INTELLECTUAL PROPERTY: A REGULATORY CONSTRAINT TO REDRESS INEQUALITIES

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1. Introduction

In the last two decades, a steady increase in the protection of intellectual property (IP) has taken place in both developed and developing countries. While in the former, such an increase was induced by internal demands of various industries (namely pharmaceuticals, entertainment, computer programs, semiconductors), in the case of the latter it was mainly the result of coercion and pressures exerted by foreign governments and industries rather than the result of local demands (Sell 2007).

One of the principal tools employed to obtain increases in the levels of IP protection in developing countries has been the inclusion of detailed chapters on the subject of free trade agreements (FTAs), in exchange for the promise–often unrealized–of increased foreign direct investment and technology transfer,[1] and of an improved trade balance with the developed countries' partners in the FTAs.[2] The IP provisions in FTAs may contribute to an increase in inequality both between and within countries, as they limit the capacity of governments to regulate commercial conduct that may have adverse economic and social effects. As noted in a set of principles issued by the Max Planck Institute for Intellectual Property and Competition Law (hereinafter "the Max Planck Institute"),

> [C]ontinuous extension of IP protection and enforcement increases the potential for law and policy conflicts with other rules of international law that aim to protect public health, the environment, biological diversity, food security, access to knowledge and human rights. At the same time, such extension often counters, rather than facilitates, the core IP goal of promoting innovation and creativity.[3]

IP provisions in FTAs may have implications on a wide range of public policy areas. For instance, anti-circumvention and technological protection measures in the field of copyright may drastically reduce the scope of generally admissible exceptions, such as fair use (Samuelson, Reichman, and Dinwoodie 2008). The obligation to join International Union for the Protection of New Varieties of Plants (UPOV) 1991 introduces undesirable rigidities in the seed supply systems, particularly as it bans the farmers' practices of saving and exchanging seeds (Correa 2015). A vast academic literature has addressed the "flexibilities" available under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the negative impact of FTAs in relation to access to medicines (Velasquez, Correa, and Seuba 2012). Several UN documents have also alerted about such impact (UNAIDS 2012). For example, the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard to Physical and Mental Health, noted that the TRIPS Agreement and FTAs have had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fully implement the right to health. He recommended developing countries and least

developed countries (LDCs) to review their laws and policies and amend them to make full use of the flexibilities available to them (United Nations 2009). UNDP and UNAIDS have argued that,

> Countries at minimum should avoid entering into FTAs that contain TRIPS-plus obligations that can impact on pharmaceuticals price or availability. Where countries have undertaken TRIPS-plus commitments, all efforts should be made to mitigate the negative impact of these commitments on access to treatment by using to the fullest extent possible, remaining public health related flexibilities available (UNDP and UNAIDS 2012).

Importantly, Goal 10 of the Sustainable Development Goals adopted by United Nations in 2015 aims at reducing "inequality within and among countries."[4] In defining this goal, the UN members recognized that, despite some reduction in income inequality between countries, it still persisted and large disparities remained between and within countries in "access to health and education services and other assets."[5] Moreover, inequality within countries has risen.[6]

This paper explores the extent to which this recommendation to use "to the fullest extent possible, remaining public health related flexibilities available" may be effectively implemented in the context of FTAs. Bilateral and regional FTAs do limit the policy space of governments to address national inequalities. The basic question addressed in this paper is whether contracting parties to FTAs can mitigate their adverse effects through interpretation and implementing regulations. It first presents a possible taxonomy of IP obligations ensuing from FTAs and the room for maneuver they leave to contracting parties. Second, it considers the so-called "certification" process unilaterally undertaken by the U.S. government. Third, it describes the interpretative framework for obligations regarding IP and, finally, it provides examples of how FTA's provisions may be interpreted in order to reduce their likely negative impact of equality in FTA's contracting parties, particularly in developing countries. The examples address two areas of significant relevance for access to medicines and public health: data exclusivity and patent/drug approval "linkage" provisions.

2. Taxonomy of IP obligations

As mentioned, a significant number of countries have entered into FTAs that generally confirm the applicability of the TRIPS Agreement's obligations regarding IP, and incorporate additional obligations not provided for in that agreement. As a result, a contracting party to an FTA that includes a specific IP chapter would be subject to standards that may be classified taking their relationship with the TRIPS Agreement into account. The reason to consider this agreement for this purpose is that, as a result of its enforcement mechanism,[7] it has become the most important international treaty in the area of IP. The IP provisions in FTAs may be classified as follows:

TRIPS minimum: National laws must implement the minimum standards of protection provided for in relation to the availability and enforcement of IP rights, as contained in the TRIPS Agreement (article 1.1 of the TRIPS Agreement). For instance, article 34 reads that the term of protection for patents "shall not end before the expiration of a period of twenty years counted from the filing date." This means that patents might be granted for a term different from 20 years, but not shorter than this period.

TRIPS-plus: Most of the provisions contained in FTAs belong to this category. TRIPS-plus provisions expand existing obligations under the TRIPS Agreement, for instance, by extending the term of protection of patents to compensate for delays in regulatory approvals, applying border measures to exports (while the TRIPS Agreement only obliges to introduce them for imports), or obliging the contracting parties to protect new uses or methods/processes relating to a known product (e.g., article 18.37.2 of the Trans-Pacific Partnership (TPP)). TRIPS plus provisions also include those that restrict the use of certain safeguards or "flexibilities," such as when parallel imports (such as in the U.S.-Morocco FTA) or the grounds to grant compulsory licenses are restricted (such as in the U.S.-Jordan FTA).

TRIPS-extra: This category of provisions is also TRIPS-plus, but with the characteristic of introducing issues not addressed by the TRIPS Agreement, such as the liability of Internet service providers (Lerman 2015), the settlement of domain name disputes (Kennedy 2015), and data exclusivity for biological products as provided for in the TPP. A further example is the so-called "linkage" between drug registration and patent protection, which is absent from the TRIPS Agreement. Under linkage provisions, as discussed below, national health authorities are bound to refuse marketing approval to a generic version of a product if a patent thereon is in force, unless by consent or acquiescence of the patent owner. Interestingly, the obligation imposed on those authorities in some U.S. FTAs sets a standard higher than the one applicable in the U.S., where the Food and Drug Administration (FDA) is only required to inform patent holders about generic producers' applications, but they must take the direct responsibility to prevent marketing approval through judicial procedures.[8]

TRIPS ceilings: Although it has often been considered that under the TRIPS Agreement, World Trade Organization (WTO) members may increase the levels of IP protection at their discretion, the broader protection that may be granted in accordance with article 1.1 of the TRIPS Agreement is subject to the proviso that "such protection does not contravene the provisions of this Agreement." There are situations where TRIPS-plus provisions may contravene the TRIPS Agreement, such as when they impede legitimate trade or erode safeguards recognized in favor of users of IP rights. Examples of these "ceilings" are the conditions established for seizure of goods in transit (Baker 2012), the idea/expression dichotomy in article 9.2 of the TRIPS Agreement, and the citation right found in Art.10 (2) of the Berne Convention (Grosse Ruse-Khan and Kur 2008). Some FTAs contain a number of provisions that may fall under this category.

TRIPS-minus: Some FTAs contain provisions that may be deemed below the TRIPS standards. For instance, the TRIPS Agreement includes a non-discrimination clause that applies in all fields of patented technologies (article 27.1). However, many FTAs do not reproduce this clause[9] and discriminate in favor of pharmaceutical companies. For instance, Dominican Republic-Central America FTA (CAFTA-DR) requires a "restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval" with respect to pharmaceutical products only (article 15.9.6(b)).[10] Other regulated products (such as agrochemicals) do not benefit from this extension.

Clearly, most of the provisions in FTAs correspond to the categories of TRIPS-plus and TRIPS-extra. The standards contained in the TRIPS Agreement forced a large number

of developing countries to introduce massive changes in their IP legislation. The prescribed standards of IP protection, generally inadequate for the level of development of those countries, had the potential to dramatically increase inequalities, particularly in the area of public health. First, the implementation of the TRIPS Agreement exacerbated the lack of access to medicines, particularly in low- and middle-income countries.[11] Second, it did not contribute to solving the problem of lack of sufficient R&D on the diseases prevailing in developing countries (Pedrique et al. 2013), as large pharmaceutical companies continued to focus on commercially attractive treatments (Correa 2016). Third, there is no evidence showing that higher standards of IP protection has led to increased technology or foreign investment flows, neither generally nor in relation to particular sectors, such as pharmaceuticals.[12]

The FTAs' expanded and tightened standards of IP protection can only aggravate the inequalities created by the "one-fits-all" model established under the TRIPS Agreement. While such standards are unlikely to have any significant impact in enhancing local innovation,[13] technology transfer, and foreign (or local) investment, they may allow right-holders to block competition and charge high prices in monopolistically controlled markets. This may lead to particularly serious effects in the area of public health (Abbott 2012), where unsustainably high prices have become an issue of global concern (‘tHoen, 2016, 107). During the past 15 years, the average price of cancer drugs has increased in the U.S. five- to 10-fold to more than $120,000 as of 2014 (Kantarjian 2015). Fifteen cancer drugs introduced in the past five years cost, in fact, more than $120,000 a year; a cholesterol-lowering treatment for those with certain rare genetic disorder costs $311,000 a year; a cystic fibrosis medicine developed partly with funding from a charity costs $300,000 annually, and the examples go on (Langreth 2014). Similar trends towards unsustainable prices are found in developing countries whenever generic competition is delayed or blocked (‘tHoen, 2016).

