *acquis* on enforcement, first through numerous bilateral agreements and afterwards by means of a failed plurilateral treaty under the name of Anti-Counterfeiting Trade Agreement (ACTA).

The reason of that volte-face can be found in the relative disenchantment with respect to enforcement norms found in TRIPS. In effect, even if the TRIPS enforcement regime was initially considered revolutionary, with the passage of time its norms were criticized for being crafted as too broad legal standards. New treaties, particularly PTAs were adopted to remedy the alleged shortcomings, transforming optional provisions into binding obligations by making ambiguous provisions into detailed prescriptive provisions. By and large, the most important vehicle for intellectual property codification after TRIPS

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[147] M. C. E. J. Bronckers, D. W. F. Verkade, N. M. McNelis, *TRIPS Agreement. Enforcement of Intellectual Property Rights*, Luxemburg: Office for Official Communications of the European Communities, 2000, p. 10.
[148] T. Dreier, "TRIPS and the Enforcement of Intellectual Property Rights" in F.K. Beier, G. Schriker (Eds), *From GATT to TRIPS: The Agreement on Trade-Related Aspects of Intellectual Property Rights*, Munich: Max Planck Institute, 1996, p. 254.
[149] J. Pauwelyn, *The Dog That Barked But Didn't Bite: Fifteen Years of Intellectual Property Disputes at the WTO*, 1 *Journal of International Dispute Resolution* (2010), 389-42
[150] J. Reinbothe, The EU Enforcement Directive 2004/48/EC as a Tool for Copyright Enforcement, *Copyright Enforcement and the Internet*, Edited I. Stamatoudi, The Hague: Kluwer, p. 5, 2010..

has been the conclusion of PTAs, which include bilateral free trade agreements as well as customs unions, economic integration agreements and partial scope agreements.

5. The burgeoning relevance of PTAs in the IP enforcement context

The number of PTAs regulating intellectual property rights has continuously grown since the adoption of TRIPS (see chapter I). PTAs have been considered an ideal tool to foster increased protection of IP while negotiations in the multilateral context make slow progress. Indeed, only a much reduced number of multilateral IP treaties has been concluded since the adoption of TRIPS (*i.e.* WIPO's *internet treaties*, and the Marrakesh VIP treaty, and the Beijing on audiovisual performances, see Box I.5, supra). While the normative and policy implications of IP provisions in PTAs have attracted significant attention, their specific and vast impact on IP enforcement has been rarely studied.

Beginning with the US, and soon thereafter the EU, the main trading powers have made IP enforcement a prominent component of the PTAs negotiated in the last ten years. As noted in chapter IV, the EU's 2004 *Strategy for the Enforcement of Intellectual Property Rights in Third Countries* announced the promotion of the adoption of new legal undertakings on enforcement. In accordance with that goal, the EU has inserted robust IP enforcement provisions in ambitious trade treaties.[151] Since 2004, as observed in the same chapter, this has been the case of the treaties concluded with South Korea, Central America, Peru, Colombia, Ukraine, Moldova, Georgia, Canada and Cariforum.

Of course, not all PTAs regulating IP address enforcement, and not all agreements that regulate enforcement do it with the same intensity. A differentiation can be made between treaties that make a general reference to IP enforcement[152] and those that regulate this area in detail.[153] The treaties covering IP enforcement in detail can be classified depending on the IP enforcement regulated: civil[154], criminal[155], border[156], digital.[157]

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[151] Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Application of the Directive 2004/48/EC of the European Parliament and the Council of 29 April 2004 on the enforcement of intellectual property rights*, Brussels, 22-12-2010, COM(2010)779 final, p. 4.

[152] EU-Mexico; EU-Montenegro; EU-Morocco; EU-Serbia; EU-Tunisia; EU-Turkey; European Economic Area; European Free Trade Association; Hong Kong, China-New Zealand; Japan-India; Republic of Korea-Chile; Republic of Korea-India; Republic of Korea-Singapore; Panama-Costa Rica; Panama-El Salvador; Turkey-Albania; Turkey-Bosnia and Herzegovina; Turkey-Croatia ; Turkey-Former Yugoslav Republic of Macedonia; Turkey-Georgia; Turkey-Israel; Turkey-Montenegro; Turkey-Morocco ; Turkey-Serbia.

