

International Regulation of Pharmaceuticals: Codification by Means of Legal Transplantation

ICTSD Programme on Innovation, Technology and Intellectual Property

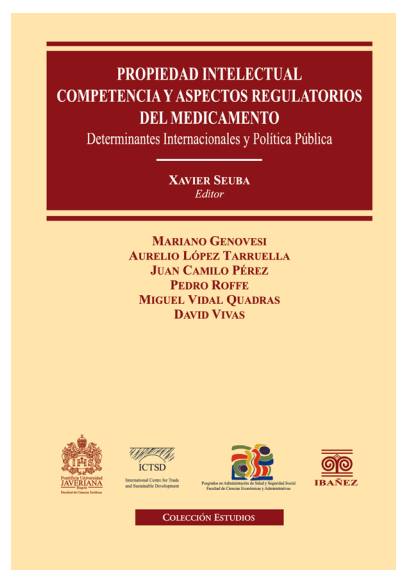
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Introduction

International Regulation of Pharmaceuticals draws on the introductory chapter of the book *Intellectual Property, Competition and Regulatory Aspects of Medicines*, jointly published in 2013, in Spanish, by Universidad Javeriana and the International Centre for Trade and Development (ICTSD).¹ The original introductory chapter has been translated into English and transformed into an independent piece focusing on the latest generation of international norms that have an impact on pharmaceutical products and the corresponding challenges they raise in terms of domestic implementation.



Against the background of growing global pharmaceutical harmonization, two-core threads are the main focus of attention. First, the importance of developing national legal orders enshrining intellectual property rules and technical standards that match the social and economic needs. Second, the corresponding need for careful negotiation of new international commitments, appropriate domestic implementation and proper interpretation of international economic agreements that interrelate closely with competition and intellectual property law.

International Regulation of Pharmaceuticals heavily relies on the chapters drafted by Pedro Roffe, Mariano Genovesi, Aurelio López-Tarruella, Juan Camilo Pérez, Miguel Vidal-Quadras, David Vivas and Xavier Seuba, and draws on their analysis of key legal institutions and the policy proposals put forward in the book *Intellectual property, competition and regulatory aspects of medicines*. With this material in mind, the present paper analyses in great depth the codification by means of legal transplantation that can be observed in norms relating to pharmaceutical products.

¹ See <http://www.ictsd.org/themes/innovation-and-ip/research/intellectual-property-competition-and-regulatory-aspects-of>.

1. Branches of law and international legal regimes relevant to international pharmaceutical regulation

The pharmaceutical chain comprises a sequence of interrelated steps that describe the life of a drug passing through the community, from their inception and development to the time the medicine is effectively used (LAPORTE, J-R., 2001, p. 122). National rules regulating the pharmaceutical chain belong to different branches of law. Norms pertaining to various areas of public and private law can be found at each step of the pharmaceutical chain, from innovation to access. For instance, rules belonging to administrative law, human rights law, competition law, and intellectual property law interact in the regulation of matters ranging from drug development to access to medicines.

Something similar occurs in the international legal order, although in this context it is more appropriate to refer to international normative regimes rather than to branches of the law. The notion of ‘international normative regime’ refers to groupings of norms of different bases. Although the term has a number of different meanings, it is particularly well suited for describing the global pharmaceutical regulation that focuses on the functional specialization of the norms comprising a regime.²

While the concepts international normative regime and branch of law are not synonymous, both are helpful for identifying rules related to pharmaceutical products in the international context as well as domestic fora. The notion of normative regime permits, for instance, the identification of norms related to pharmaceutical products that fall within the scope of the ‘human rights regime’ or the ‘international trade regime’. Although it is sometimes difficult to delimit with precision the content of some international regimes containing norms related to medicines - such as the international intellectual property regime or the international health regime - the notion of regime is still useful for explanatory purposes and to address the relationships between norms regulating the

same subject matter.

The observer’s perspective may be tuned so narrowly as to identify an international regime exclusively devoted to pharmaceutical products.³ Nevertheless, not concentrating all pharmaceuticals-related norms in a single regime but exploring the various regimes that interact and impact on medicines seems to better reflect international law and international relations. Gathering together all norms related to pharmaceutical products in a single regime does not correspond with the international governance of medicines. In daily reality, a plurality of organizations, officials and legal orders converge when regulating either pharmaceutical products or areas indirectly affecting medicines. Each organization has its principles, objectives and interests, which are subsequently applied to the rules adopted within each organization. Accordingly, it seems advisable to recognize the existing diversity and study the coexistence of norms that pertain to different regimes, sometimes even rules of private or semi-private origin, rather than treating all drug-related standards as belonging to a single products-based system. The central element for creating a regime comprising all international norms related to pharmaceuticals may be instead found in the legal interest protected by such norms and products, which is the protection of health. From that constitutive element, it will be possible to gather together all relevant norms and infer the relationships among them, as well as between that regime and other international legal regimes.

2. Harmonization by means of normative exportation

The development of norms on pharmaceutical products is notably less advanced in the international context than in national legal systems. This does not, however, impede observing an intense dynamism in international law, where progressive development and harmonization of medicines-related rules is taking place. This dynamism has been foreshadowed by decades of progressive harmonization, especially in the areas of technical standardization and

2 According to the International Law Commission the notion of regime refers to “whole fields of functional specialization, of diplomatic and academic expertise”. The International Law Commission has identified two other notions of international regime. According to the first, a regime is a “special set of secondary rules under the law of State responsibility that claims primacy to the general rules concerning consequences of a violation”, while pursuant to the second “interrelated wholes of primary and secondary rules, sometimes also referred to as “systems” or “subsystems” of rules that cover some particular problem differently from the way it would be covered under general law”. International Law Commission, *Fragmentation of International Law: Difficulties arising from the diversification and expansion of international law*, A/CN.4/L.682, 13 April 2006, par. 129.

3 While the analysis of the “fluid assemblage of laws that directly or indirectly govern the production and sale of pharmaceuticals” proposed by A. Zahl (2007) under the title *International Pharmaceutical Law and Practice* would seem to draw on norms of international nature, it is mainly a compendium of national law and analyses of local situations.

intellectual property. For a long time, issues as diverse as quality-related standards or pharmaceutical patents have been the object of attention of multilateral, regional and bilateral treaties. Although improvements also exist in other domains, the harmonization of the commercial aspects of medicines has progressed significantly faster than that of guarantees related to access to pharmaceutical products.

A relatively small number of countries have promoted greater normative integration in crucial economic areas through exporting their indigenous legal order. The terms 'legal transplantation' and 'exportation of the law' allude to a well-known legislative technique, vigorously promoted in areas related to pharmaceutical products such as technical standards and intellectual property law.⁴ While there are many possible paths for a country to export its law, multilateral, regional and bilateral 'law-transplanting international agreements' (YU, P., 2001, p. 1038) are ideal tools to export norms from one legal order to another.

The creation of the World Trade Organization (WTO) in 1994 decisively influenced the harmonization of important aspects of national pharmaceutical regulation. Other multilateral fora, particularly the World Health Organization and the United Nations human rights system, have also promoted such harmonization, although their enforcement mechanisms are much weaker. In contrast, WTO law has become the common denominator among WTO Members and the baseline for the adoption of new regulations, directly impacting on medicines-related norms of a very different nature. Some WTO agreements impacting on drug regulation were considered as concessions by developing countries to economically developed countries. This was particularly the case of

the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement codified the common denominator of the legislation of the countries of legal exportation, and became a powerful mechanism for transplanting European and American law (DREYFUSS, R., 2004, p. 21). However, the time elapsed since TRIPS was adopted, as well as the content of TRIPS-*plus* and TRIPS-*extra* agreements negotiated later on, seem to have made TRIPS an example of a 'balanced' legal text.

At the regional level, the regulation of numerous aspects of the pharmaceutical chain has been particularly intense in the European Union. Regional law contains very relevant statutes directly related to medicines, including areas such as intellectual property, the approval of medicines⁵ and transparency,⁶ among many others. Other regional integration areas have put special emphasis on particular branches of law. For instance, the Andean Community has developed a fairly complete intellectual property regime,⁷ while Central America has recently targeted the harmonization of technical standards for pharmaceutical products as an area of particular interest.⁸ Finally, some regional integration organizations, including ASEAN⁹ and Mercosur,¹⁰ have rather focused on specific aspects of drug regulation.

The relevance of legal transplantation for the promotion of normative harmonization is particularly evident in the bilateral context. Trade agreements are possibly the clearest example, since they frequently incorporate passages of the legislation of one of the trading partners. In this line, the United States Trade Act of 2002 announced that the purpose of the intellectual property chapters of free trade agreements (FTAs) is to enact a 'standard of (intellectual property) protection similar to that found in United States law'.¹¹ The European Commission has

4 Vid. *infra*. the goals announced in crucial texts such as the *US Trade and Competitiveness Promotion Act* of 2002, or the *EU Strategy for the Enforcement of Intellectual Property Rights*, adopted in 2004.