3. The "certification" process

The conclusion of an FTA with TRIPS-plus and TRIPS-extra provisions often does not put an end to the demands of further expansion and strengthening of IP rights: "[w]hat appears to be the experience of countries that have negotiated FTAs is that the process of negotiations does not conclude with the signing of the agreement" (Roffe 2007). U.S. partners, in particular, may be forced to make additional concessions in the process of the so-called "certification" required under U.S. law. This process is explained by the U.S. International Trade Administration as follows:

> Before an FTA enters into force, U.S. legislation approving the Agreement requires that the President determine that the FTA partner has taken measures to bring it into compliance with its FTA obligations as of day one of the agreement. The Office of the U.S. Trade Representative (USTR) and other agencies… review the relevant laws, regulations, and administrative practices (measures) of the FTA partner.
>
> The FTA partner is advised of any shortcomings in its laws and other measures, and the Administration consults with the FTA partner on the issue. If requested, assistance is provided to help a trading partner implement its commitments.[14]

This process is based on unilateral judgments by the U.S. Government and is used as a mechanism to put pressure on governments' trade partners (often eager to show their citizens that they have successfully concluded an FTA with the U.S.) to limit any gaps or flexibilities that they may have preserved under the signed FTA. It has been noted in this regard that,

> The U.S. has faced criticism for putting forward expectations for domestic reforms from their negotiating partners that go beyond the actual FTA text, and for using the implementation process as a vehicle to continue the negotiation of the final agreement. Indeed, Members of Congress criticized the USTR in the case of the U.S.-CAFTA-DR for: expanding the scope of what is defined as a new product that is subject to data protection rules; increasing the regulatory requirements for generic entry into the market; and allowing for patent or data protection of a new application of an existing product (Vivas-Eugui and von Braun 2016).

The implementation of the U.S.-Peru FTA provides another telling example of reduction of the policy space kept in the FTA. This example is particularly informative, since Peru (as well Colombia and Panama) benefited in their negotiations with the U.S. of a bipartisan agreement reached in June 2007 between the Republican administration and Democratic leaders in the U.S. Congress to mitigate FTA's obligations relating to public health.[15] Despite the room opened by this agreement, in the process of implementing the IP chapter, broader obligations were introduced, namely in relation to data exclusivity, that expanded the rights conferred to "originator" pharmaceutical companies (Roca 2009).

In the context of the TPP negotiations, those companies expressed their dissatisfaction with the regard to the term of protection of data exclusivity for biologicals (5-8 years) agreed upon by the U.S. government. The industry's ambition was to impose on all TPP contracting parties a 12-year period of exclusivity as recognized under the U.S. law (Biologics Price Competition and Innovation Act). In response to the criticism received, the USTR implicitly referred to the certification process as a means to fulfill industry's desires. He signaled that he was,

> listening to calls from business groups and some members of Congress to address their complaints with TPP through the way it is implemented, as well as other avenues. "At this stage, we're talking with stakeholders, members of Congress, and we're looking at the various stages that TPP goes through, including, once it's approved, there's a period of time between approval and entry into force, to look at how it's implemented."[16]

> The certification process is likely to increase the imbalance in rights and obligations inherent to FTAs provisions on IP, and thereby deepen the inequality gap between developed and developing countries' partners, as well as within the latter. For this reason, the referred to principles issued by the Max Planck Institute stated that, "IP-demanding countries should not employ unilateral certification or other assessment processes in order to influence the implementation of IP obligations."[17]

It is worth noting that, in addition to the certification process, the U.S. has attempted to further increase the levels of protection accorded in FTAs' partners through unilateral pressures, such as those exerted through the USTR reports and the classification of countries in the "watch lists" elaborated under the Special Section 301 of the U.S. Trade Act. For instance, Chile implemented the "linkage" obligation established by the FTA with the U.S. through the provision of information to the patent owner about a third party intending to commercialize a product with similar characteristics to one that is already patented.[18] This implementation is insufficient, in the U.S. government view, to comply with the FTA. The USTR Report on Special Section 301 for 2016, which keeps Chile on the "Priority Watch List," refers to "linkage" as one of the "longstanding IPR issues under the United States-Chile Free Trade Agreement" and "urges Chile to implement an effective system for addressing patent issues expeditiously in connection with applications to market pharmaceutical products."[19]

4. The interpretative framework

FTAs, as noted above, reproduce some TRIPS provisions and include additional provisions on IP. An important question is under which principles those provisions are to be interpreted and, particularly, whether there are interpretative frameworks that may mitigate the inequality generated by FTAs rules.

A. TRIPS Agreement

The TRIPS Agreement contains specific obligations that may affect access to medicines (notably, the requirement to grant patents in all fields of technology) but allows WTO members to introduce some measures (e.g. the "Bolar exception," compulsory licenses, parallel imports) (Correa 2017; Calboli and Lee 2016) that may attenuate to some extent the inequalities generated by the high prices of patented medicines. In addition, the Preamble and articles 7 and 8 of the Agreement provide elements for the interpretation of its provisions and other measures that governments may adopt to pursue public policy objectives. Importantly, the Doha Declaration on the TRIPS Agreement and Public Health (hereinafter "the Doha Declaration")[20] adopted in 2001 confirmed the right to adopt measures to protect public health (Correa and Matthews 2011).

The Preamble to the TRIPS Agreement states that that "measures and procedures to enforce intellectual property rights" should not themselves "become barriers to legitimate trade." It also recognizes "the underlying public policy objectives of national system for the protection of intellectual property rights including developmental and technological objectives." WTO panels and the Appellate Body have relied on several occasions on the Preamble in WTO disputes relating to the alleged violations of the TRIPS Agreement, particularly to define its object and purpose (Yusuf 2016).

Article 7 of the TRIPS Agreement, adopted on the basis on a proposal originally submitted by developing countries,[21] reflects the prevailing justification for the granting of IPRs in the technology-related fields as a tool for the promotion of innovation, but also the developing countries' concerns about shortcomings in the transfer and dissemination of technology and, more generally, on the "balance of rights and obligations" necessary to ensure that intellectual property works "to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare."

The inclusion of article 7 in Part I of the TRIPS Agreement, and not in the Preamble, suggests that it is not a mere hortatory provision. Its applicability to interpret the Agreement's provisions has been reinforced by the explicit reference made to the objectives and principles in the Doha Declaration.[22]

Article 8 of the TRIPS Agreement is also an important provision for framing national laws that respond to particular public health and other public interests. It makes clear that measures may be adopted in order to prevent or remedy abuses of intellectual property rights.

Although article 7 has specific wording on the objectives of the TRIPS Agreement and is incorporated into its normative part, it has seldom been mentioned less frequently by WTO panels and the Appellate Body, perhaps because most disputes have taken place among developed countries (Yusuf 2016). However, the panel report in *Canada–Patent Protection for Pharmaceutical Products* (relating to the so-called "Bolar exception") states that:

> Obviously, the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.[23]

In summary, article 7 (jointly with Article 8) of the TRIPS Agreement provides important elements for the interpretation and implementation of the rights and obligations under the Agreement with a view to respect WTO members policy space to pursue their own public policy objectives.

B. FTAs' provisions

Some FTAs contain wording inspired or reflecting articles 7 and/or 8 of the TRIPS Agreement. The FTA between the EU and Colombia, for instance, states that,

> The Parties recognize the need to maintain a balance between the rights of intellectual property holders and the interest of the public, particularly regarding education, culture, research, public health, food security, environment, access to information and technology transfer (article 196.3).[24]

Moreover, the TPP[25] reproduces in articles 18.2 and 18.3, *mutatis mutandis*, the provisions of articles 7 and 8 of the TRIPS Agreement, thereby suggesting that the same interpretive framework would apply.

Since FTAs oblige the contracting parties to comply with the obligations specifically prescribed by them but also with those under the TRIPS Agreement, the Preamble and articles 7 and 8 apply in the context of FTAs even if not explicitly mentioned therein. As a result, a country party to an FTA may invoke, under the FTA dispute settlement system, the application of the elements contained in the Preamble and article 7 and 8 in

relation to both obligations directly imposed by the TRIPS Agreement as well as to any TRIPS-plus obligation established by the FTA.