[153] Andean Community of Nations; Australia-Chile; Chile-China; Chile-Japan; Chile-Mexico; China-Costa Rica; Colombia-Mexico; Costa Rica-Mexico; Dominican Republic-Central America-United States Free Trade Agreement; EC; EFTA-Albania; EFTA-Colombia; EFTA-Hong Kong; EFTA-Mexico; EFTA-Montenegro; EFTA-Peru; EFTA-Serbia; EFTA-Ukraine; EU-CARIFORUM; EU-Colombia; EU-Republic of Korea; EU-Peru; Japan-Indonesia; Japan-Malaysia; Japan-Peru; Japan-Philippines; Japan-Switzerland; Japan-Thailand; Japan-Viet Nam; Republic of Korea-US; Mexico-El Salvador; Mexico-Guatemala; Mexico-Honduras; Mexico-Nicaragua; Nicaragua and the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; North American Free Trade Agreement; Pakistan-China; Panama-Peru; Panama-Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; Peru-China; Peru-Republic of Korea ; Singapore-Australia; Thailand-Australia; US-Australia; US-Bahrain; US-Chile; US-Colombia; US-Jordan; US-Morocco; US-Panama; US-Oman; US-Peru; US-Singapore.

[154] Andean Community of Nations; Australia-Chile; Chile-Japan; Chile-Mexico; Colombia-Mexico; Costa Rica-Mexico; Dominican Republic-Central America-United States; EC; EFTA-Colombia; EFTA-Mexico;

One of the major post-TRIPS changes is the regulation of IP enforcement in the digital domain. Since the adoption of the WIPO Internet treaties in 1996, many PTAs have included an obligation to ratify digital enforcement-related treaties. In other cases, treaties directly regulate the digital enforcement measures to be taken and allude to anti-circumvention of effective technological measures, electronic rights management information or the possibility to order an online service provider to disclose information to a right holder.[158]

6. When PTAs do not suffice

Turning to plurilaterals, ACTA tried to introduce a major systemic shift. ACTA is a plurilateral treaty on international and national enforcement of intellectual property rights negotiated between a closed group of nations. It is the only international treaty ever adopted with an exclusive focus on IP *enforcement.* While TRIPS was a compromise subject to specific boundaries, ACTA was akin to a framework agreement, which opened new avenues for the IP enforcement agenda. [159]

There is a general perception that ACTA constitutes just a springboard for new initiatives to expand enforcement standards. The agreement's in-built mechanisms would have permitted moving in that direction. Similarly, ambiguous provisions within ACTA would permit, if other conditions were met, a number of maximalist implementations. This

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EFTA-Montenegro; EFTA-Peru; EU-CARIFORUM; EU-Colombia; EU-Republic of Korea; EU-Peru; Japan-Indonesia; Japan-Malaysia; Japan-Peru; Japan-Philippines; Japan-Switzerland; Japan-Thailand; Japan-Viet Nam; Republic of Korea-US; Mexico-El Salvador; Mexico-Guatemala; Mexico-Honduras; Mexico-Nicaragua; North American Free Trade Agreement; US-Australia; US-Bahrain; US-Chile; US-Colombia; US-Jordan; US-Morocco; US-Panama; US-Oman; US-Peru; US-Singapore.

[155] Andean Community of Nations; Australia-Chile; Chile-Japan; Chile-Mexico; Colombia-Mexico; Costa Rica-Mexico; Dominican Republic-Central America-United States Free Trade Agreement; EC; EFTA-Mexico; EFTA-Montenegro; EU-CARIFORUM; EU-Colombia; EU-Republic of Korea; EU-Peru; Japan-Indonesia; Japan-Malaysia; Japan-Peru; Japan-Philippines; Japan-Switzerland; Japan-Thailand; Japan-Viet Nam; Republic of Korea-US; Mexico-El Salvador; Mexico-Guatemala; Mexico-Honduras; Mexico-Nicaragua; North American Free Trade Agreement; US-Australia; US-Bahrain; US-Chile; US-Colombia; US-Jordan; US-Morocco; US-Panama; US-Oman; US-Peru; US-Singapore.