5 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, *OJ L 136, 30.4.2004, p. 34-57*.

6 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, *OJ L 040, 11/02/1989 P. 0008 - 0011*.

7 Comisión de la Comunidad Andina, DECISIÓN 486: Régimen Común sobre Propiedad Industrial, *Gaceta Oficial del Acuerdo de Cartagena*, n° 600 de 19 de septiembre de 2000.

8 Such as drugs stability, validation of analytical methods, and labeling. Vid. Reglamento Técnico Centroamericano TCA 11.01.04:10, *Productos Farmacéuticos. Estudios de Estabilidad de Medicamento para Uso Humano*; Reglamento Técnico Centroamericano, RTCA 11.03.39:06 *Productos Farmacéuticos. Reglamento de Validación de Métodos Analíticos para la Evaluación de la Calidad de los Medicamentos*; Reglamento Técnico Centroamericano N° RTCA 11.01.02:04 *Productos Farmacéuticos. Etiquetado de Productos Farmacéuticos para Uso Humano*.

9 S. Ratanwijitrasin, *Drug Regulation and Incentives for Innovation: The case of ASEAN*, WHO-CIPIH Studies, <http://www.who.int/intellectualproperty/studies/Drugregulationincentives.pdf> (accessed September 2012).

10 In topics such as medicines policy, storage, distribution, the fight against counterfeit products, and the entry or exit of products.

11 Bipartisan Trade Promotion Authority Act, 2002, SEC. 2102, 4i(II) H. R. 3009–64.

expressed its objectives in similar terms, saying that in the negotiation of FTAs, clauses on intellectual protection should provide, as far as possible, the same level of protection as that existing in the EU, taking into account the level of development of the countries concerned.¹²

The transplantation via the text of trade agreements is accompanied by actions undertaken through activities such as technical cooperation, dispute settlement and treaty implementation. Taken together, these sources and mechanisms have radically transformed medicines-related regulation in countries that import foreign regulations. While this has been especially noticeable in the intellectual property arena, it is also clear concerning technical standards. The consequences are multiple and extend to the economic and ethical domains, affecting issues as diverse as the control of medicine prices or the rules on good clinical practice.

3. Exporters and importers of norms

The exportation of norms relating to pharmaceutical products is actively promoted by a small group of countries and regional integration areas. This group comprises highly developed countries with very sophisticated pharmaceutical industrial sectors. The United States, the European Union, the European Free Trade Association (EFTA) and, more recently, Japan are actively promoting the adoption of increasingly demanding pharmaceutical standards, frequently those found in their own local legal orders.

Developing nations are net importers of technical standards and intellectual property norms, in particular the smaller or less-developed countries. In some instances, the less power these countries have, the more demanding are the obligations assumed. Take, for instance, the CAFTA-DR Agreement, concluded between Central American countries the Dominican Republic and the United States, or the treaty between the European Union and the Forum of the Caribbean Group of African, Caribbean and Pacific States (Cariforum). Both Central American and Caribbean countries accepted most of the European and American proposals regarding intellectual property regulation. The

consequence is that presently their regulations concerning the linkage or the extension of patent protection is even stricter than that accepted by more developed countries, such as Peru and Colombia, in their agreements with the United States and the European Union (GENOVESI, L.M., ROFFE, P., 2013a, pp. 76-77; VIVAS, D., 2013b, p. 405).

Developing countries are not the only importers of intellectual property and regulatory standards. For example, the Bolar exception is an institution that has transited from the United States, Canada and the legislation of the European Union to finally reach the national statutes of European countries (VIDAL-QUADRAS, M., 2013). In a different domain, South Korea and Australia have adopted the proposal made by the United States concerning the linkage between pharmaceutical market authorization and the patent status, a proposal modeled upon the original version found in the Hatch-Waxman Act. Likewise, South Korea has adopted much of European legislation on intellectual property enforcement, and has decided to protect pharmaceutical test data of biological and biotechnological medicinal products as required by the European Union.¹³ In fact, South Korea has even agreed to fine-tune its medicine price control regime in light of the demands of the United States and the European Union,¹⁴ which has been an area of controversy for more than a decade.

Independently of the level of development of countries, the power of the industrial sector demanding higher standards of intellectual property protection is a decisive factor in regulatory transfer. While this can be observed in several sectors, in the pharmaceutical domain it seems clear that the interests of both the United States and European innovative industries coincide in fostering the exportation of flexible standards to recognize patent rights while elevating the levels of protection for the rights awarded. However, the differences between intellectual property exporting countries are relevant in other areas, such as geographical indications or intellectual property rights enforcement, where different systems and rationales for protection have been developed.

Another explanation for the import of intellectual property

¹² EUROPEAN COMMISSION, 2010, p. 16

¹³ Footnote 18 of the intellectual property chapter of the agreement between the European Union and South Korea alludes to the definition of pharmaceutical product, in respect to which test data protection systems will apply, and sends the reader the Annex specifically devoted to pharmaceutical products. There, Article 6.1 of Annex 2-D mentions as pharmaceutical products both those of chemical synthesis, biologicals and biotechnologicals. This is also the case of the Agreement between the EU, Peru and Colombia, in footnote 72 to article 231.1.

¹⁴ *Vid.* in particular Article 3.4 of the Agreement between the European Union and South Korea.

norms from the United States and the European Union may be found in the value attributed to intellectual property in the context of the negotiated agreement. For developing countries, the overriding interest of concluding a trade treaty with the United States or the European Union is usually gaining access to affluent markets. In this regard, intellectual property is a relatively marginal area, and certainly not a priority for developing countries. While in the case of developed countries negotiating with the United States and the European Union the importance of the regulation of intellectual property is duly recognized, this area is treated as currency for more immediate and tangible benefits in other sectors (GEIST, M., 2003, D3).

A noticeable feature of legal transplantation of medicines-related norms is the lack of correlation between such transplantation and the economic and social context of the importing country. Countries as diverse as Morocco, South Korea, El Salvador, Canada, Colombia and Australia have imported exactly the same rules in their agreements with the European Union and the United States, particularly in the area of intellectual property. Institutions that in countries of legal exportation have kept pace with the industrial and scientific development - and that have been fine-tuned through administrative practice or judicial interpretation over time - are exported regardless the level of the development. Take, for instance, the case of product patent protection for pharmaceuticals. Several OECD member countries did not grant product patent protection for pharmaceuticals until the early nineties of the 20th century. This policy choice enabled some of those countries to develop competitive pharmaceutical industries that, with the passage of time, became innovative. Nevertheless, TRIPS obliged WTO Members to grant product patent protection without discrimination as to the field of technology. In practice, and even where transition periods were applicable, this implied that within a very reduced time-lapse the same level of protection would be available in developing and developed countries even if in many cases the latter had only recently started to grant such protection.

In another context, it must be noted that transplantation may take place in a competitive fashion, and the first country capable of transferring its own regulation will generally block the adoption of proposals with different

content originating from other commercial powers. This introduces an extra incentive to be the first to negotiate and to do so as quickly as possible. For instance, the European Union has been successful in having its civil enforcement *acquis* transplanted into the Cariforum agreement, and key features of its border measures regime transplanted into the treaty with South Korea. Similarly, the United States has managed to insert institutions such as the *linkage* in various Latin American countries, and has exported a regime that, unlike the European one, allows the registration of scent marks (BURRELL, R., WEATHERALL, K., 2008, p. 284). While in some cases the changes may be minor and therefore it is not decisive whether the European Union or the United States negotiate first - for instance, with regard to the US extension of patents *vis-à-vis* the EU granting of 'supplementary protection certificates' when the granting responds to delays in marketing authorization process¹⁵ - in other areas the differences may be relevant. In this regard, it must be noted that institutions such as the *linkage* or, to a lesser extent, the protection of pharmaceutical test data, are regulated differently in Europe and in the United States.

4. Means of legal exportation

The most important channel for fostering legal transplantation is the text of trade agreements itself. In fact, the United States and the European Union have made clear that exporting their local law is one of the purposes of these treaties.¹⁶ This is reflected both in the proposals they put forward to their partners and in the final text of the agreement. Local European and United States law is also identified as the limit of new agreements, when European and North-American institutions and trade diplomats declare that such agreements will not, in any case, exceed the content of their local law (EUROPEAN COMM'N, 2008, p. 2; USTR, 2008, p. 4). This was clearly the case of the Anti-Counterfeiting Trade Agreement (ACTA). In order to soften the strong reaction against ACTA, European and North-American officials repetitively declared that the treaty would not exceed local standards.