The adoption of the Doha Declaration created the expectation that it could serve as a barrier against the ratcheting up of IP protection through FTAs and other processes (such as the accession to WTO). Many FTAs contain specific references recognizing the "principles"[26] or the "importance"[27] of the Declaration. Although it has not prevented developed countries from imposing higher levels of IP protection for pharmaceuticals, it may be credited with some effects, notably the inclusion of no limitations to the grounds for granting compulsory licenses of patents, as provided for in pre-Doha Declaration FTAs (Correa and Matthews 2011). In the case of the U.S. FTAs with Peru, Colombia, and Panama, the FTAs provide that, notwithstanding the requirements regarding data exclusivity, "a Party may take measures to protect public health in accordance with" that Declaration.[28] The extent to which this provision may allow to derogate from the required data protection is unclear, since the Doha Declaration confirms certain "flexibilities" in the TRIPS Agreement, but it does not create exceptions nor does it refer to the issue of data protection. However, the alluded provision may facilitate "a pro-public health interpretation of the provisions on regulated products, as well as other sections of the FTA" (Roffe and Vivas Eugui 2007).

The provisions in FTAs referring to the TRIPS objectives and principles, and the references to the Doha Declaration, suggest that these agreements have generally preserved some (limited) space for contracting parties to protect their public interests, notably in the area of public health. The interpretation of the TRIPS-plus provisions contained in such agreements should be conducted with reference to the TRIPS Agreement and its subsequent developments (namely, the Doha Declaration) (Xiong 2012).

It must be borne in mind, however, that the effect of articles 7 and 8 (and the Doha Declaration) in interpreting the obligations under an FTA may be limited to situations where the content or scope of the established obligations are ambiguous. They may not help to overcome or mitigate clearly worded TRIPS-plus obligations. Since a deliberate objective of FTAs, as proposed by developed countries, has been to increase IP protection beyond the levels required by the TRIPS Agreement, there is also a risk that disputes settlement bodies under FTAs tend to give primacy to IP rules in case of conflict with national measures adopted pursuant to public interests such as the protection of public health or the environment (Correa 2013). Notwithstanding that the interpretive rules of the Vienna Convention on the Law of Treaties (VCLT) may be applied under the FTAs dispute settlement systems,[29] such bodies may be prone to expansive interpretations of the adopted obligations, for instance, through the principle of "evolutionary interpretation" (Bjorge 2014) based on new developments or subsequent agreements. This may generate broader understandings of the obligations than those that should be admissible under the WTO dispute settlement mechanism.[30] In addition, the procedures are different, to the extent that there is no possibility of a review of the legal arguments as may currently be done by the Appellate Body of the WTO (Mehmet 2008) and that third parties may not be permitted to express their views as allowed under article 10 of the WTO Dispute Settlement Understanding.[31]

Moreover, FTAs may allow for a choice of forum between the WTO and the particular FTA dispute settlement system,[32] provided that the subject of the dispute is regulated

under the substantive provisions of WTO agreements and the particular FTA. This opens the door for "forum shopping": the complaining party is likely to choose the forum most likely to provide a judgment favorable to its own position. One important issue is, therefore, the extent to which the interpretations of TRIPS provisions incorporated into FTAs that may be given by FTAs' dispute settlement bodies may substantially differ from those of a WTO panel or Appellate Body, and whether such interpretations may subsequently influence WTO jurisprudence.[33] Interestingly, the TPP contains a provision aiming at recognizing WTO jurisprudence in relation to obligations established by WTO agreements:

> With respect to any obligation of any WTO agreement that has been incorporated into this Agreement, the panel shall also consider relevant interpretations in reports of panels and the WTO Appellate Body adopted by the WTO Dispute Settlement Body (Article 28.11).[34]

To sum up: FTA have as a clear objective the expansion and strengthening of intellectual property rights, thereby providing an inherently biased context for interpretation of substantive and enforcement obligations. Although this may favor commercial over public interest's considerations, FTAs dispute settlement bodies would in any case be bound by the Preamble and articles 7 and 8 of the TRIPS Agreement, as well as by other specific provisions contained in the FTAs requiring a balance of rights and obligations. Although these provisions may help to attenuate the negative impact of those FTAs obligations likely to increase inequalities, they would not be sufficient to redress the imbalance created by the high standards of IP protection embedded in those agreements.

C. The limited impact of "side-letters"

In response to the concerns raised by health authorities and non-governmental organizations (NGOs) about the impact of a number of FTAs' IP standards on access to medicines, some FTAs signed by the U.S. included "side letters" or "understandings" that allude to the contracting parties' ability to protect public health. For instance, the U.S. and Morocco exchanged letters in June 2004 indicating that:

> The obligations of Chapter Fifteen of the Agreement do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively the "TRIPS/health solution"), Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution…[35]

The wording of the first sentence of this side-letter is ambiguous and its legal effect uncertain. One possible interpretation is that measures "necessary" to protect public health may be adopted even if they imply a derogation or limitation to the existing

obligations under the FTA. Another interpretation is, however, that the contracting parties understand that the adoption of such measures would not give them a right to ignore their treaty obligations, as they would be presumed to be neutral or entirely consistent with the protection of public health.

In a letter by the General Counsel of the USTR to a member of the U.S. Congress on the U.S.-Morocco FTA, he stated that

> As stated in the side letter, the letter constitutes a formal agreement between the Parties. It is, thus, a significant part of the interpretive context for this agreement and not merely rhetorical. According to Article 31 of the Vienna Convention on the Law of Treaties, which reflects customary rules of treaty interpretation in international law, the terms of a treaty must be interpreted "in their context," and that "context" includes "any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty."[36]

The USTR General Counsel went further and argued that if circumstances ever arise in which a drug is produced under a compulsory license, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, "the data protection provision in the FTA would not stand in the way."[37] However, the possible use of side letters or understandings to limit FTAs obligations is likely to be limited, and only provide contextual elements for interpretation. As noted in a U.S. congressional report,

> [I]n the event that a brand name drug company challenges a decision to approve a generic drug produced under a compulsory license, the Bush Administration has acknowledged that the conflict will only be "informed" by the letter and will have to be "resolved on the merits of a particular case" (Waxman 2005, 13).

A "side letter" or "understanding" may be deemed in fact, as noted by the USTR General Counsel, a "subsequent agreement between the parties regarding the interpretation of the treaty or the applications of its provisions" that should "be taken into account together with the context."[38] Hence, the side letters may give the false impression that they are able to effectively address the public health concerns generated by the TRIPS-plus and TRIPS-extra obligations provided for by FTAs, while their role in actually reducing the inequalities they generate may actually be limited.

5. Flexibilities within FTAs

A vast literature has addressed the "flexibilities" that WTO members may utilize in implementing the TRIPS Agreement (Velasquez, Correa, and Seuba 2012) and observed the limitations developing countries have faced to effectively apply them (Deere 2009). Most analyses on FTAs have focused on how they increase the TRIPS Agreement's standards and further limit the contracting parties' space to design IP systems consistent with different levels of development and public policy objectives. Given this situation, is it still possible to articulate implementing laws, regulations, and practices to pursue such objectives? The following sections examine the (limited) extent to which it is possible to do so in relation to two regulatory areas that may significantly increase inequalities between and within FTAs' partners. The suggestions made below

might also be applied by WTO members that accepted TRIPS-plus obligations in the process of accession to the WTO, as is the case for China (Correa and Abbott 2009).

A. Test data protection

FTAs signed by the U.S. and the E.U. systematically include a *sui generis* protection (generally called data exclusivity) applicable to the outcome of clinical studies conducted to demonstrate the efficacy and safety of a drug or agrochemical product.[39] The extent and modalities of the protection conferred varies among different FTAs.[40] Although it is not possible to make specific suggestions for implementing the obligations with a pro-public health perspective applicable to all FTAs, some options discussed below may be relevant to all or most FTAs.[41]

How protection is acquired? Data exclusivity generally is the corollary of the registration of a medicine incorporating a new chemical entity (see below). However, protection does not need to arise automatically as a result of such registration. It may be granted by the competent authority[42] upon determination that an application has been duly made and that the legally prescribed conditions have been met. As in the case of other titles, an initial fee and annual maintenance fees may be established. Competent authorities may be bound to publish the products for which protection is granted and third parties may be permitted to request the revocation of the grant.

Period to seek protection: National regulations may provide periods within which marketing approval should be requested after the first approval in the world of a medicine in order to obtain data exclusivity protection. This period may be, for instance, of six months or one year (as established for the Paris Convention in relation to the priority right).[43]

Covered products: The exclusive protection of test data is generally conferred under FTAs only in relation to products that contain "new" entities, that is, active principles not included in a product approved previously in the same country. Hence, products that contain salts, esters, or variants of active principles already incorporated in products approved in the Party are excluded from such protection. Moreover, national regulations may limit the protection to cases where there is a new "active moiety," as provided for under U.S. legislation.[44] The adoption of this concept would imply that protection should not be granted to test data relating to products containing chemical entities with a functional unit contained in a previously approved product, such as when marketing approval of a pro-drug for an already registered drug is applied for.