[156] Albania-EFTA; Andean Community of Nations; Australia-Chile; Chile-Japan; Chile-Mexico; China-Costa Rica; Colombia-Mexico; Costa Rica-Mexico; Dominican Republic-Central America-United States; EC; EFTA-Colombia ; EFTA-Hong Kong; EFTA-Mexico; EFTA-Montenegro; EFTA-Peru; EFTA-Serbia; EFTA-Ukraine; EU-CARIFORUM; EU-Colombia; EU-Republic of Korea; EU-Peru; Japan-Indonesia; Japan-Malaysia; Japan-Peru; Japan-Philippines; Japan-Switzerland; Japan-Thailand; Japan-Viet Nam; Republic of Korea-US; Mexico-El Salvador; Mexico-Guatemala; Mexico-Honduras; Mexico-Nicaragua; North American Free Trade Agreement; Pakistan-China; Panama-Peru; Panama-Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; Peru-Republic of Korea; Peru-China; Singapore-Australia; Thailand-Australia; US-Australia; US-Bahrain; US-Chile; US-Colombia; US-Jordan; US-Morocco; US-Panama; US-Oman; US-Peru; US-Singapore.

[157] Australia-Chile; Dominican Republic-Central America-United States Free Trade Agreement; EC; EU-Colombia; EU-Republic of Korea ;EU-Peru; Japan-Peru; Japan-Switzerland; Republic of Korea-US; Mexico-Nicaragua; North American Free Trade Agreement; US-Australia; US-Bahrain; US-Chile; US-Colombia; US-Morocco; US-Panama; US-Oman; US-Peru; US-Singapore.

[158] *See* note 157 supra on the treaties directly -and not by means of legislation by reference- regulating digital enforcement.

[159] See, P. Roffe, X. Seuba, (Eds), *The ACTA and the Plurilateral Enforcement Agenda: Genesis and Aftermath*, Cambridge: Cambridge University Press, 2015.

is why it has been noted that the main problem in ACTA was "the vague and uncertain nature of some provisions and the lack of clear limits."[160] Even if the implementation of the treaty fails, ACTA is already shaping new bilateral and plurilateral initiatives –such in the case of the original proposals made in the context of the TPP- and used as a standard to assess other countries' performance in the context of unilateral evaluations.

From a normative point of view, ACTA has two notable characteristics. First, in relation to civil, criminal and border enforcement it incorporates a number of TRIPS provisions, but remains silent on the many instances where TRIPS regulates the rights of alleged infringers.[161] Second, ACTA strengthens the standards of protection for right holders in areas not specifically regulated in TRIPS, such as digital enforcement. Surprisingly, though, and contrary to what it could be inferred from the controversy that the ACTA negotiation and conclusion attracted, numerous ACTA provisions are already present in the legal orders of many developing countries. This responds, on the one hand, to the fact that at the end of the negotiations the content of ACTA was fairly balanced, in particular when compared with inception texts. On the other hand, it is also noticeable that many developing economies in the last decade have profoundly enhanced their IP enforcement normative and institutional infrastructures, frequently as a result of soft and hard forms of cooperation on the part of developed economies.