Multilateral and plurilateral agreements are also channels of legal exportation. Fifteen years after TRIPS, ACTA and the Trans-Pacific Partnership Agreement have intended to transfer at the plurilateral level the content of bilateral

15 Although these institutions greatly coincide, they are different and when the European Union has tried to export SPC has found that the US had already achieved to have patent extensions recognized. It must be noted that SPC are not granted to respond to delays in the granting of patents, just to the delays in the marketing authorization process.

16 *Vid. supra.* footnote 10 and EUROPEAN COMMISSION, 2010, p. 16.

agreements previously agreed by the United States and the European Union. This has been noticed with respect to the exportation of the Digital Millennium Copyright Act (HINZE, G., 2009) as well as with respect to the exportation of the United States system of damages in cases of intellectual property infringement (GEIST, M., 2012, p. 37).

Legal transplantation is promoted through diverse channels and by means of several mechanisms, in addition to the text of the agreement. Among these are the implementation process of the agreement, the dispute settlement system, activities in the area of technical cooperation, the creation of *ad hoc* bodies in specific areas, the setting up of monitoring mechanisms non-related to the treaty, the relevance of international mechanisms of certification of the national legislation, and the commitment included in some treaties to adopt specific rules in the future. Exportation may also occur due to other reasons, such as the mimesis between administrative bodies following cooperation, as has happened with respect to patentability standards.

4.1 The implementation process

The implementation process may have an importance comparable to that of the negotiation of the agreement (ROFFE, P., GENOVESI, L.M., 2009, p. 12). To start with, implementation merely limited to the transcription of the text of the treaty is problematic, since the intellectual property chapter is often incomplete and unbalanced. On the other hand, implementation may sometimes entail the renegotiation of the treaty, and limit options that are legitimate according to the treaty but deemed unacceptable by the counterpart. In fact, when implementing intellectual property chapters contained in trade agreements countries do not generally take advantage of all the options available in the treaty. While this may respond to a sovereign decision of the country, it may also arise from the characteristics of the implementation process. This is usually observed with respect to the implementation of exceptions or flexible interpretations of the treaty commitments (BURRELL, R., WEATHERALL, K., 2008, p. 274).

In the case of agreements concluded by the United

States, the United States Trade Representative's (USTR) oversees the normative implementation both through informal contacts and the inter-exchange of diplomatic notes. The demands of the USTR are persuasive and if the counterpart does not accept them, the treaty will probably not enter into force for the United States. The legal basis for the process of 'certification' of conformity with US implementation of the agreement is found in the text of many agreements itself. The agreements concluded with the United States usually contain a provision stating that "At such time as the President determines that (*name of the country*) has taken measures necessary to comply with those provisions of the Agreement that are to take effect on the date on which the Agreement enters into force, the President is authorized to exchange notes with the Government of (*name of the country*) providing for the entry into force, on or after (*date*), of the Agreement with respect to the United States."¹⁷

This powerful tool is usually employed in a context of limited information to external stakeholders, since third parties rarely have access to the details of the implementation process. In fact, transparency is even more limited in that context than during the negotiating phase of the treaty. Beyond some mid-range officials discussing technical aspects of great practical relevance, and a limited number of companies, the content of the negotiations in the implementation process is often unknown, which naturally facilitates exerting pressure and even putting forward new demands.

4.2 Dispute Settlement

The dispute settlement mechanism provided for interstate differences in trade agreements is an additional channel to continue the exportation of the law. The usually *ad-hoc* appointed bodies may have competence to rule on 'any dispute concerning the interpretation and application of this Agreement, in particular when one of the Parties considers that a measure taken by another Party is or could be inconsistent with its obligations under this Agreement'.¹⁸

Some treaties foresee special rules and, arguably, dispute settlement mechanisms for intellectual property

17 For instance, United States-Panama Trade Promotion Agreement Implementation Act, Section 101 (b); 102(b) of the United States-Peru Trade Promotion Agreement.

18 Article 299 of the Agreement between Peru, Colombia and the European Union.

disputes.¹⁹ Moreover, in some cases the dispute settlement system is entrusted to solve disputes on matters not yet agreed in the multilateral context. This is, for example, the case in disputes concerning the nullification and impairment of benefits, even if the cause of such nullification and impairment is not contrary to the agreement.²⁰ This naturally opens an uncertain scenario and a chilling effect with regard to what measures can be adopted in the regulatory and intellectual property domains without fearing retaliation under the dispute settlement system of the treaty.

In addition to deterrence, the dispute settlement system can be also instrumental to exert a persistent pressure with regards the actions that can be undertaken by the other party. In this regard, the European Union has stated that institutional mechanisms of agreements regulating intellectual property²¹ ‘can be used to monitor and discuss legislation and enforcement problems from a very early stage’ (EUROPEAN COMMISSION, 2005, p. 5). From the perspective of countries importing intellectual property standards, this approach should be viewed with caution, since it can be a channel to go beyond the provisions of the treaty. Indeed, the dispute settlement mechanism can be instrumental to reintroducing old aspirations or insisting on the primacy of a particular interpretation that does not fit in the text of the agreement.

The existence of a dispute settlement system in free trade agreements helps understand another phenomenon. It is often questioned why each and every commitment already made by one or both of the parties in treaties with other states is reiterated. The fact that the implementation of international treaties generally requires the adoption of internal rules, added to the national treatment principle, would seem enough to extend the benefits deriving from intellectual property provisions contained therein to the nationals of any other country. In the same line, treaties frequently include a commitment to ratify international treaties to which parties are already party, as is the case of numerous WIPO treaties.

A plausible explanation of such reiteration can be found in the dispute resolution system. Given the link established between the material area covered by the treaty and the dispute settlement mechanism, parties may have an interest in repeating substantive law and including the commitment to subscribe treaties already in force. This will enable the activation of the bilateral dispute settlement system in areas where it would be otherwise impossible, and allow obtaining the tangible and intangible benefits that this entails. Similarly, the obligation contained in trade agreements to ratify multilateral WIPO treaties opens the door to submitting commitments acquired in the multilateral context to the bilateral dispute settlement regime. Both the alleged breaches of the treaty and the impairing of the expected benefits, even without infringement, may then be considered by the dispute settlement body of the bilateral treaty. The importance of the dispute settlement mechanism is evidenced by the fact that sometimes, even by means of side letters or special statements accompanying the agreements, it is stated that intellectual property areas not regulated by the agreement shall be brought to the dispute settlement body of the treaty.²²

4.3 Cooperation

Another institutional channel for promoting the adoption of legal standards related to pharmaceutical products that reflect specific policy options is the commitment to cooperate, both in the field of intellectual property and with respect to technical standards.

Numerous intellectual property chapters contained in FTAs include provisions on cooperation and exchange of good practices. These activities are usually designed by the countries exporting their intellectual property standards (DREYFUSS, 2004, p. 21; BLAKENEY, M., MENGISTIE, G. 2011, p. 75), something that can be subsequently observed in the content of the cooperation. For instance, the US Intellectual Property Enforcement Coordinator reports that “in October 2011, Ukraine adopted a new law making the manufacture

19 This is for instance the case of the decision concerning the registry or protection of a geographical indication under Article 250 of the Agreement between Central America and the European Union.

20 Article 21.2(c) of the Trade Promotion Agreement between Peru and the United States establishes that the dispute settlement provisions will apply when a party considers that “a benefit the Party could reasonably have expected to accrue to it under Chapter Two (National Treatment and Market Access for Goods), Three (Textiles and Apparel), Four (Rules of Origin and Origin Procedures), Nine (Government Procurement), Eleven (Cross-Border Trade in Services), or Sixteen (Intellectual Property Rights) is being nullified or impaired as a result of a measure of another Party that is not inconsistent with this Agreement.”

21 Although these mechanisms are not dispute settlement bodies, they fulfil functions related with the monitoring of the agreement. They may also act as a forum to provide an amicable solution to a dispute concerning the meaning of the obligations of the parties pursuant to the agreement.

22 *Vid.* Agreement between the European Union and Central America, *Declaration of the EU Party on Data Protection of Certain regulated Products*. See also US FTAs.

or distribution of counterfeit medicines a crime. This legislation resulted from a legislative recommendation put forward at a May 2011 workshop on counterfeit medicines put on by U.S. Embassy Kyiv and the U.S. Commercial Law Development Program” (INTELLECTUAL PROPERTY ENFORCEMENT COORDINATOR, 2011, p. 27).

With regard to the regulatory domain, parties frequently include an obligation to foster initiatives concerning trade facilitation related to technical standards, such as cooperation in regulatory affairs²³ or the obligation to notify the trading partner of the detention of goods that did not meet the standards set up in technical regulations.²⁴ This is another front for promoting the harmonization of the regulatory framework affecting pharmaceuticals. Although variations do exist, the “demandeurs” of high standards of surveillance and control often coincide with those demanding increased levels of intellectual property protection.