Undisclosed data: In line with article 39.3 of the TRIPS Agreement, FTAs require the protection of *undisclosed* test data. This means that whenever the test data for a particular product has been made publicly available, data exclusivity may not be obtained or would cease to exist. National laws may determine that public availability of a summary of clinical studies or of information in scientific literature is sufficient to consider the test data as disclosed. Interestingly, many drug regulatory authorities are moving in the direction of making available all test data related to an approved drug. For instance, in accordance with a policy applied since January 2015 by the European Medicines Agency in general the information about clinical studies cannot be considered "commercial confidential information." This information is to be published on the web (European Medicines Agency 2013). While the "clinical reports may not be

used to support a MAA [marketing authorization application]/extensions or variations to a MA nor to make any unfair commercial use of the clinical reports" (European Medicines Agency 2013), this restriction does not change the nature of the information as *disclosed* to the extent that it is publicly available.

Scope of exclusive rights: The right granted under data exclusivity protection only covers the *commercialisation* of the protected product in the territory where marketing approval has been obtained. Hence, the right-holder cannot prevent third parties from importing or manufacturing and distributing the product without commercial purposes, for example, distribution made in public hospitals or with humanitarian purpose.[45] Likewise, since only commercialization that is taking place within the territory where data protection was obtained should be impeded, data exclusivity cannot be enforced against manufacturing and exportation of the covered products, even if made with commercial purposes.

Early working: If a product were subject to data exclusivity, a generic company could nevertheless produce or import samples in order to undertake the studies required for marketing approval. Thus, a generic company could initiate the procedures during the data exclusivity term of protection in order to start commercialization immediately after the expiry of that term. If the product were on-patent, the possibility of undertaking the required studies would depend on the recognition of a "Bolar exception" (Correa 2017).

Exclusion of protection: Like in the case of patents, exceptions may be provided for data exclusivity protection, such as for cases of emergency, public health reasons, or when duplicating the test data would be unethical. As noted above, the E.U.–Colombia–Peru FTAs state that "in interpreting and implementing the rights and obligations under this Title, the Parties shall ensure consistency with this Declaration" (Article 197:2). In the case of the Chilean regulation, for instance, the hypothesis of exclusion included anti-competitive practices and reasons of public health, national security, public non-commercial use, national emergency, or other circumstances of extreme urgency established by a supreme decree of the Ministry of Health, which justifies to terminate the protection, lack of commercialization of the protected product within 12 months of its approval for marketing (article 9 (a) and (b), Decree 107/2010).

Compulsory licenses/government use: A data exclusivity regime could be an obstacle for the execution of a compulsory license or government use of a patent. Hence, it may be necessary to waive the rights conferred under data exclusivity in order to allow a compulsory licensee to obtain marketing approval of the licensed product.[46] National regulations may provide that data exclusivity shall have no effects against a compulsory licensee granted for any of the grounds established under the applicable patent law, nor against persons authorized to undertake a governmental non-commercial use of the patented product.

Termination of protection National laws may provide for a number of grounds for terminating data exclusivity protection, such as:

-when the right-holder or a person authorised by him does not commercialize the approved product in a way sufficient to supply the demand within a period (e.g. twelve months) from the date of approval for commercialisation or when the commercialization

is interrupted, for more than *x* consecutive months (e.g. six months), except in cases of *force majeure* or governments' acts that prevent such commercialisation.

-for public interest reasons such as national security, emergency or circumstances of extreme urgency that justify the termination of the period of exclusivity;

-when, as a result of administrative or judicial procedures, it is determined that the right-holder has abused his rights, for example, through practices declared as anti-competitive.

B. Patent/drug approval linkage[47]

U.S. FTAs typically require the contracting parties to create a "linkage" between patent protection and drug-marketing approval, thereby stretching the patent owner's exclusive rights by allowing him to block the regulatory approval for marketing of competing generic products.[48] This linkage obviates the fact that the objectives of these two areas of regulation differ completely. While patent protection aims at rewarding new and inventive contributions to the state of the art, drug-approval regulations seek to ensure that only drugs with proven efficacy and safety are commercialized. As noted by a commentator, "[t]he newly delegated role of the regulatory authority as an "enforcer" of a private right is therefore a significant benefit to the rights holder" (Mercurio 2006). By significantly delaying the marketing approval for generic drugs, linkage provisions may limit states' actions aimed at progressively realizing the human right to health, as required by the International Covenant of Economic, Social, and Cultural Rights.[49]

The USTR has championed the adoption of "linkage" provisions in FTAs and has systematically threatened unilateral sanctions under Special Section 301 of the U.S. Trade Act against those countries that do not implement some form of drug-patent/registration linkage.[50] Paradoxically, the modality of "linkage" imposed on developing countries by the U.S. in some FTAs is more restrictive than that applied in the U.S. (Abbott 2006). On the one hand, in the U.S. the drug regulatory authority only provides information to the patent owner in order for him to initiate judicial proceedings against potential infringers.[51] The U.S. linkage system is, thus, based on a limited intervention by the Food and Drug Administration (FDA).[52] Any disputes arising from the marketing approval of a generic product are settled by the courts. In many FTAs, however, it is the drug regulatory authority itself–rather than the patent owner–who is obliged to deny an application of marketing approval of a generic product. As a result of this "administrative linkage," it is the State which may be bound to assume the responsibility for unduly refusing an application for marketing approval of a generic medicine in cases where the patents were actually invalid or non-infringed.

A major problem with the administrative linkage is that drug regulatory authorities have no legal capacity to determine whether a particular patent is infringed and whether it would overcome a challenge of invalidity. This is aggravated when patent offices and courts allow for the proliferation of pharmaceutical patents on marginal developments aimed at "evergreening" basic patents, as a result of deficient examination or the application of low standards of patentability and various legal fictions (Correa 2015). In these situations, marketing approval might be denied if there were, for instance, patents over a particular salt or formulation of a drug, even where the drug itself may be off-patent.

An exhaustive study conducted in Canada–where linkage came into force in 1993–has shown how pharmaceutical companies have strategically used linkage provisions and "evergreening" to delay the market entry of generic products; data reported there revealed a "strong and increasing use of linkage regulations by pharmaceutical firms in order to restrain generic competition" (Bouchard et al. 2010, 220). In particular, it showed that firms were obtaining the most extensive patent protection through the linkage provisions "on drugs with the least innovative value" as such provisions were "primarily utilized only for follow-on drugs" (Bouchard et al. 2010, 220). The authors noted,

> [T]hat private firms may be obtaining extended patent protection for weakly inventive products while at the same time generic competition is chilled and public are deprived of reasonably priced pharmaceuticals raises the possibility that the *quid pro quo* of the traditional patent bargain is breached, yielding a result that would be at odds with legislative intent (Bouchard et al. 2010, 222).

and concluded that,

> Together, the results reported here show that the combination of conventional patent law, emerging linkage regulation regimes and existing drug approval framework provide a powerful mechanism for multinational pharmaceutical firms to efficiently and effectively identify attractive new and follow-on drug candidates for market exclusivity. The linkage regulation regime in particular has proven to be an excellent vehicle for firms to obtain extended legal protection on drugs at all stages of development, including drugs about to come off patent protection, drugs moving through the regulatory approval stage, and drugs that are currently in development (Bouchard et al. 2010, 227).

An administrative type of linkage–where under the drug regulatory authority should take action on its own to refuse an application for marketing of a generic product–creates an almost absolute presumption of validity for pharmaceutical patents. The U.S. Federal Trade Commission (FTC), however, has held that the circumstances under which a patent is granted "suggest that an overly strong presumption of a patent's validity is inappropriate," and that it "does not seem sensible to treat an issued patent as though it had met some higher standard of patentability" (U.S. Federal Trade Commission 2003, 8-10). In dealing with preliminary injunctions, U.S. courts do not recognize a presumption of validity when the patent is challenged by the alleged infringer. In *New England Braiding*, for instance, the court stated that "unless the alleged infringer undertakes to challenge validity with evidence, the patentee need do nothing to establish its rights under the patent…However, the presumption does not relieve a patentee who moves for a preliminary injunction from carrying the normal burden of demonstrating that it will likely succeed on all disputed liability issues at trial, even when the issue concerns the patent's validity."[53] While a bill was introduced to the U.S. Congress in April 2007 that proposed a reduction in the threshold to obtain the invalidation of a patent (by establishing a "preponderance of the evidence" and not "a clear and convincing evidence" standard), the *America Invents Act* adopted in 2011 provided that during the procedures before the USPTO Patent Trial and Appeal Board (PTAB) the patent has no presumption of validity.[54]

The vulnerability of patents is also recognized in other jurisdictions. In India, for instance, it is settled law that in an action for infringement of a patent, an injunction would not be granted where the validity of the patent itself has been questioned and a revocation petition has been filed.[55] In Argentina, a reform introduced pursuant to a complaint by the U.S. under the WTO dispute settlement rules provides that, in dealing with applications for a preliminary injunction, the judge needs to consider whether a patent will be deemed valid if challenged by the alleged infringer (article 83).