The TPP has revived some of the concerns expressed during the ACTA negotiations. In fact, in some enforcement-related aspects, some of the TPP provisions go even further than ACTA. It is thus extremely important to keep vigilant with this section of the TPP intellectual property chapter. There are two areas of particular concern. With regards to civil enforcement, the absence of numerous safeguards would give rise to an unbalanced text. As in many other chapters found in contemporaneous PTAs, not mentioning the principle of proportionality is not only a significant threat, but also an absence with tangible effects.[162] The same can be said with respect to the lack of safeguards in key provisions, such as that on provisional measures. With regards to criminal enforcement, the last leaked version of the TPP is not only TRIPS plus but also ACTA plus. It is particularly disturbing the low level of exigency with respect to the TRIPS requirement of "commercial scale", required to assess the existence of an infringement of criminal nature.[163] If the text were adopted as it stands, acts not commonly considered of

[160] H. Grosse Ruse-Khan, "Criminal enforcement and international IP law", C. Geiger, *Criminal Enforcement of Intellectual Property. A Handbook of Contemporary Research*, Cheltenham: Edward Elgar, 2012, p. 171.

[161] There are many examples, for instance the rules on the search and seizure of alleged infringing goods, or the silence with respect the right of the alleged infringer to be heard and to be given notice enshrined in TRIPS.

[162] This is for instance the case of the agreements concluded between the European Union, Georgia and Moldova in 2014. See Chapter IV, supra.

[163] The WTO *China-Intellectual Property Rights* panel report held that "commercial scale" is "the magnitude or extent of typical or usual commercial activity". Therefore, counterfeiting or piracy on a commercial scale refers to counterfeiting or piracy carried on at the magnitude or extent typical or usual commercial activity with respect to a given product in a given market. That is, according to the Panel, acts of commercial scale require specific magnitude, this being contextual to a given product in a given market. *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, Report of the Panel, WT/DS362/R, 26 January 2009, pars. 7.577-7.578.

commercial nature, including some acts performed in the private domain, would be criminalized.

It should be noted, in the above context -as pointed out in Chapter V-A, supra-, that criminal sanctions would be in principle excluded in the case of the commented TTIP negotiations, according to the European mandate for negotiations.[164]

[164] The declassified mandate of the EU Commission specifically stated that the TTIP would not include criminal sanctions. *See* the Council of the European document Nr. 11103/13 dated June 17, 2013, restricted document, available at: http://data.consilium.europa.eu/doc/document/ST-11103-2013-DCL-1/en/pdf.

Annexes

Annex A

List of Trade Agreements including IP provisions

Main Commercial Partner	Concluded Treaties	Treaties under discussion
Australia	Asia & Oceania: Malaysia; Singapore; Thailand The Americas: Chile; US	
Canada	Africa & Middle East: Israel The Americas: Chile; Colombia; Costa Rica; NAFTA; Peru.	Europe: Comprehensive Economic and Trade Agreement (CETA)
China	Africa & Middle East: Pakistan. Asia & Oceania: Hong Kong; Macao; New Zealand. The Americas: Chile; Costa Rica; Peru.	
European Free Trade Association (EFTA)	Africa & Middle East: Egypt; Gulf Cooperation Council; Israel; Jordan; Lebanon; Morocco; Palestinian Authority; Southern African Customs Union; Tunisia; Turkey; Balkans and other European countries: Albania; Bosnia and Herzegovina; Macedonia; Montenegro; Serbia; Ukraine. Asia & Oceania: Hong Kong; Korea; Singapore The Americas: Chile; Colombia; Costa Rica; Mexico; Panama; Peru.	

Annex A

List of Trade Agreements including IP provisions

Main Commercial Partner	Concluded Treaties	Treaties under discussion
European Union	Africa & Middle East: Algeria; Cameroon; Egypt; Israel; Jordan; Lebanon; Morocco; Palestinian Authority; South Africa; Tunisia; Turkey. Asia & Oceania: Korea, Singapore Balkans and other European countries: Albania; Bosnia and Herzegovina; Croatia; Macedonia; Montenegro; Serbia, Ukraine, Moldova, Georgia The Americas: CARIFORUM (Antigua and Barbuda, Bahamas, Barbados, Belize, Dominica, Dominican Republic, Grenada, Guyana, Haiti, Jamaica, St. Christopher and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, Trinidad and Tobago); Central America; Chile; Colombia; Mexico; Peru; Ecuador, Canada	- Trans-Atlantic Trade and Investment Partnership (T-TIP): US and EU
Japan	Asia & Oceania: Brunei; India; Indonesia; Malaysia; Philippines; Singapore; Thailand; Viet Nam. Europe: Switzerland. The Americas: Chile; Mexico; Peru.	
Korea (Republic of)	Africa & Middle East: Turkey. Asia & Oceania: India; Singapore. Europe: EFTA; EU The Americas: Chile; Peru; US.	
New Zealand and Singapore	- Trans-Pacific Strategic Economic Partnership (TPP): Brunei, Chile.	
Taiwan	The Americas: Guatemala; Nicaragua; Panama.	