This influence is translated to the institutional level through the creation of sub-committees on intellectual property rights in FTAs. The powers of these sub-committees are more or less forceful depending on the agreement but, in general, these are fora for dialogue and monitoring of the issues raised in the treaties.

More recently, some treaties have set up bodies specifically dealing with medicines regulation and policy. This is the case of the agreements between the European Union and South Korea, the United States and South Korea and also proposed in the Trans-Pacific Partnership Agreement. The agreement between the United States and South Korea envisages the establishment of a dedicated body to ‘maintain an ongoing dialogue about health issues and drug regulation’.²⁵ While the agreement between the European Union and South Korea specifically states that the group should be composed of public servants working in the pharmaceutical field, the agreement between the United States and South Korea provides

that an officer of the commercial area will co-chair the medicines group.²⁶

4.4 Monitoring outside the dispute settlement system

Both the European Union and the United States have set up their own mechanisms for monitoring unilaterally the policy and practice of other countries with regard to medicines in areas such as intellectual property and technical standards.

Processes such as United States Section 301 of the Omnibus Trade and Competitiveness Act, or the mechanism set up in the European Regulation 3286/94 - both cases are triggered by information provided by the industry - are important channels to put pressure on the trading partner’s legislation and administrative practices. In fact, as the USTR points out, compliance with the TRIPS Agreement is not an obstacle to exert pressure on trading partners.²⁷

The implementation of Section 301 has resulted in the withdrawal of development aid and the suspension of trade benefits in response to the non-modification of specific rules impacting on medicines. The most dramatic case concerns measures adopted against South Africa in 1997/98 for its parallel importation regime of HIV/AIDS medicines (KLUG, H., 2012, p. 168). Presently, virtually all of the thirteen Latin American countries that appear in the 2013 *Special 301 Report* are included due to their test data protection regimes and the United States’ disagreement with respect to the system they chose to implement the linkage between market authorization and patent status. In its turn, the European Regulation 3286/94 has enabled the European Union to file - at the request of the European Federation of Pharmaceutical Industries and Associations, an umbrella organization of the pharmaceutical innovative industry - a case against South Korea based on a disagreement with the system set up by that country to control drug prices (EUROPEAN COMMISSION DG TRADE, 2012).

23 “Such initiatives may include cooperation on regulatory issues, such as convergence, alignment with international standards, reliance on a supplier’s declaration of conformity, the recognition and acceptance of the results of conformity assessment procedures, and the use of accreditation to qualify conformity assessment bodies”. Article 7.3.1 of the Trade Promotion Agreement between Colombia and the United States.

24 Article 7.3.3 of the Trade Promotion Agreement between Colombia and the United States.

25 Article 15.3.1 of the text of the treaty and Article 5 of the Annex 2-D of the Agreement between South Korea and the European Union.

26 *Ibid.*

27 For the USTR, non-reasonable acts or policies include those impeding the effective protection of intellectual “notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 3511 (d)(15) of this title”. 19 U.S.C. § 2411(d)(3)(B)(i)(II) (2006).

4.5 Certification systems

Regulatory harmonization does not take place just in the bilateral context, but also through multilateral channels. In this sense, international standardization of technical rules pertaining to the pharmaceutical domain may be a route to export technical standards developed by a small group of nations that regularly participate in the preparation of international standards of reference.

In this case exportation takes place indirectly since, as established by the WTO Agreement on Technical Barriers to Trade, national technical standards are validated if they are in accordance with international standards of reference. However, regulations and standards may be intentionally or unintentionally designed in a manner that, even if they are adopted by international standardization bodies, can become an unjustified barrier to trade or used in a manner affecting competition (SEUBA, X., VIVAS, D., 2013a, p. 273).

4.6 Commitment to adopt or fulfill specific norms in the future

Another channel to maintain normative influence on trading partners involves inserting into international treaties the obligation to adopt specific norms in the future, the obligation to consult and negotiate new pharmaceutical norms, and the commitment to amend pharmaceutical norms in conformity with international standards influenced by the exporting country. The examples are numerous.

In the intellectual property context, under the association agreement between Cariforum and the European Union the 'Cariforum States agree to collaborate to expand' the scope of border measures so that goods infringing all intellectual property rights are covered.²⁸ Examples also exist concerning technical regulations. For instance, the treaty between the United States and South Korea includes a commitment to negotiate an agreement on good manufacturing practices of pharmaceutical products, good laboratory practices, and the approval of generic drugs.²⁹ In the same vein, the agreement between South Korea and the European Union requires South Korea to review

its rules and practices concerning the control of medicine prices, as well as to review technical regulations.³⁰ Tellingly, the agreement between Central America and the European Union provides that 'where international standards have not been used as a basis, (it is necessary) to explain, upon request of the other Party, the reasons why such standards have been judged inappropriate or ineffective for the aim being pursued'.³¹

4.7 Mimesis

Sometimes the transplantation of rules and practices is undertaken by administrative bodies, such as intellectual property or health monitoring agencies. Such transplantation exceeds the activity of bodies having the power to represent the State internationally and reaches other layers of the public administration. This phenomenon can be explained as a result of the interaction of such agencies with foreign counterparts, and also because management decisions reflect the views of their governing bodies.

The mimesis takes place both between national intellectual property offices and drug regulatory agencies. For example, the European Patent Office (EPO) and the United Kingdom Intellectual Property Office (UKIPO) have imported criteria developed by the United States Patent and Trademark Office (USPTO). As a result of the mimesis, the EPO and the UKIPO have imported the standard of specific, substantial, and credible utility, thus altering the standard requiring industrial application. As has been noted, the transplantation of this standard puts the British and European patent offices in the center of the legal change and design of the patentability policy, when these offices have been neither entitled nor conceived for such purpose (THAMBISSETTY, S., 2008, p. 1).

5. Conflictive aspects of the exportation of norms

5.1 The viability of legal transplants

Although the importation of norms is rather frequent, several reasons have made legal transplantation a controversial legislative practice. The central aspect of the

28 Footnote 2(c) of Article 163.

29 *Vid.* Article 5.6.1 Chapter Five of the Agreement between United States and South Korea.

30 *Vid.* South Korea Annex 2-D, Art. 3.4.1.

31 Article 129(a).

debate over transplantation is whether the transplanted norms can be accommodated and fully functional in the new environment. In this debate Watson and Legrand represent the opposite poles: while the former has held that transplantation occurs just naturally, the latter has strongly opposed the viability of legal transplants. (WATSON, A., 1974; LEGRAND, P., 1997).

Another aspect making transplantation controversial has to do with whether transplantation is an interesting option from a social and economic point of view. The socioeconomic situation in exporting and importing countries may diverge greatly, and these differences may ultimately have even more importance than those relating to the legal system. This is a particularly significant issue in agreements between countries with differing levels of development, in which less-developed countries adopt institutions that needed decades to mature in the exporting countries.

In fact, and for a number of reasons, the controversial nature of some institutions can be anticipated even before their importation. For instance, the transplanted norms may be particularly complex and thus very difficult to implement, or they can conflict with the existing local regime or other international obligations, or they may still be controversial in the country of exportation.

Legal transplantation may give rise to unbalanced and dysfunctional intellectual property regimes, as often happens when exportation is promoted in free trade agreements. It is often difficult to assess whether specific institutions are appropriate for a particular country or purpose, since only isolated excerpts of the original version of the institution have been transferred to the importing country, and always in the same direction, i.e. increasing the level of intellectual property protection (SEUBA, X., 2013a).

5.2 Conflicts of norms

Countries may have accepted the incorporation of norms originating from very different national legal orders into their national law. The obligations undertaken are not necessarily coincidental or shared by the exporters of the norms, and sometimes there is disagreement even regarding the acceptability of the exported institutions.

An example of conflicting importation relates to the battle between the European Union and the United States over the model of protection for geographical indications, either based on the protection of trademarks - as promoted by the United States - or on a particular system of protection - as advocated by the European Union. Both have tried to export their systems into the national law of their trading partners, frequently targeting the very same countries. As a consequence, the texts of those countries' agreements with either major commercial power reflect the fact that only by infringing one agreement will it be possible to fulfill the other. Take, for instance, the agreement between the European Union and Cariforum, which establishes that parties 'shall provide for the fair use of descriptive terms, including geographical indications, as a limited exception to the rights conferred by a trade mark'.³² In stark contrast, the treaty between CAFTA-DR and the United States establishes that parties 'shall provide that the owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs, including geographical indications, for goods or services that are related to those goods or services in respect of which the owner's trademark is registered, where such use would result in a likelihood of confusion'. The treaty also states that 'in case of the use of an identical sign, including a geographical indication, for identical goods or services, a likelihood of confusion shall be presumed'.³³ It is difficult to ascertain what the content in the case of the Dominican Republic law should be, as the country has concluded agreements with both Cariforum and the United States.