The negative impact of linkage provisions on public health[56] may be attenuated by indirect and direct measures. Indirect measures include

a) A rigorous examination of patent applications in order to only grant patents when genuine inventive contributions have been made. The calibration of the patentability standards so as to make them compatible with national policies (in the area of public health, industrial policy, environmental protection, food security etc.) is one of the most important flexibilities allowed by the TRIPS Agreement. [57] FTAs have not generally reduced the room for maneuver left to contracting parties in this regard.[58]

b) Limiting the presumption of validity of patents to the compliance with legal procedures rather than substantive requirements.

c) Reducing the room for pharmaceutical companies' abuse of preliminary injunctions (Correa 2007). In order to prevent the risk of such abuse, national laws and regulations may provide that the grant of such measures by judicial authorities should be subject to an evaluation by the court of several admissibility factors, such as, whether: the patentee is likely to prevail if the validity of the patent were challenged, there would be an "irreparable harm" if an injunction were not granted, the balance of equities tips in the patentee's favor, and granting the preliminary injunction would be in the public interest.[59] In addition, such measures may not be granted without giving an opportunity to the alleged infringer to articulate its defense.[60]

Direct measures to mitigate the negative impact on the accessibility of medicines are discussed below.

C. Scope of patent claims

As mentioned, the pharmaceutical industry often applies for and obtains, where allowed by national laws, regulations and practices, patents on derivatives and other developments (e.g. salts, formulations, uses) of existing drugs in order to artificially extend a monopolistic position with regard to particular drugs. This "evergreening" strategy has been documented in developed (European Commission 2009) as well as in developing countries (Correa eds. 2013). A study made in Chile, for example, showed that "72% of active ingredients that were protected by a single patent were in fact protected by a secondary patent. Among the drugs that were protected by several patents, in most cases they were protected by only secondary patents or a combination of primary and secondary patents" (Abud, Hall, and Helmers 2015, 12). In accordance with another study,

> If the future looks like the past (and the patent landscape in other countries like that in the U.S.) a conservative estimate is that eliminating secondary patents

> could free up 36% of new medicines for generic production, since only 64% of drugs in our sample had patents with chemical compound claims. Additionally, for those drugs that still come under patent because a chemical compound claim exists, exclusions on secondary patents could limit the duration of patent protection by 4–5 years (Kapczynski, Park, and Sampat 2012).

The effects of evergreening may be drastically limited if linkage provisions only apply in respect of patents in force on the *active ingredients*, with exclusion of those covering other subject matter. This distinction may be crucial to preserving a competitive market when the active ingredients are off-patent. In the case of sofosbuvir, for instance–an exorbitantly high priced drug[61]–in addition to the patent on the active ingredient, Gilead has obtained in many countries a patent on the most thermodynamically stable polymorphic form of sofosbuvir (WHO 2016). If the patent on the active ingredient is not granted or has expired, the polymorph patent might be used to refuse the marketing approval of a generic product.

The extent to which the scope of the linkage obligations may be limited will ultimately depend on their wording in the respective FTAs and implementing legislation. For instance, the TPP refers to a "patent claiming the approved product or its approved method of use" (article 18.53(1)(a)). In this case, a patent covering a particular polymorph, salt, or formulation may not be invoked to prevent a generic product from being approved for marketing, unless the "approved product" has been characterized as a specific polymorph, salt, or formulation.

Infringement

As mentioned, drug regulatory authorities lack the capacity to assess whether the infringement of a patent might occur. There are different ways of interpreting patent claims. Various theories and methodologies are applied by courts (Cotropia 2005) with regard to what is protected and eventually infringed. The same claims may be read as covering or not a certain product. In addition, an infringement may be "literal" or by "equivalence." There is no harmonized doctrine to determine when a product or process not identical to the one patented is infringing (Westin 1998). This creates a great deal of uncertainty and allows for discretion in determining when a patent is infringed.

In view of these circumstances, linkage implementing regulations may stipulate that linkage provisions would be applied only when a patent in force would be literally infringed by the product whose registration is sought. In the case of sofosbuvir mentioned above, for instance, the linkage provisions should not apply if generic companies developed a different stable molecular dispersion, liquid, or amorphous form, and have taken care of preventing conversion of the developed product to the stable polymorphic form covered by the patent WHO 2016).

Listing of patents

As is the case in the U.S. with the "Orange book," countries subject to linkage obligations may establish that a patent may only be invoked to refuse the marketing approval of a generic product when the patent was previously included in a public available database.[62] The listing of a patent may be subject to deadlines (within a certain period after grant) and to some exclusions. For instance, under U.S. FDA's Orange

Book regulations, no metabolite, intermediate, or packaging patents may be listed. Patents having only method of making (process) claims, those claiming formulations that do not cover the marketed drug product, and methods of use covering unapproved indications are not listable either (Hemphill and Sampat 2012). Like in the case of the FDA, if a patent covers a polymorph, it may be required that the patentee submits, within a given period, test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the National Drug Administration (NDA) (bioequivalence).

Setting deadlines

As suggested above, some terms may be provided for in order to trigger the application of linkage provisions. This may refer to the listing of patents, the submission of test data (when required), and the bringing of an infringement action. For instance, under the U.S. FDA regulations such an action must be initiated within 45 days after receiving notice about an application for marketing approval of a generic product.[63]

Patent litigation may last for years. Delays in reaching final decisions may be due to an inefficient or overburdened judicial system, the technical complexity of issues to be addressed, as well as to dilatory tactics by the parties. Hence, if a provisional measure that prevents the drug regulatory agency to approve a generic drug was obtained, the exclusion of the market may last for years, even when there was no justification for it. For this reason, implementing regulations may provide for a maximum period of suspension. In the case of the U.S., for instance, the approval of a generic product may be made effective 30 months after the date of the receipt of the notice of certification regarding the application for a generic product, "unless the court has extended or reduced the period because of a failure of either the plaintiff or defendant to cooperate reasonably in expediting the action."[64]

Damages

If linkage provisions are unduly used to exclude generic products from the market, the patentee should be liable for damages and might be imposed other penalties as well, like in the case of Australia when baseless litigation by a pharmaceutical company takes place. Thus, in accordance with section 26D of the Therapeutic Goods Act 1989, if a provisional measure was granted and the infringement proceedings are subsequently discontinued or dismissed, or they had no reasonable prospect of success, the court may award compensation to the applicant as well as to the government for losses sustained as a result of the injunction (Correa 2014). Of course, this would not apply if the drug regulatory authority acted *ex-officio*. Implementing regulations may ensure that, even in the case of administrative linkage, action is only taken upon formal request of the patent owner, thereby making him liable in case of wrong suspension or refusal of the marketing approval of a generic product.

Publicly available information

In accordance with some FTAs, contracting parties must put in place "a transparent system" to provide notice to a patent holder that another person is seeking to market an approved pharmaceutical product during the term of a patent covering the product or its approved method of use.[65]

One way of complying with linkage provisions without an excessive burden on the drug regulatory agencies is to make publicly available, for instance, through a web page, information on all filings for marketing approval. Companies that consider that their patents might be infringed, could –within a given period- initiate legal actions before the courts.

Compulsory licenses

The administrative linkage, as implemented under FTAs, may make it impracticable compulsory licenses and non-commercial government use—since generic companies would be unable to get approval to market their generic products, even if permitted under the patent law. As noted by one commentator,

> It is unclear whether a compulsory license may be issued to provide entry of generic drugs where the law does not allow registration prior to the expiration of the patent. This potential impediment is caused by the fact that a manufacturer granted authority to produce under compulsory license still must be registered by the national drug regulatory authority. Thus, if the regulatory authority is prohibited from registering generics until the patent expires, the compulsory license will be prevented from coming to fruition (Mercurio 2006, 226).

In order to avoid a possible limitation on compulsory licenses and government use of patents derived from linkage provisions, specific safeguards may be provided for in implementing regulations, so as to ensure that marketing approval is granted for the products to be marketed under such authorizations.