Annex A
List of Trade Agreements including IP provisions

Main Commercial Partner	Concluded Treaties	Treaties under discussion
United States of America	Africa & Middle East: Bahrain; Israel; Jordan; Morocco; Oman. Asia & Oceania: Australia; Korea; Singapore; Vietnam. The Americas: CAFTA-DR (Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua and Dominican Republic); Chile; Colombia; NAFTA (Canada and Mexico); Panama; Peru.	- Trans-Pacific Strategic Economic Partnership (TPP): Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, US, Vietnam. - Trans-Atlantic Trade and Investment Partnership (T-TIP): US and EU.

Main sources used in the preparation of the table: Australia, Department of Foreign Affairs and Trade, http://www.dfat.gov.au/fta/. Canada, Department of Foreign Affairs, Trade and Development, http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/fta-ale.aspx?lang=eng. China (People's Republic of) Ministry of Commerce, China FTA Network, http://fta.mofcom.gov.cn/english/index.shtml. European Commission, http://ec.europa.eu/enlargement/. European Free Trade Association, http://www.efta.int/free-trade/free-trade-agreements/. Hong Kong, Trade and Industry Department, http://www.tid.gov.hk/english/cepa/. India, Ministry of Commerce and Industry, http://www.commerce.nic.in/trade/international_ta.asp?id=2&trade=i. Japan, Ministry of Foreign Affairs, http://www.mofa.go.jp/policy/economy/fta/index.html. New Zealand, Ministry of Foreign Affairs and Trade, http://www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/index.php. Organization of American States, Foreign Trade Information System, SICE-OAS, http://www.sice.oas.org/. Singapore Ministry of Trade and Industry, http://www.fta.gov.sg/sg_fta.asp. US, Office of the United States Trade Representative, http://www.ustr.gov/trade-agreements/free-trade-agreements/. Xavier Seuba, "Intellectual Property in Free Trade Agreements: What treaties, what content…, Annex 4. Carsten Fink, "Intellectual Property Rights", in… Chapter 18, Table 18.2 Principal TRIPS+ Provisions in U.S. Free Trade Agreements (FTAs) ratified between 2001 and 2006. World Trade Organization, Regional Trade Agreements Information System (RTA-IS), http://rtais.wto.org/UI/PublicMaintainRTAHome.aspx.
Note that because of their variations, the dates of conclusion of the negotiations or the date of entry into force of the respective treaty in not mentioned. Detailed information on this is to be found in the respective annotated source.

ANNEX B

MAIN IP STATISTICS[165], GDP & POPULATION DATA OF TPP NEGOTATING PARTIES

Country name	PATENTS	PATENTS	TRADEMARKS	TRADEMARKS	DESIGNS	DESIGNS	UTILITY MODELS	UTILITY MODELS	GDP USD	Population
	Applications	Grants	Applications	Registers	Applications	Grants	Applications	Grants	(Billions)	(Millions)
Australia	29.717	17.112	62.541	45.340	6.912	7.064	1.676	450	990,23	23,13
Brunei Darussalam	11				11	11			29,03	0,42
Canada	34.741	23.833	760	28.995	5.346	3.785			1.472,74	35,16
Japan	328.436	277.079	33.564	101.526	31.125	28.288	7.622	7.363	4.518,72	127,34
Malaysia	7.205	2.660	117.198	26.979	2.053	2.001	145	31	670,29	29,72
Mexico	15.444	10.368	32.225	81.985	4.011	2.851	714	193	1.992,89	122,33
New Zealand	6.781	4.752	103.994	18.195	1.186	1.071			146,50	4,47
Peru	1.266	287	18.776		499	372	140	17	346,29	30,38
Singapore	9.722	5.575	20.968	15.436	2.393	2.387			411,62	5,40
United States	571.513	277.835	342.287	199.726	36.034	23.468			16.265,06	316,13
Vietnam	3.995	1.182	36.454	24.360	2.095	1.348	273	92	459,73	89,71
Total	**1.011.903**	**621.581**	**818.586**	**564.710**	**92.427**	**73.101**	**10.674**	**8.176**	**27.685,69**	**801,81**