Another example of conflict and confusion relates to patentability criteria. The United States promotes the 'utility' standard, and proposes assimilating the 'industrial applicability' standard to that of 'utility'. It does not say so in these terms, but the consequence of affirming the equivalence of both standards is, precisely, a more flexible 'industrial application' standard. This relaxation not only conflicts with the content of the legal order of many the United States' trading partners, but also with previous commitments made by of some of those partners, as well as with the standard required by the European Union. Regardless of this, the United States seeks considering synonymous both standards, which is only possible if some of the limits established

32 Article 144F.

33 Article 15.2.3.

by the industrial applicability criteria are neglected and broader patentability is accepted. In effect, 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 criteria³⁴ (GENOVESI, L.M., 2013, p. 331).

5.3 Exporting controversy, limiting the future

Some of the exported norms are conflictive even in the country of exportation. Controversy arises from the fact that the transplanted rules are either legally 'shaky' (YU, P., 2004, p. 396) or because they regulate sensitive topics. This has led some scholars to underline that 'controversy is exported' (BURRELL, R., WEATHERALL, K., 2008, p. 259). Examples include specific intellectual property categories, in particular copyright (YU, P., 2011, p. 1037) and intellectual property enforcement norms, such as criminal enforcement (SEUBA, X., 2009, pp. 47-49; GEIGER, C., 2012, p. 46).

European intellectual property border enforcement provisions provide a good example of 'exportation of controversy'. The possibility of controlling the transit of patent-protected products and assessing the legality of suspect products pursuant to local law - i.e. whether such products would be infringing in the country of transit - has been challenged in the WTO dispute settlement system. The complainants alleged violations of fundamental principles of both the intellectual property regime and the multilateral trading system. The controversial European legislation has nevertheless been exported to South Korea,³⁵ and the agreement between the European Union and Cariforum includes a commitment to implement it in the future.³⁶ This practice is also actively promoted by the European Union to other trading partners.

The internationalization of weak norms does not seem a great idea for either the importers or the exporters. It implies limiting the possibility of amending the

transplanted legislation or adopting different norms in the future in both countries (YU, P., 2011, p. 1066). This limitation creates a particularly problematic scenario if transplanted legislation takes place in the midst of a controversy in the country of exportation. There are numerous examples of such situations, both with regard to intellectual property categories unrelated to pharmaceutical products³⁷ and institutions directly linked to pharmaceuticals. For instance, the agreements between the United States, Australia, Morocco and Singapore discard the international exhaustion of intellectual property rights, affirming that placing the product in a foreign market does not prevent the rightholder from controlling importation. It has been pointed out that 'compliance with the FTA intellectual property provisions may be an issue should Congress attempt to alter U.S. law in the future' (THOMAS, J. R., 2005, p. 19).

In a related fashion, reference must be made to conflicts arising from the exportation of complex institutions. Mariano Genovesi and Pedro Roffe have underlined the difficulties inherent to the implementation of the *linkage* in the United States. Linking market authorization for medicines and their patent status has proved complex even in the United States where authorities are strongly trained and sophisticated, and measures to mitigate the detrimental consequences have been adopted (GENOVESI, L. M., ROFFE, P., 2013, p. 107). Moreover, imported norms may clash with previously existing national norms, as illustrated by the conflict between the right to receive and impart information and FTA provisions concerning pharmaceutical test data protection (PÉREZ, J-C., 2013, pp. 243-250).

5.4 Impact on regional law and multilateral trade rules

Legal transplanted legislation may have side-effects on regional law. Sometimes, these may be positive and favor regional integration, for instance when new agreements require the harmonization of pharmaceutical technical standards at the regional level or the creation of centralized mechanisms for the authorization of medicinal products. In other instances, however, legal transplanted legislation may provoke a weakening of both regional law and regional

34 Vid. EPO Decision T74/93; OMPI, *Requisitos de 'aplicación industrial' y 'utilidad': puntos comunes y diferencias*, SCP 9/5, 2003, p. 4.

35 Article 10.67.1.

36 In Article 163.1, on border measures, it is said that "The EC Party and the Signatory CARIFORUM States agree to collaborate to expand the scope of this definition to cover goods infringing all intellectual property rights."

37 While the United States was exporting its copyright rules in the digital environment, local courts were still discussing important aspects of anti-circumvention measures. Vid. *Chamberlain Group, Inc. v. Skylink Tech., Inc.* 381 F.3d 1178, 1204 (Fed. Cir. 2004).

integration. Although it is legitimate to question whether legal transplantation occurs because regional law is weak or, on the contrary, legal transplantation debilitates regional law, the fact is that the exportation of law through bilateral agreements has visibly debilitated regional integration.

A good example of such a deleterious effect can be found in the intellectual property law of the Andean Community. While tensions generated by the test data protection system promoted in FTAs motivated the adoption of an amendment of regional law so as to allow countries to establish differentiated rules, the current conflict concerns the relationship between 'industrial application' and 'utility' patentability standards. The assimilation of industrial application to utility that seems to prevail in US FTAs would imply a breach of the Andean law - which requires industrial application - as well as the agreement between some Andean countries and EFTA, which also mandates industrial application. Mariano Genovesi proposes avoiding such a conflict through exploring hermeneutic options. He concludes that the only way to reconcile the Andean norm with that established in PTAs is to consider the latter provision optional, thus allowing trading partners to maintain their respective criteria (GENOVESI, L.M., 2013, pp. 381-382).

The transplantation of the law and technical standards of a reduced number of countries may also cause problems with respect to the fulfillment of multilateral obligations undertaken by countries importing legal standards. This is the case of obligations deriving from the multilateral human rights and environmental regimes, which may conflict with obligations in new bilateral treaties. Concerning the human rights regime, problems related to access to products deriving from new intellectual property commitments have been extensively explored by scholars and human rights bodies. A relatively less researched area concerns the protection of pharmaceutical test data, which may generate problems with human rights law, consumer law and ethics (SEUBA, X., 2013b, p. 171; PÉREZ, J-C., 217). In the environmental context, a new angle of study on the intersection between intellectual property law and international environmental law concerns the relationship between prior and informed consent and patent nullity procedures (VIVAS, D., 2013, p. 396).

6. Partial exportation

From the previous sections it could be inferred that

exporting countries' intention is to export their legal system into other national legal orders. In fact, what it is frequently proposed is only a partial transplantation, reflecting content that is generally unbalanced compared to the original legal order. There are two types of partial exportation. The first relates to the partial exportation in terms of legal regimes. In this sense, while intellectual property law is a priority in all preferential trade agreements, competition law receives only marginal attention or no attention at all. The other type of partial exportation has to do with the content of the exported institutions, in the sense that it is common to export the obligations favoring the rightholder but not the checks and balances embedded in the legal systems of exporting countries.

6.1 Legal branches prioritized

The first partial transplantation, of great relevance in systemic terms, is that occurring when certain branches of the legal order are prioritized in relation to others that happen to be specially connected. This is the case of competition law and intellectual property law, which are intimately related in national legal orders. This relationship is rather marginal in the intellectual property chapters of FTAs, which generally focus on the promotion and strengthening of the market power of intellectual property rightholders. In those chapters, competition law is marginalized or simply not mentioned at all (GENOVESI, L. M., ROFFE, P, 2013b, p. 484).

This is indeed a significant gap, firstly because of the intrinsic relevance of competition law. As the European Commission has stated, 'intellectual property rights promote dynamic competition by encouraging undertakings to invest in developing new or improved products and processes. So does competition by putting pressure on undertakings to innovate. Therefore, both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof' (EUROPEAN COMMISSION, 2004, p. 101). On the other hand, the development of competition law has been largely negligible in countries that now import intellectual property norms, a logical feature of nations not having developed highly demanding intellectual property systems. Now these countries have strengthened intellectual property norms in circumstances totally different from those of developed nations with 'mature legal systems of corrective interventions' capable of addressing situations where 'the exercise of IPRs threatens

to be anticompetitive or excessively costly in social terms' (MASKUS, K., 2012, p. 237).

6.2 Incomplete institutions

The partial transplantation of intellectual property norms has resulted in the adoption of norms protecting the rights of rightholders while neglecting the interests of competitors and users of protected works or inventions. The perplexing effect of this practice is that countries importing norms have, in some areas, developed a regime that is stricter than the original source. If implemented as enshrined in the corresponding treaty, the regime will probably be anticompetitive and dysfunctional, and may even generate problems from the point of view of the protection of fundamental rights.

A good example concerns the partial transplantation of the US Hatch-Waxman Act, which created a system aimed at promoting innovation and competition in the pharmaceutical market by means of a delicate system of checks and balances. The Hatch-Waxman Act introduced a fairly complete system to stimulate innovation and competition, and incorporated legal institutions such as an abridged process to obtain market authorization, the extension of the period of patent protection to compensate for the time consumed in the marketing approval process, the Bolar exception, the 180 days exclusivity to challenge patent validity, and the *linkage* between patents and market authorization.