6. Conclusions

IP provisions contained in FTAs are likely to aggravate current inequalities amongst and within countries, namely low and middle income countries. Those agreements normally contain a set of obligations that increase the level of IP protection beyond what is required under the TRIPS Agreement, and what would be adequate to developing countries that have signed up those agreements. Moreover, the "certification" process conducted by the U.S. government may expand the obligations agreed upon under particular FTAs, thereby enhancing the potential benefits of FTAs provisions for foreign right-holders without any positive impact for the US partner countries. Some provisions in the TRIPS Agreement and FTAs that broadly refer to welfare implications of IP protection may attenuate the negative implications of such agreements in vital areas, such as public health, but the room for interpretations in the public interest is limited. This also applies to 'side letters' incorporated into some FTAs, which would not allow a contracting party to ignore unambiguously defined treaty obligations.

There is some space, however, to explore options for the implementation of IP obligations imposed by FTAs with the aim of limiting their potential negative impact. As illustrated by the discussion above on two areas (data exclusivity and linkage) of particular importance for access to medicines, contracting parties may introduce a number of conditions for that purpose. Such space may be fully exploited in the case of countries that have accepted TRIPS-plus obligations in the process of accessing to the

WTO or preserved the freedom to implement FTAs obligations. It is more limited when a contracting party is subject to the referred to 'certification' process. Nevertheless, some measures -such as limiting the presumption of validity of patents and applying rigorous standards to examine patent applications- may be implemented in all cases in order to mitigate the impact of linkage provisions which, in essence, are incompatible with the independence of functions performed by patent offices and drug regulatory agencies and with the vulnerability of granted patents to validity challenges.

Reference List

Abbott, F. M. 2006. *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law*. UNCTAD - ICTSD Project on IPRs and Sustainable Development (12).

Abbott, R. 2012. "Access to Medicines and Intellectual Property in Jordan." *Intellectual Property Watch*. Retrieved from: http://ssrn.com/abstract=2116096.

Abud, M. J., B. Hall, and C. Helmers. 2015. "An Empirical Analysis of Primary and Secondary Pharmaceutical Patents in Chile." PLOS One | DOI:10.1371/journal.pone.0124257

Baker, B. K. 2012. "Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough." PIJIP Research Paper Series. Retrieved from: http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1026&context=research.

Bjorge, E. 2014. *The Evolutionary Interpretation of Treaties*. Oxford Scholarship Online. Retrieved from: https://www.ilsa.org/jessup/jessup15/Second%20Batch/EirikBjorgeCh3.pdf.

Bouchard, R. A., R. W. Hawkins, R. Clark, R. Hagtvedt, and J. Sawani. 2010. "Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals." 8 Nw. J. Tech. & Intell. Prop. 174. Retrieved from: http://scholarlycommons.law.northwestern.edu/njtip/vol8/iss2/2, p. 220.

Calboli, I., and E. Lee (eds.). 2016. *Research Handbook on Intellectual Property Exhaustion and Parallel Imports.* Cheltenham: Edward Elgar.

Chandler, C., and M. Dhanay. 2010. "Pharmaceutical Patents and Marketing Approvals within the U.S. – Chile Free Trade Agreement Context: A Brief Analysis." In *Search Of New IP Regimes*, 201-18. IPR University Center. Retrieved from: http://ssrn.com/abstract=1602883.

Clift, C. 2007. *A Guide to Assessing the Impact of TRIPS-Plus Provisions on Drug Prices in Developing Countries.* ICTSD Programme on IPRs & Sustainable Development. Retrieved from: http://www.ictsd.org/downloads/2009/06/1_guide_impact_assessment.pdf.

Correa, C. 2007. “TRIPS and TRIPS-plus Protection and Impacts in Latin America.” In *Intellectual Property, Trade and Development Strategies to Optimize Economic Development in a TRIPS Plus Era*, eds. D. Gervais. Oxford: Oxford University Press.

Correa, C. 2008. “Expanding Patent Rights in Pharmaceuticals: The Linkage Between Patents and Drug Registration.” In *The Development Agenda; Global Intellectual Property and Developing Countries*, eds. N. Netanel. Oxford: Oxford University Press.

Correa, C. 2013. “The Impact of the Economic Partnership Agreements on WTO Law.” In *EU Bilateral Trade Agreements & Intellectual Property For Better or Worse*, eds. J. Drexl, H. G. Ruse-Khan, and S. Nadde-Phlix. Springer: MPI Studies Series.

Correa, C. (eds.). 2013. *Pharmaceutical innovation, incremental patenting and compulsory licensing*. Geneva: South Centre.

Correa, C. 2014. “Tackling the Proliferation of Patents: How to Avoid Undue Limitations to Competition and the Public Domain.” In *Droit, économie et valeurs. Le droit économique, maître ou esclave de l’économie ? Hommage au Professeur Bernard Remiche*. Brussels: Larcier.

Correa, C. (with contributions from S. Shashikant and F. Meienberg). 2015. *Plant Variety Protection in Developing Countries. A Tool for Designing a Sui Generis Plant Variety Protection System: An Alternative to UPOV 1991*, APBREBES, Berne Declaration, TWN, SEARICE, Utviklingfondet, Alfter (Germany). Retrieved from: http://www.apbrebes.org/news/new-publication-plant-variety-protection-developing-countries-tool-designing-sui-generis-plant.

Correa, C. 2016. “The Current System of Trade And Intellectual Property Rights.” *European Yearbook of International Economic Law 2016* (7).

Correa, C. 2017. “The Bolar exception: legislative models and drafting options.” In *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options*, eds. B. Mercurio. Routledge.

Correa, C., and F. Abbott. 2009. “The Accession Process and its Legal Consequences.” In *The WTO and Accession Countries*, eds. C.A. Primo Braga and O. Cattaneo. London: Edward Elgar.

Correa, C., and D. Matthews. 2011. *The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health*, UNDP. Retrieved from: http://www.undp.org/content/dam/undp/library/hivaids/Discussion_Paper_Doha_Declaration_Public_Health.pdf.

Cotropia, C. A. 2005. “Patent Claim Interpretation Methodologies and Their Claim Scope Paradigms.” *William and Mary Law Review*. Volume No. 47: 1(3). Retrieved from: http://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=1220&context=wmlr.

Chael, M. 2004. “Court: FDA’s Role is Not to Analyze Patent Claims.” Retrieved from http://www.patentlyo.com/patent/2004/08/court_fdas_role.html.

Deere, C. 2009. *The Implementation game – The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*. Oxford: Oxford University Press.

European Commission. 2009. *Final Report, Pharmaceuticals Sector Inquiry*. Retrieved from: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

European Medicines Agency. 2013. *European Medicines Agency policy on publication of clinical data for medicinal products for human use*. Retrieved from: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf.

Foellmi, R., and J. Zweimüller. 2016. "Is inequality harmful for innovation and growth? Price versus market size effects." *Journal of Evolutionary Economics*.

Frankel, S. 2006. "WTO Application of the Customary Rules of Interpretation of Public International Law to Intellectual Property." 46 VA. J. INT'L L: 365, 384-90.

Global Commission on HIV and the Law. 2012. *HIV and the Law: Risks, Rights & Health*. Retrieved from: http://www.hivlawcommission.org/index.php/report.

Grosse Ruse-Khan, H., and A. Kur. 2008. "Enough is Enough - The Notion of Binding Ceilings in International Intellectual Property Protection." Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series No. 09-01. Retrieved from: http://ssrn.com/abstract=1326429 or http://dx.doi.org/10.2139/ssrn.1326429.

Hemphill, C. S., and B. N. Sampat. 2012. "Weak Patents Are a Weak Deterrent: Patent Portfolios, the Orange Book Listing Standard, and Generic Entry in Pharmaceuticals." Retrieved from: http://www.nber.org/chapters/c13215.pdf.

Kantarjian, H. 2015. "High cost of cancer drugs goes beyond the price." *Modern Health Care*. Retrieved from: http://www.modernhealthcare.com/article/20150404/MAGAZINE/304049978.

Kapczynski, A., C. Park, and B. Sampat. 2012. "Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents." *PLoS ONE*: 7(12). Retrieved from: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470.

Kennedy, M. 2015. *WTO Dispute Settlement and the Trips Agreement. Applying Intellectual Property Standards in a Trade Law Framework*. Cambridge: Cambridge University Press.
See article 1.1 of the TRIPS Agreement.

Langreth, R. 2014. "Big Pharma's Favorite Prescription: Higher Prices." Retrieved from: http://www.businessweek.com/articles/2014-05-08/why-prescription-drug-prices-keep-rising-higher.

Lerman, C. 2015. *Impact of Free Trade Agreements on Internet Policy*. Center For Global Communication Studies. Retrieved from: http://globalnetpolicy.org/wp-content/uploads/2015/09/Lerman_Impact-of-Free-Trade-Agreements-on-Internet-Policy.pdf.

Marceau, G. 2001. "Conflicts of norms and conflicts of jurisdictions. The relationship between the WTO Agreement and MEAs and other treaties." *Journal of World Trade* 35(6):1081-131.