Source: WIPO Statistics Database and Country Profile.

[165] Data corresponding to year 2013.

ANNEX C

Regional Trade Agreements NOTIFIED TO THE WTO BY TPP NEGOTIATING COUNTRIES

Country name	Notified agreements to the WTO	Early announcement of an agreement
Australia (10)	ASEAN-New Zealand; Chile; New Zealand (ANZCERTA); Papua New Guinea (PATCRA); Korea; Malaysia; Singapore; South Pacific Trade & Cooperation Agreement (SPATECA); Thailand; US.	China; Golf Cooperation Council (GCC).
Brunei Darussalam (6)	ASEAN-New Zealand; ASEAN-China; ASEAN-India; ASEAN-Japan; ASEAN Free Trade Area (AFTA); Japan.	
Canada	Chile; Colombia; Costa Rica; Israel; Jordan; Panama; Peru; EFTA; NAFTA.	CARICOM; Dominican Republic; El Salvador, Honduras, Guatemala, & Nicaragua; Singapore; Ukraine; EU; Korea.
Chile (24)	Australia; Canada, China; Colombia; Cosa Rica (Central America); El Salvador (Central America); Guatemala (Central America); Honduras (Central America); India; Japan; Malaysia; Mexico; Nicaragua (Central America); EFTA; EU; Global Preferences Among Developing Countries (GSTP); Hong Kong; Korea; Latina American Integration Association (LAIA); Panama; Peru; Protocol on Trade Negotiations (PTN); Turkey; US.	
Japan (16)	ASEAN; Brunei; Chile; India; Indonesia; Malaysia; Mexico; Peru; Philippines; Singapore; Switzerland; Thailand; Vietnam.	EU; GCC; Korea.
Malaysia (13)	ASEAN-Australia-New Zealand; ASEAN-China; ASEAN-India; Japan; Australia; New Zealand; Pakistan.	EU.
Mexico (14)	Chile; Colombia; EFTA; EU; GTSP; Israel Japan; LAIA; Central America; Uruguay; NAFTA; Peru; PTN.	Korea.
New Zealand	ASEAN-Australia, New Zealand (ANZCERTA); China, Hong-Kong; Chinese Taipei; Malaysia; Singapore; SPARTECA; Thailand.	Russian Federation.
Peru (16)	Andean Community (CAN); Canada, Costa Rica; EFTA, EU-Colombia; GSTP; Japan; LAIA; Panama; Chile; China; Korea; Mexico; Singapore; PTN, US.	

Singapore (19)	ASEAN-Australia-New Zealand; ASEAN-China; ASEAN-India; ASEAN Japan; Korea; AFTA; China; Costa Rica; EFTA; GSTP; India; Japan; Jordan; Korea; New Zealand; Panama; Peru; US.	Canada; EU; Ukraine.
United States of America (14)	Dominican Republic-Central America (CAFTA-DR); Korea; NAFTA; Australia; Bahrain; Chile; Colombia; Israel; Jordan; Morocco; Oman; Panama; Peru; Singapore.	EU (TTIP).
Vietnam (8)	ASEAN-Australia; ASEAN New Zealand; ASEAN-India; ASEAN-China; ASEAN-Japan; ASEAN-Korea; ASEAN-AFTA; GTSP; Japan.	EFTA; EU; Russian Federation.