While in third-generation FTAs the *linkage* has become optional, this was not the case in earlier treaties concluded between the United States and Central and South American states or Middle Eastern countries. The related provision that enshrines the *linkage* in United States treaties contains two of the obligations listed above: the prohibition to grant marketing authorization if the product is protected by a patent and the obligation of pharmaceutical authorities to inform the rightholder on the application for market authorization. However, no mention is made of several institutions that promote competition in the US, such as the possibility to challenge a patent and the granting of advantages for whoever successfully challenges a patent in force or demonstrates that the patent is not infringed (GENOVESI, L. M., ROFFE, P., 2013a, p. 82).³⁸

Partial transplantation is also manifest with regard to intellectual property enforcement. While the European Union exports those aspects of its enforcement directive and regulations that benefit the rightholder, provisions concerning the rights of competitors or the interests of the users are not included in its treaty proposals to trading partners. Measures for the preservation of evidence are a telling example. These measures fundamentally include a description of goods and the seizure of the infringing goods and, sometimes, also of the materials used to produce those goods. These *ex parte* measures are subject to the presentation of reasonably available evidence about the infringement and must be prompt and effective and may be ordered *inaudita parte*. The European legislation includes some additional guarantees to avoid abuse and preserve proportionality. However, none of the following European parameters are present in the agreements promoted by the European Union: i) to give notice immediately after the execution of the measure; ii) the right to ask for a review of the measure; iii) the revocation of the measure in case proceedings leading to a decision are not instituted within a reasonable period of time; iv) the lodging by the applicant of an adequate security or an equivalent assurance; v) the award of compensation in cases of undeserved or unjustified measures.

The origin of unbalanced norms is not to be found only in the text of international agreements. Internal decisions play an important role. Policy choices with regard to patentability standards has in some instances resulted in very permissible texts,³⁹ which have made obligatory pro-patentability standards that were optional in the original treaty while neglecting most of the requirements recognized in the country of origin. This implies that in some countries patent examiners would implement flexible standards originating in other without taking into consideration the experience and doctrinal practices developed in the countries of origin (GENOVESI, L.M, 2013, p 375).

7. The exportation of a particular model

Different reasons explain why only a reduced number of countries export their law. Some of the reasons have to do with the characteristics of the field of regulation, which relate to the sophistication of the pharmaceutical sector

³⁸ This appears however to have been taken into account in recent proposals for the Trans-Pacific Partnership Agreement.

³⁹ A case in point is the Colombian Instructivo Examen de Solicitudes de Patente de Invención y Modelo de Utilidad, Memorando 12-2282-1-1, 8 February 2012, adopted by Jefe de la Oficina Asesora de Planeación de la Superintendencia de Industria y Comercio.

in the countries of legal exportation. Other reasons can be found in the asymmetry of power between exporting and importing countries, the characteristics of the international negotiating process, and the influence of industry on the content of the norms.

7.1 Characteristics of the object of regulation

The mature and sophisticated pharmaceutical sectors in norms-exporting countries permit understanding the credit given to these countries to propose the exportation of their own norms. For the importers of norms, the transplantation of the legal framework of a robust market of products of great technical and scientific complexity seems to be a guarantee of success, in the sense that replicating the model should probably allow avoiding errors and move faster towards full pharmaceutical industrial development.

The normative *acquis* of the United States, the European Union, EFTA, Japan and similar countries and organizations has become a reference for several countries and international organizations. The examples are numerous, even in the area of technical standards. The most recent case can be found in the European regulation of biosimilar drugs, which has become the reference either to follow or to modify in the context of other national and international regulations on biosimilars since the European basic norm was adopted in 2004.

The influence of developed countries to transplant their respective statutes varies depending on the legal branches under consideration. In this sense - notwithstanding the fact that the technical standards and intellectual property regulation of the both the European Union and the United States law have become the models to follow - the reasons and the ultimate justification vary in each legal area.

With regard to technical standards, a parallel is often drawn between the level of economic development and the intensity of regulatory requirements. Although this is not entirely accurate - due to the existence of important differences between countries of similar (high) level of development, and climatic and genetic specificities often make it necessary to adopt different norms in different countries - it is generally correct to affirm that the most developed pharmaceutical markets have also adopted more demanding standards. While highly demanding

technical standards may pursue different objectives than just guaranteeing quality, security and efficacy (even anticompetitive objectives), in general the sophistication and level of exigency of the norms correspond to higher levels of drug quality. This is why the norms proposed by the United States Food and Drug Administration, the European Medicines Agency and the Japanese Pharmaceutical and Medical Devices Agency are generally followed, as happens in the global context with the guidelines adopted by the International Conference on Harmonization of Technical Requirements for Registration of Medicines for Human Use (ICH). Distinguishing what is the content of the norms that can be shared by all states and which are the norms indicated for a limited number of countries, or that should even be discarded, is a task that should be carried out by the WHO. This is indeed a much more modest activity than that identified in the WHO Constitution: 'to act as the directing and coordinating authority on international health work' and 'to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products'.⁴⁰ Why the ICH has occupied that central space is a question worth posing in light of the complexities and vital interests affected by pharmaceutical regulation.

Intellectual property norms have a different background and rationale compared to technical standards. Despite this, the standard description of intellectual property norms is similar to that offered above regarding technical standards, i.e. economic and social development would match with stricter levels of intellectual property protection. This, however, is a misleading statement, since it only takes into account the final picture, which effectively reflects that countries with high levels of development generally have strong systems of intellectual property protection. Nevertheless, that final image does not explain how the process of industrial development in presently developed countries occurred, and how intellectual property protection varied and accompanied such a process. In the patents area, high standards of protection, including product patent protection, were adopted only after the establishment of a strong pharmaceutical sector.

7.2 The asymmetries between exporting and importing countries

Transplantation of intellectual property law and technical

⁴⁰ WHO Constitution Preamble (a) (u).

standards is closely related to currently existing power asymmetries between countries exporting and importing norms. While power asymmetry can be easily identified in the area of intellectual property law, technical standards are not immune to it. A signal of how decisive such power relations can be is the point of departure of the negotiations for concluding FTAs, which changes radically depending on the negotiating parties.

The European Union usually proposes a comprehensive intellectual property chapter to its trading partners, which includes substantive, institutional and enforcement-related norms. In the case of countries with less to offer to the European Union, or with little bargaining power, that point of departure is not questioned and the European proposal is likely to become the final text after the introduction of some relatively minor changes probably reducing the level of exigency. This pattern contrasts greatly with recent negotiating experiences between the European Union and Mercosur, as well as between the European Union and India, both of which are obviously powerful trading partners.

The European Union delivered to Mercosur the same text it commonly proposes to trading partners with minor commercial power. However, in contrast to the reaction of other countries or regional organizations, Mercosur replied to the proposal with an entirely new text, which adopted a totally different tone from that of the original text. The Mercosur proposal was structured taking into consideration very basic elements: the WIPO Development Agenda, the public-interest provisions of the TRIPS Agreement, the importance of flexibility in the implementation phase, and the need to assess the impact that any new regulation would have on access to public goods. While it remains to be seen what the final text of an eventual agreement between the European Union and Mercosur will be, the position of Mercosur differs radically from that of previous European trading partners, effectively indicating the relevance of the South American bloc's bargaining power.

7.3 The characteristics of the international negotiating process

Numerous norms are transplanted from one country to another via commercial agreements. These are treaties that commonly tackle a large number of topics, including areas as different as tariffs, services or investment. Among the diverse topics, intellectual property and technical

barriers to trade are the most closely related to the regulation of pharmaceutical products. While other areas, such as tariffs, do indeed impact on access, they are not meant to introduce relevant changes in local regulation.

The aspiration of the parties to a commercial treaty is to reach an overall balance in the agreement. Negotiating states do not expect all their demands to be recognized in the treaty. This implies that countries will reach interesting results in some areas, while making concessions in others. This *quid pro quo* is exemplified by the technique of the 'package deal', which establishes a quasi-contractual relationship and implies that in some areas concessions are made while in others benefits are obtained, arriving to a positive overall equilibrium of advantages and concessions.

In the internal domain, the acceptability of the 'package deal' should imply transferring rents from sectors that have benefited to those that may have been negatively affected. This is particularly the case of the health sector and other areas closely related to the protection of fundamental rights. However, even when this transfer of rents occurs, the overall outcome may be unsatisfactory. In modern trade treaties the 'package deal' implies accepting compromises that are not optimum for an entire legal branch, such as intellectual property, in exchange of trade concessions. This is quite different from accepting a trade-off in the tariffs context. Gaining benefits in certain economic sectors while neglecting key policy areas may be logical in the short term, but not in the long run. This is particularly true in the pharmaceutical sector where benefits are typically reaped in the mid- to long-term.