Mehmet, K. 2008. *Assessing the Development Friendliness of Dispute Settlement Mechanisms in the Economic Partnership Agreements & an Analytical and Comparative Guide to the Dispute Settlement Provisions in the EU'S FTAs*. European Studies Centre University of Oxford. The Global Trade Ethics Programme, Occasional Paper. Retrieved from: https://www.oxfam.org.nz/sites/default/files/oldimgs/whatwedo/mtf/mtf%20in%20pacific/dispute%20settlement%20in%20epas.pdf.

Mercurio, B. 2006. "TRIPS-Plus Provisions in FTAs: Recent Trends." In *Regional Trade Agreements and the WTO Legal System: 215-37, Oxford University Press, 2006*, eds. L. Bartels and F. Ortino: 225. Retrieved from: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=947767.

Palmedo, M. 2015. *USTR Identifies TPP Implementation Process As Opportunity to Address Industry Concerns with Final Text*. Infojustice.org Retrieved from: http://infojustice.org/archives/35661.

Pedrique, B., N. Stub-Wourgaft, C. Some, P. Olliavo, P. Trouiller, N. Ford, B. Pécoul, and J. Bradol. 2013. "The Drug and Vaccine Landscape for Neglected Diseases (2000—11): A Systematic Assessment." *The Lancet Global Health* 1(6): e371-e379. Retrieved from: http://dx.doi.org/10.1016/S2214-109X(13)70078-0.

Roca, S. 2009. "Demócratas, salud pública y propiedad intelectual en el APC Perú-EE.UU." *Puentes* 10(2). Retrieved from: http://www.ictsd.org/bridges-news/puentes/news/dem%C3%B3cratas-salud-p%C3%BAblica-y-propiedad-intelectual-en-el-apc-per%C3%BA-eeuu#_edn4.

Roffe, P. 2007. *Intellectual Property, Bilateral Agreements and Sustainable Development: The Challenges of Implementation*. CIEL: 6. Retrieved from: http://www.ciel.org/Publications/FTA_ImplementationPub_Jan07.pdf.

Roffe, P., and D. V. Eugui. 2007. "A Shift in Intellectual Property Policy in US FTAs?" *Bridges* 11(5). Retrieved from: http://www.ictsd.org/bridges-news/bridges/news/a-shift-in-intellectual-property-policy-in-us-ftas.

Roy, V., and L. King. 2016."Betting on hepatitis C: how financial speculation in drug development influences access to medicines." *BMJ*: 354. Retrieved from: http://www.bmj.com/content/354/bmj.i3718.

Samuelson, P., J.H. Reichman, and G. Dinwoodie. 2008. "How to Achieve (Some) Balance in AntiCircumvention Laws." Comm. ACM . Retrieved from: http://scholarship.law.berkeley.edu/facpubs/2367.

Sell, S. 2007. "TRIPS-Plus Free Trade Agreements and Access to Medicines." *Liverpool Law Review* 28:41–75. Retrieved from DOI 10.1007/s10991-007-9011-8.

Stevens, C., I. Irfan, I. Massa, and J. Kennan. 2015. *The Impact of Free Trade Agreements between Developed and Developing Countries on Economic Development in Developing Countries: A Rapid Evidence Assessment*. Overseas Development Institute. London. Retrieved from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/448862/REA_FreeTradeAgreements.pdf. See also http://www.ase.tufts.edu/gdae/policy_research/MexicoUnderNafta.html.

'tHoen, E. 2016. *Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines.* HAI. Retrieved from: http://haiweb.org/publication/private-patents-public-health-changing-intellectual-property-rules-access-medicines/.

UNAIDS. 2012. *The Potential Impact of Free Trade Agreements on Public Health*. Geneva. Retrieved from: http://www.unaids.org/sites/default/files/media_asset/JC2349_Issue_Brief_Free-Trade-Agreements_en_0.pdf.

UNDP and UNAIDS. 2012. *The Potential Impact of Free Trade Agreements on Public Health*: 5. Retrieved from: http://www.unaids.org/sites/default/files/media_asset/JC2349_Issue_Brief_Free-Trade-Agreements_en_0.pdf.

UNITAID. 2016. *An Economic Perspective on Delinking the Cost of R&D from the Price of Medicines.* WHO.

United Nations. 2009. *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*. United Nations General Assembly, 11th Session, Agenda Item 3, A/HRC/11/12. New York: United Nations.

U.S. Federal Trade Commission. 2003. "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy." Retrieved from: http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

Velasquez, G., C. Correa, and X. Seuba. 2012. *IPR, R&D, Human Rights and Access to Medicines - An Annotated and Selected Bibliography*. Geneva: South Centre.

Vivas-Eugui, D., and J. von Braun. *Beyond FTA Negotiations – Implementing the New Generation of Intellectual Property Obligations*. Retrieved from: http://infojustice.org/wp-content/uploads/2016/01/vivas-and-von-braun.pdf.

Waxman, H. 2005. *Trade Agreements and access to medications under the Bush Administration*. Washington, DC: United States House of Representatives. Retrieved from: : http://democrats.reform.house.gov/Documents/ 20050609094902-11945.pdf..

Weston Jr., R. D. 1998. "A Comparative Analysis Of The Doctrine Of Equivalents: Can European Approaches Solve An American Dilemma?" *IDEA: The Journal of Law and Technology*, 39 J.L. & TECH. 35.

WHO. 2011. *Trends in local production of medicines and related technology transfer*. WHO/ICTSD. Retrieved from: http://apps.who.int/medicinedocs/documents/s19063en/s19063en.pdf.

WHO. 2016. *Patent Situation of Key Products for Treatment of Hepatitis C-Sofosbuvir*. Working Paper, WHO. Retrieved from: http://www.who.int/phi/implementation/ip_trade/sofosbuvir_report.pdf?ua=1.

Xiong, P. 2012. "Patents in TRIPS-Plus Provisions and the Approaches to Interpretation of Free Trade Agreements and TRIPS: Do They Affect Public Health?" *Journal of World Trade* 46(1): 155–86.

Yu, P. 2009. "The Objectives and Principles of the TRIPs Agreement." *Houston Law Review* 46: 797-1046. Retrieved from: http://ssrn.com/abstract=1398746.

Yusuf, A. 2016. "Chapter 1." In *Intellectual Property and International Trade: TRIPS Agreement,* eds. C. Correa and A. Yusuf. Kluwer Law International, 3rd ed.

[1] While noting the dearth of empirical evidence on the general economic and social impact of FTAs in developing countries, a recent report concluded that "[t]here is limited evidence that FTAs can encourage investment, technology transfer and firm upgrading, which is valuable because of the importance of supply capacity" (Stevens et al. 2015).

[2] However, in accordance with estimates by the U.S. International Trade Commission, FTAs entered into by the U.S. "had a significant positive effect on U.S. bilateral trade balances. The agreements increased U.S. bilateral trade surpluses or reduced bilateral trade deficits by $4.4 billion per country per year on average, and by $87.5 billion per year in total (59.2 percent) in 2015" (see http://www.reuters.com/article/us-usa-trade-study-idUSKCN0ZG083).

[3] *Principles for Intellectual Property Provisions in Bilateral and Regional Agreements*, available at http://www.ip.mpg.de/fileadmin/ipmpg/content/forschung_aktuell/06_principles_for_intellectua/principles_for_ip_provisions_in_bilateral_and_regional_agreements_final1.pdf.

[4] See http://indicators.report/goals/goal-10/.

[5] See http://www.un.org/sustainabledevelopment/inequality/.

[6] Id.

[7] Unlike other IP international treaties, non-compliance with the obligations set out by the TRIPS Agreement may lead to trade retaliations. See e.g., Kennedy (2015).

[8] For this and other examples of FTAs provisions that go beyond U.S. law, see, e.g. Abbott (2006).

[9] For instance, article 15.9 of CAFTA-DR reproduces the first sentence of article 27.1 but omits the second one about non-discrimination ("patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced").

[10] This extension delays the entry of generic competitors. For instance, the anticancer drug Gleevec "received a patent term extension in the U.S., from 28 May 2013 to 4 January 2015. Extensions have also been obtained in major European markets to 2016...Thus generic competition, with the consequent falls in price, is delayed by two or three years in major markets beyond expiry of the original patent. Introduction of similar provisions in developing countries will have the same delaying effect" (Clift 2007, 22).
[11] See, e.g., Global Commission on HIV and the Law (2012, 5). The Commission recommended, inter alia, that the WTO "suspend TRIPS as it relates to essential pharmaceutical products for low- and middle-income countries" (14).