Source: WTO RTAs webpage:
http://www.wto.org/english/tratop_e/region_e/rta_participation_map_e.htm

ANNEX D
WEB OF THE FREE TRADE (FTA) AND ECONOMIC PARTNERSHIP (EPA) AGREEMENTS BETWEEN TPP COUNTRIES[166]

	Australia	Brunei	Canada	Chile	Japan	Malaysia	Mexico	New Zealand	Peru	Singapore	United States	Vietnam
Australia				FTA EIF Mar. 6, 2009	EPA signed Jul. 8, 2014	FTA EIF Jan. 1, 2013		FTA EIF Jan. 1, 2011		AANZFTA signed Feb 27, 2009	FTA EIF Jan. 1, 2005	ASEAN Australia
Brunei				EPA P4 EIF Nov. 8, 2006	EPA EIF Jun. 1, 2009			P4 EIF Jul. 12, 2006		ASEAN AFTA EIF Jan 1, 1993		ASEAN AJCEP
Canada				FTA EIF Jul. 5, 1997			NAFTA EIF Jan. 1, 1994		FTA EIF Aug. 1, 2009		NAFTA EIF Jan. 1, 1994	
Chile	FTA EIF Mar. 6, 2009	EPA P4 EIF Nov. 8, 2006	FTA EIF Jul. 5, 1997		EPA EIF Sep. 3, 2007	FTA EIF Feb. 25, 2012	FTA EIF Jul. 31, 1999	FTA P3 EIF Nov. 11, 2006	EPA EIF Mar. 1, 2009	FTA P3 EIF Nov. 8, 2006	FTA EIF Jan. 1., 2004	FTA EIF Jan. 1, 2014
Japan	EPA signed Jul. 8, 2014	EPA EIF Jun. 1, 2009		EPA EIF Sep. 3, 2007		EPA EIF Jul. 13, 2006	EPA EIF Apr. 1, 2005		EPA EIF Mar. 1, 2012	ASEAN JA AJCEP signed Apr. 14, 2008		EPA EIF Oct. 1, 2009
Malaysia	FTA EIF Jan. 1, 2013			FTA EIF Feb. 25, 2012	EPA EIF Jul. 13, 2006			FTA EIF Aug. 1, 2010		ASEAN AFTA EIF Jan 1, 1993		
Mexico			NAFTA EIF Jan. 1, 1994	FTA EIF Jul. 31, 1999	EPA EIF Apr. 1, 2005				EPA EIF Feb. 1, 2012		NAFTA EIF Jan. 1, 1994	
New Zealand	FTA EIF Jan. 1, 2011	P4 EIF Jul. 12, 2006		FTA P3 EIF Nov. 11, 2006		FTA EIF Aug. 1, 2010				AANZFTA signed Feb 27, 2009		ASEAN New Zealand

[166] Only the latest signed agreement has been included between the different parties concerned.

Peru			FTA EIF Aug. 1, 2009	EPA EIF Mar. 1, 2009	EPA EIF Mar. 1, 2012		EPA EIF Feb. 1, 2012			FTA EI Aug. 1, 2009	EPA EIF Feb. 1, 2009	
Singapore	AANZFTA signed Feb 27, 2009	ASEAN AFTA EIF Jan 1, 1993		FTA P3 EIF Nov. 8, 2006	ASEAN JA AJCEP signed Apr. 14, 2008	ASEAN AFTA EIF Jan 1, 1993		AANZFTA signed Feb 27, 2009	FTA EIF Aug. 1, 2009		FTA EIF Jan. 1, 2004	ASEAN AJCEP
United States	FTA EIF Jan. 1, 2005		NAFTA EIF Jan. 1, 1994	FTA EIF Jan. 1., 2004			NAFTA EIF Jan. 1, 1994		EPA EIF Feb. 1, 2009	FTA EIF Jan. 1, 2004		
Vietnam	ASEAN Australia	ASEAN AJCEP		FTA EIF Jan. 1, 2014	EPA EIF Oct. 1, 2009			ASEAN New Zealand		ASEAN AJCEP		