The 'package deal' implies that parties approach intellectual property negotiations as a bargaining process, haggling with their counterparts rather than focusing on a positive contribution to the construction of a coherent intellectual property legal regime. In the course of the negotiations, parties may exaggerate or feign interest in compromises that are not really a priority for them, with the objective to reach more moderate goals. Treaty proposals may also include demands currently debated domestically, or demands that may not even be acceptable under the local legislation of the proponent. In response to this approach and technique, the extension of the principle of good faith in the negotiations of the treaty has been vindicated. This principle is, however, customarily constrained to the implementation phase of the treaties (SEUBA, X., 2013b).

The last aspect of the negotiating process concerns the attention paid and the relevance given to stakeholders having different interests in the pharmaceutical sector. Commercial agreements are usually the outcome of numerous negotiation rounds dealing with different subjects. Each area is negotiated at a particular negotiation table, made up of public officials specialized in that particular domain. Sometimes, representatives of innovator and generic industries are present as observers, and are briefed on the evolution of the negotiations. Discussions aimed at persuading the other party are held and the content of the negotiating text is successively amended. An aspect usually overlooked is that, while developing countries confer with representatives of both sectors, as well as with representatives of the civil society, the same cannot be said concerning developed countries, which are generally mostly influenced by the innovator sector. This implies that some negotiating positions are defended or at least listened to by both sides at the table, while others only merit the attention of one side.

7.4 The role of the industry

The pharmaceutical industry is actively engaged in the adoption of new technical standards and intellectual property norms. Sometimes this participation includes not only the possibility to express an opinion, or to lobby governments, but also voting power. The case of the ICH is particularly noteworthy in this regard (ABRAHAM, J., 2004, p. 150).

Literature concerning the participation of the industry in pharmaceutical standard-setting is sparse, particularly when compared with that focusing on the participation of the industry in intellectual property norm-setting. Against the backdrop of the impact on public health this lack of balance needs to be redressed. Technical standards relate to innovation, access and the quality of medicines. Moreover, the participation of industry in the technical domain has interesting particularities. Arguably, such participation may be more necessary than in the intellectual property context. In effect, while intellectual property is a highly specialized domain, professionals working for pharmaceutical companies do not generally possess greater knowledge than public officials working in intellectual property offices or trade and industry ministries. The same cannot be said with respect to the scientific and regulatory aspects of the pharmaceutical chain, where knowledge is generally found at the intersection between companies, scientific

institutions and public authorities. Professionals working for pharmaceutical companies may be optimally placed to propose normative responses to scientifically complex matters, since they may have been the promoters of the scientific achievement in question and thus better placed to understand its implications. This is probably the underlying justification for the industry's role in the ICH. Although the governance of the ICH can be greatly improved, it contains elements of what could be the optimal governance of the pharmaceutical regulation in the 21st century.

The different levels and fora of the industry's participation in global pharmaceutical governance, and the rationales for such participation, have attracted academic analysis. At the end of the 1990s, the term 'international private authority' was coined to allude to the influence that the innovative pharmaceutical industry had in international intellectual property law-making (SELL, S., 1999, p. 169; SELL, S., 2003). From another perspective, 'epistemic communities' wield considerable influence (HAAS, P. M., 1992) in the adoption of international technical standards, as well as new norms and interpretations of the norms in the intellectual property domain. With regard to technical standards, the role of those communities is evident in several areas. Take, for instance, the case of pharmacovigilance, where a small group of experts sharing basic methodologies, principles and beliefs meets regularly in the context of the 'Red Panamericana para la Armonización de la Reglamentación Farmacéutica' in the Americas to adopt standards that are later transplanted into local norms. It is also noticeable that scholars and experts in general have become relevant actors in the intellectual property domain, both in stimulating debate and vigorously expressing their views.

Another perspective focuses on the power of the industry to self-regulate its activities and create an autonomously regulated community. This is particularly interesting because it allows treating intellectual property and technical standardization in tandem. Companies participating in international standard-setting organizations follow different strategies to manage intellectual property rights that accompany specific standards. They may choose between *open* or *closed* systems, depending on whether intellectual property rights are permitted in relation to specific standards. They may also prefer to adopt mechanisms that permit leaving the standard open regardless of the fact that intellectual property rights are allowed, for instance

making it compulsory to license in ‘fair, reasonable and non-discriminatory’ terms (SEUBA, X, VIVAS, D., 2013a, p. 267). This can be compared to a private order (similar to patent pools) which tries to solve one of the main dilemmas occurring in the intellectual property domain: while intellectual property rights seem to incentivize innovation in some industries, they also obstruct it in others (LEMLEY, M. A., 2002, p. 1901).

Nevertheless, even if industry participation may be justified from a technical point of view, or because of the complexity of the sector, conflicts of interest may arise, since companies will be the ultimate addressees of the norms they have assisted to adopt. This may contribute to one of the features of the present legal scenario, i.e. the unbalanced content of the norms. This characteristic responds, among other already mentioned reasons, to the fact that sometimes new norms are adopted to satisfy private interests of stakeholders interacting in the pharmaceutical sector. This not only permits explaining the internal unbalance that characterizes a number of intellectual property norms, but also the fact that the development of some legal regimes is prioritized over other legal regimes related to pharmaceutical products.

8. Conclusion

How to improve the existing legal scenario

Some norms have made an interesting journey from national legal orders to international treaties and from there to other national legal orders. The question is whether such exportation is positive. Previous sections have introduced the reasons that make legal transplantation controversial. Different social and economic realities, as well as differences between the legal traditions of countries of origin and destination, are among the key factors to be taken into account. Nevertheless, these factors alone have not impeded governments from looking to foreign legal orders upon which to model domestic regulations. The contribution of imported norms may indeed be positive for fine-tuning existing institutions or incorporating new standards and best practices. In our view, more than questioning the phenomenon *per se*, the doubts relate to the origin, size and specific content of legal transplantation.

Improvements can be made both with respect to the substantive content of the norms and the institutional

shaping of the organizations that deal with international pharmaceutical regulation. In relation to the latter, the case of the ICH is paradigmatic, since it is clearly necessary to open its governance to other states and relevant stakeholders. Presently, only the industrial associations of innovative companies from the United States, the European Union and Japan, as well as their health regulatory agencies, participate in this very important initiative. The impact of ICH guidelines on developing and emerging nations, as well as on the activity of generic producers and users of medicines, makes it necessary to open it in a meaningful manner - i.e. with voting power - to other countries, international organizations and relevant stakeholders.

With regard to the substantive content of the transplanted norms, a source of inspiration to improve them may be paradoxically found in the legal order of origin of those norms. Frequently, only part of the regulation is transplanted to other countries. Moreover, exporting countries sometimes propose norms that exceed their own legal order. If the legal order of origin is considered, the missing checks and balances may be incorporated in the importing legal order, while aspects that exceed it could be rejected. Of course, there are no restrictions on looking at foreign legal orders, and optimal regulation may be found through combining several foreign norms and other creatively constructed rules as well as best practices.

Clearly, in the area of enforcement, better knowledge of the legal order of origin would allow transplanting the missing checks and balances. There are also many examples concerning substantive areas. For instance, the United States’ compensatory system for test data protection of agro-chemical products may be a good source of inspiration to assess whether the ‘relevant effort’ required to grant test data protection has been made (WEISSMAN, R., 2006, p. 156) in cases where a European or a US model of test data protection has been adopted. Another example relates to the EU’s regulation of the Bolar exception, where the preparatory work on a generic version of a protected invention may be considered administrative in nature, implying therefore that it does not fall within the acts that the right holder can prohibit and it is not necessary claiming an exception to patent rights (VIDAL-QUADRAS, M., 2013, p. 312).

Sometimes countries may adopt their own interpretations

concerning imported norms when the latter need further specification. This is, for instance, the case of the 'utility' criteria for the patentability of inventions. While this requirement may have been subject to litigation and rich jurisprudence in the country of origin, it may be unfamiliar to countries now accepting it. Thus, the importing countries' courts and authorities still have lot to say concerning the concrete meaning of specific, credible and substantial utility.

Ultimately, the coherence of the legal order has to prevail. This involves not just the internal equilibrium of the norms, but also their conformity with norms of a higher order, such as those on human rights. Fulfilling this objective calls for interministerial cooperation and taking into account the fact that pharmaceutical products fulfill a vital social function and therefore should not be subject to undifferentiated regulation across nations.