[12] See generally on this issue, WHO (2011).
[13] Inequality may negatively affect the incentive to innovate via a price and a market size effect (Foellmi and Zweimüller 2016).
[14] See http://trade.gov/fta/compliance.asp.
[15] http://www.hktdc.com/info/mi/a/baus/en/1X0078EY/1/Business-Alert-%E2%80%93-US/Congress--Administration-Announce-Trade-Policy-Agreement.htm.
[16] Quoted in Palmedo (2015).
[17] Op. cit. para. 29.
[18] In September 2nd, 2002 the Quinta Sala from the I Corte de Apelaciones (I Court of Appeals, Fifth Chamber) of Chile ruled that the Instituto de Salud Publica, which issues sanitary registries, "had no power whatsoever to either deny a marketing approval or to acknowledge rights derived from a patent" (Chandler and Dhanay 2010)
[19] USTR, *Special 301 Report* (2016, 49) available at https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf
[20] In the case of the EU–Colombia–Peru FTA, a reference to the importance of the Doha Declaration is complemented by a provision stating that "in interpreting and implementing the rights and obligations under this Title, the Parties shall ensure consistency with this Declaration" (Article 197:2).
[21] See document MTN.GNG/NG11/W/71, 19 May 1990.
[22] Paragraph 5(a): "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles." See also Yu (2009, 999).
[23] Report of the panel, WT/DS114/R (2000), para 7.26.
[24] Available at http://trade.ec.europa.eu/doclib/docs/2011/march/tradoc_147704.pdf.
[25] This Agreement has not entered into force, pending ratification by the negotiating parties.
[26] See, e.g., U.S.–Chile FTA, preamble.
[27] See, e.g., E.U.–CARIFORUM Economic Partnership Agreement (EPA), Article 147(b).
[28] Articles 16.10.2.(e)(i) (Peru, Colombia) and 15.10.2.(e)(i) (Panama).
[29] See, e.g., Part III, Article 18 of the E.U.-CARIFORUM EPA.
[30] However, some WTO rulings have relied on an "evolutionary interpretation." In *United States-Section 110(5) of the U.S. Copyright Act* the WTO panel incorrectly considered the World Intellectual Property Organization (WIPO) Copyright Treaty as a subsequent development, even though it has neither come into force nor been ratified by either party. See, e.g., Frankel (2006); Marceau (2001).
[31] The TPP provides, however, for the participation of third parties in disputes (article 28.14).
[32] See, e.g., Article 28.4 of the TPP.
[33] Rulings in the context of FTAs have influenced WTO jurisprudence in some cases. For instance, in *Brazil-Tyres* the WTO panel referred to a MERCOSUR ruling in support of its finding that Brazil's exemption for MERCOSUR imports was not "arbitrary" within the meaning of Article XX of the General Agreement on Tariffs and Trade (GATT) of 1994. See *Brazil - Measures Affecting Imports of Retreaded Tyres* (DS332) available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds332_e.htm.
[34] The wording "shall also consider," however, may leave room to deviate from those interpretations.
[35] A similar statement is contained in an "Understanding regarding certain public health measures" made between the signatories of CAFTA on August 5, 2004 and in an exchange of letters with Bahrain.

[36]Letter from USTR General Counsel John K. Veroneau to Congressman Levin dated July 19, 2004, Congressional Record, V. 150, PT. 13, July 22, 2004 to September 14, 2004, 17294, available at http://www.who.int/intellectualproperty/topics/ip/en/Morocco.FTA.letter.pdf.

[37] Id.
[38] Article 31.3 (a) of the Vienna Convention on the Law of the Treaties.
[39] The following analysis focuses on drugs.
[40] For instance, CAFTA-DR provides that a Party "may require" that the original firm applies for approval within five years after having obtained approval for commercialisation in the other territory, a condition absent in other FTAs.
[41] These options are non-exhaustive.
[42] A certificate of protection may be issued, separately or as an integral part of the certificate of approval for commercialisation or sanitary registration.

[43] See, e.g., article 4.4, Decree 107/2010 of Chile, available at http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/DS_MINSAL_107-2010.pdf.
[44] See Section 505(b) of the US Federal Food, Drug, and Cosmetics Act; article 4.2(i) of the Malaysian Directive on Data Exclusivity, 2011, available at http://npra.moh.gov.my/images/reg-info/DataEx/Directive_on_DE.pdf.
[45] It should be noted that there will be no "commercial purposes" merely because a price is charged for the product. The title-holder cannot prevent acts of use, production or importation of the product that do not imply commercialisation.
[46] See, e.g., article 10 (c) of Decree 107/2010 of Chile, available at http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/DS_MINSAL_107-2010.pdf.
[47] This section is substantially based on Correa (2008).
[48] It should be noted that the patent-registration linkage is not required in the E.U.--where there is complete independence between intellectual property protection and drug registration--nor under the FTAs signed by the E.U.
[49] *See* for example, Xavier Seuba, *On the Right to Health as a Human Right, Human Rights and Intellectual Property Rights*, in Carlos M. Correa and Abdulqawi A. Yusuf, *Intellectual Property and International Trade: The TRIPS Agreement* (Kluwer 3d ed, 2016); Yaël R. Hazan and Philippe Chastonay, eds., *Santé et droits de l'homme* (CMS 2004); Alicia E. Yamin, "Not Just a Tragedy: Access to Medications as a Right under International Law," 21 *Boston University International Law Journal* 325; *See* also Phillipe Cullet, "Patents and Medicines: The Relationship between TRIPS and the Human Right to Health," 79:1 *International Affairs* 139 (2003).

[50] See, e.g., USTR, *Special 301 Report* (2016, 49), available at https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf
[51] The TPP seems to allow for this possibility since the linkage mechanism may provide that notice be given to a patent holder, or to allow for a patent holder to be notified, prior to the marketing of a pharmaceutical product, that other person 'is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use' (article 18.53(1)(a)). TPP contracting parties may opt to provide for 'judicial or administrative proceedings' (article 18.53(1)(c)).

[52]In *Alphapharm PTY v Tommy G. Thompson* (Secretary of Health and Human Services) (DDC 2004) (CA 03-2269), the District Court in Washington, D.C., ruled that the US law does not require the FDA "to police the listing process by analyzing whether the patents listed by NDA (New Drug Application) applicants actually claim the subject drugs or applicable methods of using those drugs." See Chael (2004).
[53] New England Braiding Co., INC. and Seal Company of New England, Inc., v. A.W. Chesterton Company (970 F.2d 878, 23 U.S.P.Q.2d 1622, July 28, 1992) available at http://openjurist.org/970/f2d/878/new-england-braiding-co-inc-v-aw-chesterton-company.
[54] P.L. 112-29, the Leahy-Smith America Invents Act.
[55] *See* http://spicyipindia.blogspot.com/2007/05/bilcare-decisions-by-delhi-high-court.html.

[56] Such negative impact of the administrative linkage provisions as originally adopted in the FTAs with Peru and Panama (similar to those in DR-CAFTA), and the excessive burden put on states' regulatory agencies, were recognized in the bipartisan agreement reached in June 2007

referred to above. Those provisions were consequently revised and more flexibility allowed for their implementation.

[57] See, e.g., *Declaration on patent protection. Regulatory Sovereignty under TRIPS*, issued by the Max Planck Institute for Intellectual Property and Competition Law (2014), available at https://www.mpg.de/8132986/Patent-Declaration.pdf; see also Carlos Correa (2016).

[58] One exception is, for instance, the TPP obligation to grant patents on "at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product" (Article 18.37.2).
[59] These are the factors generally considered by US courts. The irreparable harm is not to be presumed. See AIPPI National Group: United States, "Injunctions in cases of infringement of IPRs," available at https://www.aippi.org/download/commitees/219/GR219usa.pdf.
[60] Note that the TRIPS Agreement leaves judicial authorities discretion to grant or not preliminary measures *inaudita altera parte* (article 50). This also seems to be the situation under FTAs. For instance, the TPP provides that "[e]ach Party's authorities shall act on a request for relief in respect of an intellectual property right *inaudita altera parte* expeditiously in accordance with that Party's judicial rules" (Article 18.75.1). The reference to the "Party's judicial rules" leaves the door open for different policies on the matter, subject to what is provided for under national laws.
[61] This drug is priced at US$ 2500 per gram in some high-income countries, while it can probably be manufactured for US$ 2−4 per gram (UNITAID 2016, 8). Although the Pharmasset, the company that originally developed sofosbuvir, had initially considered a price of $36 000, 'Gilead ultimately set $84 000 as its market list price after internal deliberation over multiple factors, including an evaluation of the high prices of previous drugs and how much health systems could bear' (Roy and King 2016).

[62] In the case of the U.S. FDA regulations, drug makers are required to list any patent containing at least one claim that covers the drug's active ingredient, its formulation, or any method of use pertaining to an approved indication, issued before NDA approval. See, e.g., Hemphill and Sampat (2012).
[63] CFR - Code of Federal Regulations Title 21, Sec. 314.107(3).
[64] CFR - Code of Federal Regulations Title 21, Sec. 314.107(3).
[65] See, e.g. Article 16.10.3 (c) of the US-Peru FTA.