References

- Abraham, J. (2004) "Pharmaceuticals, the state and the global harmonisation process", *Australian Health Review*, vol. 28, n° 2, pp. 150-160.
- Blakeney, M. and Mengistie G. (2011) "Intellectual property policy formulation in LDCs in Sub-Saharan Africa", *African Journal of International and Comparative Law*, vol. 19, n° 1, pp. 66-98.
- Burrell, R. and Weatherall, K. (2008) "Exporting controversy? Reactions to the Copyright Provisions of the U.S.-Australia Free Trade Agreement: Lessons for U.S. Trade Policy", *University of Illinois Journal of Law, Technology and Policy*, vol. 2008, n° 2, pp. 259-319.
- Dreyfuss, R. C. (2004) "TRIPS-Round II: Should Users Strike Back?", *University of Chicago Law Review*, vol. 71, pp. 21-35.
- Geiger, C., (2012), "Anti-Counterfeiting Trade Agreement: A Comprehensive Assessment from a European Perspective", EU DG for External Policies, *Workshop. The Anti-Counterfeiting Trade Agreement (ACTA)*, EXPO/B/INTA/FWC/2009-01/Lot7/25.
- Geist, M. (2003) "Why We Must Stand on Guard Over Copyright", *Toronto Star*, Oct. 20, available at www.michaelgeist.ca/index2.php?option=com_content&do_pdf=1&id=1753&task=view, accessed September 2012.
- Geist, M., (2012) "The trouble with ACTA: an analysis of the Anti-Counterfeiting Trade Agreement", DG for External Policies, *Workshop. The Anti-Counterfeiting Trade Agreement (ACTA)*, EXPO/B/INTA/FWC/2009-01/Lot7/25.
- Genovesi, L-M. (2013) "La aplicación industrial y la utilidad como requisitos de patentabilidad: diferencias y semejanzas. Consecuencias de su aplicación", in Seuba, X. (Ed.) *Propiedad Intelectual, Competencia y Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, pp. 331-382.
- Genovesi, L-M. and Roffe, P. (2013a) "Vinculación o *linkage* entre patentes y autorización sanitaria de medicamentos", in Seuba, X. (Ed.) *Propiedad Intelectual, Competencia y Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, pp. 73-110.
- Genovesi, L-M. and Roffe, P. (2013b) "El nexus propiedad intelectual y derecho de la competencia en los tratados de libre comercio", in Seuba, X. (Ed.) *Propiedad Intelectual, Competencia y Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, pp. 457-488.
- Haas, P. M. (1992) "Introduction: Epistemic Communities and International Policy Coordination", *International Organization*, vol. 46, n° 1, pp. 1-35.
- Hinze, G. (2009) *Leaked ACTA Internet Provisions: Three Strikes and a Global DMCA*, Electronic Frontier Foundation (Nov. 3, 2009), available at <https://www.eff.org/deeplinks/2009/11/leaked-acta-internet-provisions-three-strikes-and->, accessed October 2013.
- Intellectual Property Enforcement Coordinator (2012) *2011 U.S. Intellectual Property Enforcement Coordinator Annual Report on Intellectual Property Enforcement*, available at http://www.whitehouse.gov/sites/default/files/omb/IPEC/ipec_annual_2011_report.pdf accessed August 2012.
- Laporte, J-R. (2001) *Principios básicos de investigación clínica*, Barcelona: Astra-Zeneca.
- Legrand, P. (1997) "The Impossibility of 'Legal Transplants'", *Maastricht Journal of European and Comparative Law*, vol. 4, pp. 111-124.
- Lemley, M. A. (2002) "Intellectual Property Rights and Standard-Setting Organizations", *California Law Review*, vol. 90, pp. 1889-1980.
- Lerner, J. (2002) "Does stronger patents induce more local innovation?", in REICHMAN, J. H., *International Public Goods and Transfer of Technology*, Cambridge: Cambridge University Press, pp. 309-320.
- López-Tarruella Martínez, A. (2013) "El acceso al conocimiento en la estrategia de propiedad intelectual de la Unión Europea en sus relaciones con terceros Estados", in Seuba, X. (Ed.) *Propiedad Intelectual, Competencia y Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, pp. 489-517.

- Klug, H. (2012) "Access to medicine and the transformation of the South-African State", in G. Shaffer (Ed) *Transnational Legal Order and State Change*, Cambridge: Cambridge University Press, pp. 148-179.
- Pérez, J-C. (2013), "La relación entre protección de los datos de prueba y los derechos de los consumidores. La obligación de no divulgación y el derecho fundamental a recibir información veraz e imparcial", in Seuba, X. (Ed.) *Propiedad Intelectual, Competencia y Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, pp. 217-252.
- Roffe P. and Genovesi, L. M. (2009) *Propuesta de estrategia y plan de acción: implementación del Acuerdo de Promoción Comercial con los EEUU en el área de propiedad intelectual*, Washington D.C.: Banco Interamericano de Desarrollo, Vicepresidencia de Sectores y Conocimiento, Sector de Integración y Comercio, Washington, D.C., available at <http://idbdocs.iadb.org/wsdocs/getdocument.aspx?docnum=2054292>, accessed May 2012.
- Roffe P. and Genovesi, L-M. (2013) "La recepción de la excepción regulatoria, o excepción Bolar, en la normativa interna", in Seuba, X. (Ed.) *Propiedad Intelectual, Competencia y Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, pp. 277-295.
- Sell, S. K. (1999) "Multinational Corporations as Agents of Change: The Globalization of Intellectual Property Rights", in A. C. Cutler, V. Haufler, T. Porter (Eds.) *Private Authority and International Affairs*, Albany, State University of New York Press, pp. 169-198.
- Sell, S. K. (2003) *Private Power, Public Law. The Globalization of Intellectual Property Rights*, Cambridge, Cambridge University Press.
- Seuba, X. (2009) *Health Protection in the European and Andean Association Agreement*, Amsterdam: HAI, <http://www.haiweb.org/23032009/18%20Mar%202009%20Policy%20Paper%20EU-CAN%20Association%20Agreement%20FINAL.pdf>
- Seuba, X. (2013a) "Checks and balances in the intellectual property enforcement field: reconstructing EU trade agreements", in Geiger, C. (Dir) *Constructing European IP: Achievements and New Perspectives*. Cheltenham: Edward Elgar Publishing, pp. 409-431.
- Seuba, X. (2013b) "The Relevance of the Principles for Intellectual Property Provisions in Bilateral and Regional Agreements vis-à-vis European Preferential Trade Agreements", *International Review of Intellectual Property and Competition Law*, vol. 44, n° 3, pp. 943-947.
- Seuba, X. and Genovesi, L-M. (2013) "La implementación del régimen de protección de datos de prueba presentados al registro farmacéutico", in Seuba, X., *Propiedad Intelectual, Competencia y Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, pp. 111-170.
- Seuba, X. and Vivas, D. (2013), "El fomento de la competencia y el equilibrio de derechos en la implementación de las normas sobre la observancia de los derechos de propiedad intelectual", in Seuba, X. (Ed.) *Propiedad Intelectual, Competencia y Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, pp. 423-457.
- Thambisetty, S. (2008) "Legal Transplants in Patent Law: Why Utility is the New Industrial Applicability", *LSE Law, Society and Economy Working Papers 6/2008*, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1111966, accessed September 2013.
- Thomas, J.R. (2005) *Intellectual Property and the Free Trade Agreements: Innovation Policy Issues*, CSR Report.
- Vidal-Quadras, M. (2013) "La recepción de la cláusula Bolar en Europa", in Seuba, X. (Ed.) *Propiedad Intelectual, Competencia y Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, pp. 295-330.
- Vivas, D. (2013) "Las causales de nulidad de las patentes y opciones para mejorar la coherencia e implementación de los tratados de libre comercio", in Seuba, X. (Ed.) *Propiedad Intelectual, Competencia y Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, pp. 383-402.
- Vivas, D. (2013) "La extensión del término de duración de las patentes: la implementación de los Tratados de Libre Comercio desde una perspectiva de salud pública", in Seuba, X. (Ed.) *Propiedad Intelectual, Competencia y Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, pp. 403-422.

- Seuba, X. and Vivas, D. (2013), “Estándares técnicos de referencia internacional sobre productos farmacéuticos”, in Seuba, X. (Ed.) *Propiedad Intelectual, Competencia y Aspectos Regulatorios del Medicamento*, Bogotá: PUJ-ICTSD, pp. 253-277.
- Watson, A. (1974) *Legal Transplants: An Approach to Comparative Law*, Edinburgh: Scottish Academic Press.
- Weissman, R. (2006) “Data protection: options for implementation”, in P. Roffe, G. Tansey, D. Vivas-Eugui (Eds.) *Negotiating Health: Intellectual Property and Access to Medicines*, Earthscan, pp. 151-179.
- Yu, P. (2004) “Currents and Crosscurrents in the International Intellectual Property Regime”, *Loyola of Los Angeles Law Review*, vol. 38, p. 396.
- Yu, P. (2011) “Six Secret (and now Open) Fears of ACTA”, *SMU Law Review*, vol. 64.
- Zahl, A. et al. (2007) *International Pharmaceutical Law and Practice*, Lexis Nexis.

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